Patient-Rated Assessment of Acute Ankle Sprains among Competitive College Athletes

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UEMATSU, Daisuke

研究指導教員： 福林 徹 教授
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# Table of Contents

**ABBREVIATIONS** ................................................................................................................................. 3

**CHAPTER 1: INTRODUCTION/BACKGROUND** ......................................................................................... 5  
  SECTION 1-1: ABSTRACT ......................................................................................................................... 5  
  SECTION 1-2: PATIENT-RATED OUTCOME MEASURE ............................................................................. 8  
  SECTION 1-3: ANKLE SPRAINS ............................................................................................................. 17  
  SECTION 1-4: AIMS OF THIS THESIS ................................................................................................... 30

**CHAPTER 2: EVIDENCE OF VALIDITY FOR THE JAPANESE VERSION OF THE FOOT AND ANKLE ABILITY MEASURE** ........................................................................................................... 31  
  SECTION 2-1: ABSTRACT ......................................................................................................................... 31  
  SECTION 2-2: INTRODUCTION ................................................................................................................. 33  
  SECTION 2-3: METHODS ......................................................................................................................... 33  
  SECTION 2-4: RESULTS ......................................................................................................................... 39  
  SECTION 2-5: DISCUSSION ..................................................................................................................... 43  
  SECTION 2-6: CONCLUSION .................................................................................................................. 51

**CHAPTER 3: SELF-REPORTED FUNCTIONS AND SINGLE-LIMB HOP TEST PERFORMANCE AT RETURN-TO-PLAY PHASE FOLLOWING TRAUMATIC LATERAL ANKLE SPRAINS AMONG COMPETITIVE COLLEGE BASKETBALL PLAYERS** ............................................................................................................. 52  
  SECTION 3-1: ABSTRACT ......................................................................................................................... 52  
  SECTION 3-2: INTRODUCTION ............................................................................................................... 53  
  SECTION 3-3: METHODS ......................................................................................................................... 54  
  SECTION 3-4: RESULTS ......................................................................................................................... 61  
  SECTION 3-5: DISCUSSION ..................................................................................................................... 68  
  SECTION 3-6: CONCLUSION .................................................................................................................. 77

**CHAPTER 4: PROGNOSTIC ABILITY OF PATIENT- AND CLINICIAN-RATED MEASURES**
FOR TRAUMATIC LATERAL ANKLE SPRAINS AMONG COLLEGIATE BASKETBALL PLAYERS

SECTION 4-1: ABSTRACT .................................................................................................................. 78
SECTION 4-2: INTRODUCTION ....................................................................................................... 80
SECTION 4-3: METHODS .................................................................................................................. 80
SECTION 4-4: RESULTS ................................................................................................................... 89
SECTION 4-5: DISCUSSION .......................................................................................................... 93
SECTION 4-6: CONCLUSION ......................................................................................................... 98

CHAPTER 5: DISCUSSIONS ........................................................................................................... 99

CHAPTER 6: CONCLUSIONS ........................................................................................................ 105

REFERENCE ..................................................................................................................................... 106

APPENDIX ........................................................................................................................................ 117
# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL</td>
<td>Activity of Daily Living</td>
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<tr>
<td>CAI</td>
<td>Chronic Ankle Instability</td>
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<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>DF</td>
<td>Dorsiflexion</td>
</tr>
<tr>
<td>DOE</td>
<td>Disease-Oriented Evidence</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence Based Practice</td>
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<tr>
<td>EV</td>
<td>Eversion</td>
</tr>
<tr>
<td>FAAM</td>
<td>Foot and Ankle Ability Measure</td>
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<tr>
<td>FPT</td>
<td>Functional Performance Tests</td>
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<tr>
<td>GRF</td>
<td>Global Rating of Function</td>
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<tr>
<td>HR-QOL</td>
<td>Health Related Quality of Life</td>
</tr>
<tr>
<td>ICF</td>
<td>International Classification of Functioning</td>
</tr>
<tr>
<td>MDC</td>
<td>Minimum Detectable Change</td>
</tr>
<tr>
<td>POEM</td>
<td>Patient-Oriented Evidence that Matters</td>
</tr>
<tr>
<td>RTP</td>
<td>Return-To-Play</td>
</tr>
<tr>
<td>SEM</td>
<td>Standard Error of Measurement</td>
</tr>
</tbody>
</table>
SLHT  Single Leg Hop Test

VAS   Visual Analogue Scale
Chapter 1:
Introduction/Background

SECTION 1-1: ABSTRACT

In the previous decades, the evidence based practice (EBP) has been emphasized in the field of sports medicine as well as athletic training. Disease Oriented Evidence (DOE) focuses on the disease or injury and may not necessarily be related to the improvement of the patient’s function. Therefore, it may not be as meaningful to the patient. On the other hand, Patient-Oriented Evidence that Matters (POEM) are related to morbidity, mortality, and symptom improvement. Therefore, it is directly important and meaningful to Heath Related Quality of Life (HR-QOL) of the patient.

The World Health Organization’s International Classification of Functioning (ICF) provides a theoretical framework that looks at functioning and disability in a dynamic or complex interaction between various health conditions and contextual factors. In the ICF, functioning is divided in 3 levels; functioning at the body parts, the whole person, and the whole person in their complete environment. Correspondingly, the disability is described as impairment, activity limitation, and participation restriction.
Similar impairments may result in different degrees of activity limitations and participation restrictions, or disability, depending on environmental and personal factors. Therefore, it is imperative for clinicians to look at impacts of a health condition not only in terms of impairments, but also activity limitations and participation restrictions.

Along with the EBP, patient-centered medicine is the guiding principle in the modern medicine. Accordingly, the emphasis in outcome measure is shifting from clinician-based to patient-based outcome measure in recent years. Despite its importance, the lack of patient-based outcome measures in the fields of Sports Medicine and Athletic Training has been reported in the literature.

A self-reported outcome instrument allows clinicians to include patient’s values into the medical treatment and to evaluate the effectiveness of interventions from the patient’s perspective. The Foot and Ankle Ability Measure (FAAM) is a region specific self-reported outcome instrument and developed by the American Physical Therapy Association Foot and Ankle Special Interest Group. The use of the FAAM is recommended to be included in the RTP decision making process and outcome measure of acute ankle sprains by the National Athletic Trainers’ Association and American Physical Therapy Association.
Ankle sprains are frequently reported to be one of the most common types of athletic injuries in the literature. Often times, the severity of the ankle sprain is misjudged, and inappropriate management results in recurrent ankle sprains and chronic conditions.

Functional performance tests (FPTs) have been used to assess functional recovery and patient confidence in the limb, help RTP decisions, and identify those who are at risk of re-injury. FPTs of single-limb hop maneuvers have been found to be effective in achieving these intended purposes by challenging the lateral aspect of the ankle. However, previous studies have been mostly conducted on general adult populations with chronic conditions, and hence the applicability of FPTs to athletic populations after traumatic lateral ankle sprains is unknown.

Largely based upon impairment measures, traumatic lateral ankle sprains are typically classified as mild, moderate, or severe despite that there is relatively limited evidence is available to support such a classification system. Furthermore, prediction of RTP after traumatic lateral ankle sprains has been reported to be more accurate and valid when it is based upon patient-rated measures such as activity limitations and weight bearing status, rather than
SECTION 1-2: Patient-Rated Outcome Measure

Evidence Based Practice

In the previous decades, the evidence based practice (EBP) has been emphasized in the fields of sports medicine and athletic training.\textsuperscript{128,144,148,159} The EBP is the fundamental principle that the quality of patient care is dependent on the clinician’s ability to make sound clinical decisions based upon the best evidence currently available.\textsuperscript{132,139}

There are two kinds of evidence that guide the EBP; Disease Oriented Evidence (DOE) and Patient-Oriented Evidence that Matters (POEM).\textsuperscript{41,42,78} The DOE focus on the disease or injury itself, and gain the information about the cause, pathomechanics, prevalence, and etiology. Therefore, DOE inherently may not be as meaningful to the patient. Also, DOE are not always applicable for use in practice as they may or may not be related to the improvement of the patient’s function.\textsuperscript{42,78} On the other hand, POEMs focus on the information that is directly important and meaningful to Health Related Quality of Life (HR-QOL) of the patient.\textsuperscript{41,42,78} The examples of the POEMs include information such as clinician-rated measures.
morbidity, mortality, symptom improvement, and cost reduction.\textsuperscript{41,42,78} POEMs are gained only from the studies that include the outcome measure that is important to the patient. Therefore, it is crucial to the EBP in that it incorporate the patient's perspective into the assessment of the intervention given to the patient.

**International Classification of Functioning**

The World Health Organization's (WHO's) International Classification of Functioning (ICF), modified from Nagi's disablement model, provides a theoretical framework that describes how globally a health condition impacts the patient's HR-QOL.\textsuperscript{82,81,84,152,182} The ICF provides a unifying framework of disablement concepts and terminology which allows efficient communications among clinicians and scientists. The ICF looks at functioning and disability in a dynamic or complex interaction between various health conditions and contextual factors.\textsuperscript{84,82,152,182} (FIGURE1-1) Therefore, the ICF synthesizes biological, personal, and social perspectives of functioning and disability, and provides a biopsychosocial comprehensible framework.\textsuperscript{182} Definitions of key concepts in the ICF are presented in TABLE 1-1.
FIGURE 1-1 Interactions between the components of ICF

(from World Health Organization, Fig 1.182)
### TABLE 1-1 Definitions of key concepts

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health condition</td>
<td>an umbrella term for disease (acute or chronic), disorder, injury or trauma.</td>
</tr>
<tr>
<td>Functioning</td>
<td>an umbrella term encompassing all body functions, activities and participation</td>
</tr>
<tr>
<td>Disability</td>
<td>an umbrella term for impairments, activity limitations or participation restrictions</td>
</tr>
<tr>
<td>Body function</td>
<td>the physiological functions of body systems</td>
</tr>
<tr>
<td>Body structure</td>
<td>anatomical parts of the body such as organs, limbs and their components</td>
</tr>
<tr>
<td>Impairment</td>
<td>problems in body function or structure such as a significant deviation or loss</td>
</tr>
<tr>
<td>Activity</td>
<td>the execution of a task or action by an individual</td>
</tr>
<tr>
<td>Participation</td>
<td>involvement in a life situation</td>
</tr>
<tr>
<td>Activity limitations</td>
<td>difficulties an individual may have in executing activities</td>
</tr>
<tr>
<td>Participation restrictions</td>
<td>problems an individual may experience in involvement in life situations</td>
</tr>
</tbody>
</table>
In the ICF, functioning is divided into 3 levels: functioning at the body parts, the whole person, and the whole person in their complete environment. Correspondingly, the ICF describes the disability in terms of 3 interrelated factors: impairment, activity limitation, and participation restriction. Impairments are loss of or abnormalities of an anatomical, physiological nature and problems in body functions and structures due to the active pathologic condition. Activity limitations are difficulties experienced by a person in executing relatively simple activities and tasks as a person, regardless of the context in which simple tasks and activities are being performed, and vary in degrees according to the levels of the functions expected to each person. Participation restrictions are problems a patient may experience performing socially defined roles in a life situation. Therefore, although activity and participation are interrelated and difficult to differentiate, a single level of activity limitations may result in different participation restrictions to different individuals.

ICF-based patient evaluations allow clinicians to look at impacts of a health condition not only in terms of body functions and structures, or impairments, but also activity limitations and participation restrictions, providing
a comprehensive framework for the assessment of the effect of a health condition on a patient’s overall HR-QOL. This is important as two patients with similar impairments may have different degrees of activity limitations and participation restrictions, or disability, depending on environmental and personal factors. Furthermore, the reduction of impairments does not necessarily correlate with the reduction of disability. Additionally, impairments, besides pain, are not associated with long-term goals of patients. Therefore, goals of treatment and rehabilitation should be directed at reducing disability and improving HR-QOL by relieving symptoms and restoring functions and abilities of patients.

**Patient-Rated Outcome Measure**

Outcome measures are essential to EBP in that they offer a basis for clinical decisions. Clinical outcome measures can be clinician-based and patient-based depending on the way in which outcomes are collected. Clinician-based outcome is gained from clinician’s perspective; on the other hand, patient-based outcome measure is acquired through the patient’s view.
Along with the EBP, patient-centered medicine is the guiding principle in the modern medicine. Patient-centered care is defined by the Institute of Medicine as “identify, respect, and care about patients’ differences, values, preferences and expressed needs…” Accordingly, the emphasis in outcome measure is shifting from clinician-based to patient-based outcome measures in recent years. Furthermore, patient-based outcome measures include patient’s view of his or her HR-QOL, and hence helps provide POEMs.

Most clinician-based outcome measures in the Sports Medicine and Athletic Training fields relate to impairment measures such as muscle strength, range of motion, pain, swelling, ligament integrity and so forth. They are measured by clinician. On the other hand, patient-based outcome measures are granted by the patient through a questionnaire or self-reported outcome instrument, and relate to symptoms, activity limitations, and participation restrictions that the he or she is experiencing in ADL and sports activities from a health condition.

Previous studies suggest that clinician-rated measures and patient-rated measures capture different aspects of HR-QOL. Therefore, it is imperative for clinicians to incorporate both clinician- and patient-rated measures to
effectively assess the whole impact of a health condition on patients.

Despite its importance, the lack of patient-based outcome measures in the fields of Sports Medicine and Athletic Training has been reported in the literature.\textsuperscript{50,114,115,127,128,144,159} Likewise, the predominant use of the impairment measures in the treatment and rehabilitation process as well as Return-to-Play (RTP) decisions were criticized in sport rehabilitation fields.\textsuperscript{19,50,115}

**Self-Reported Outcome Instrument and the Foot Ankle Ability Measure**

A self-reported outcome instrument allows clinicians to include patient’s values into the medical treatment and to evaluate the effectiveness of interventions from the patient’s perspective. There are various types of self-reported outcome instruments, which can be generic or specific.\textsuperscript{53,63} The specificity of self-reported outcome instruments includes disease, body region, dimension, summary item, and individualized measures.\textsuperscript{53} Clinicians need to choose a self-reported outcome instrument based upon the intended use. Before a self-reported outcome instrument is used for the above mentioned purposes, evidence must be provided. Such evidence includes, but not limited to: face validity, content validity, construct validity, internal consistency, and
Furthermore, a self-reported outcome instrument needs to be translated and cross-culturally adapted if it is to be used in another language or culture. 

There have been more than a dozen types of self-reported outcome instruments developed for the foot and ankle region. The Foot and Ankle Ability Measure (FAAM) was developed by the American Physical Therapy Association Foot and Ankle Special Interest group, with involvement from actual patients. This development process gives the FAAM a higher content validity as well as construct validity. The original version of the FAAM is one of the four instruments that provided evidence of content validity, construct validity, reliability, and responsiveness. The 29-item questionnaire is divided into two subscales; a 21-item ADL and an 8-item Sports subscales. Each item is scored on a 5-point Likert scale. The FAAM measures activity limitations and participation restrictions that patients are experiencing from foot and ankle disorders.

The use of the FAAM is recommended to be included in the RTP decision making process and outcome measure of acute ankle sprains by the National Athletic Trainers’ Association and American Physical Therapy
Patient-Rated Outcome Measure of Physically Active Individuals and Athletes

Patient-rated outcome measures need to be specific to the nature of the patient as it has been reported that HR-QOL of athletes may be impacted by an injury differently than that of general population. Therefore, the evidence from the patient-rated outcome measures that is specific to athletes is necessary to effectively guide the treatment and rehabilitation process to the successful RTP.

SECTION 1-3: Ankle Sprains

Epidemiology

Ankle sprains are frequently reported to be one of the most common types of athletic injuries among the literatures. A recent meta-analysis revealed that indoor, court sports carry the highest risk of ankle sprain, with lateral ankle sprain being the most frequently observed ankle injury. The greater risk of suffering an ankle sprain is a previous injury and as high as
73 % of re-injury rate has been reported.\textsuperscript{184} Furthermore, POEMs concerning common clinical conditions, such as ankle sprains, are considered to have the greatest value.\textsuperscript{41}

**Chronic Ankle Instability**

Often times, the severity of the ankle sprain is misjudged and inappropriate management such as premature RTP results in recurrent ankle sprain and chronic ankle instability, or CAI.\textsuperscript{33,58,67,77,113,160} Middelkoop et al reported self-reported pain at rest and re-sprains for the first 3 months following the initial ankle sprain have been associated chronic symptoms.\textsuperscript{160} Such chronic symptoms can extend more than decades while associated symptoms can progressively deteriorate.\textsuperscript{98,166} As a result, repetitive ankle sprains and chronic symptoms have been reported to be associated with higher risk of osteoarthritis.\textsuperscript{62}

Traditionally, CAI has been reported to be composed of two major subgroups; mechanical instability and functional instability.\textsuperscript{67} (FIGURE 1-2) Although the mechanical instability has been generally defined and accepted as the pathologic ligamentous laxity, the functional instability has been vaguely
A recent study suggested that "sensations of instability are the most commonly reported and perhaps the most serious symptom of CAI," and yet it has not been sufficiently addressed in the literatures despite the staggering prevalence of this symptoms with the CAI. The term functional instability has been proposed to be replaced by "perceived instability" as the "functional instability" has been used to express widely different meanings. Similarly, feeling of ankle joint instability is separately defined as "situation whereby during ADL and sporting activities the subject feels that the ankle joint is unstable and is usually associated with the fear of sustaining an acute ligament sprain" whereas "giving way" of the ankle joint is defined as "uncontrolled and unpredictable episodes of excessive inversion of the rear foot..., which do not result in an acute lateral ankle sprain."
**Functional Performance Tests**

Recent systemic review and meta-analysis showed that postural control is impaired as a result of acute ankle sprains, contributing to increased risk of re-injury and development of CAI. Adverse effects of this impairment may influence contralateral uninjured limbs due to centrally mediated motor control pattern alterations, and therefore contralateral uninjured limbs may not be appropriate as a reference of normal postural control. Furthermore, it is suggested that static single-limb stance tasks may not be “challenging enough” to detect these postural control deficits, and hence more challenging dynamic tasks may be more appropriate as an outcome measure.

Although predominantly investigated on the patients with the anterior cruciate ligament deficient and reconstructed knee, functional performance tests (FPTs) challenge various aspects of the sensory motor system to assess functional recovery, and confidence in the limb, help RTP decisions, and identify those who are at risk of re-injury. Often, the limb symmetry index of <90% or more than 10% difference between the injured and noninjured limbs is considered as unsatisfactory following ACL injury. A positive correlation between the single leg hop limb symmetry index and
self-reported functions, and prognostic ability of single leg hop limb symmetry index for long term outcome have been reported.\textsuperscript{61,99}

Numerous studies have reported FPTs are able to effectively identify individuals with ankle sprains and CAI.\textsuperscript{13,14,30,37,43,45,44,58,86,119,118,142,176} although a few studies have demonstrated otherwise.\textsuperscript{31,120,183} Furthermore, a few studies found its effectiveness when a feeling of instability or "giving way" during FPTs was included in the analysis.\textsuperscript{13,14,37} Similarly, Eechaute et al reported a FPT can reliably detect individuals with CAI based upon perceived difficulty with the FPT as rated the visual analogue scale (VAS).\textsuperscript{43,45,44}

Typical mechanisms of injury of lateral ankle sprains involve excessive supination of the rearfoot, coupled with external rotation of the lower leg immediately after initial contact to the ground during athletic activities.\textsuperscript{67} FPTs achieve the intended purposes by replicating the stress that is placed on the body during sports activities. As expected, those FPTs which found to be effective typically involve single-limb hop maneuvers, challenging the lateral aspect of the ankle.\textsuperscript{13,14,30,37,43,45,44,58,86,119,118,142,176,180} Summary of the findings from those studies is presented in the TABLE 1-2.

As most of the studies, except three studies, were conducted on general
adult populations or recreational athletes with chronic conditions, their applicability to competitive athletes are unknown. Also, prior to their participations in these studies, participants did not receive formal rehabilitation\(^{30,119,142,176,180}\) or such information was not provided in most of studies.\(^{13,14,43,45,44,119,142,176,180}\) Furthermore, only two studies provided self-reported outcome scores of their participants.\(^{86,176}\) Therefore, severities of disability of participants were unknown and difficult to compare, and the relationship between performance in FPTs and disabilities cannot be elucidated.
### TABLE 1-2. Summary of the studies on Functional Performance Test of Ankle Joint

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Rehabilitation</th>
<th>Self-reported outcome score</th>
<th>FPT</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buchanan AS, et al. 2008.(^{13})</td>
<td>20 physically active, college-aged individuals with FAI vs. 20 controls</td>
<td>Not reported.</td>
<td>Single-limb hopping test (for Agility)(Lateral Direction) Single-Limb Hurdle Test (for Agility) (Lateral Direction)</td>
<td>No significant differences between the FAI and control groups for the Single-limb hopping or Single-Limb Hurdle Tests. Nearly 50 % the individuals with FAI and none of the individuals in the control reported a feeling of instability during the tests. Significant differences between the FAI with a feeling of instability and both the controls and the FAI without a feeling of instability.</td>
</tr>
<tr>
<td>Caffrey EC 2009.(^{14})</td>
<td>30 physically active young adults with FAI vs. 30 controls</td>
<td>Not reported.</td>
<td>6-meter crossover hop (for Agility) Figure-of-8 hop (for Agility) Side hop (for Agility) Square hop (for Agility)</td>
<td>Although relatively small, significant functional performance deficits were present in the individuals with FAI who also had a feeling of instability during the tests.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Conditions</td>
<td>Tests</td>
<td>Results</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
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<td>---------</td>
</tr>
<tr>
<td>Delahunt E, et al. 2007&lt;sup&gt;30&lt;/sup&gt;</td>
<td>26 young adults with FAI vs. 24 controls</td>
<td>Not receiving formal rehabilitation at the time of testing</td>
<td>Side hop test (for Agility)</td>
<td>The individuals with FAI had a significantly less-everted position of the ankle joint before and following initial contact with the ground. The ankle joint neuromuscular control system might be challenged in the lateral hopping. Clinicians may be able to identify altered kinematic, kinetic and muscle activity patterns in individuals with FAI. Frontal, sagittal or transverse plane movements or velocities at the hip or knee joints were not significantly different between the groups.</td>
</tr>
<tr>
<td>Docherty CL, et al. 2005&lt;sup&gt;37&lt;/sup&gt;</td>
<td>42 healthy college students with unilateral FAI vs. 18 controls</td>
<td>Not reported.</td>
<td>Figure-of-8 hop test (for Agility) Side-hop test (for Agility) Up-down hop test (for Agility) Single-hop test (for Distance)</td>
<td>The individuals with higher FAI index had greater performance deficits on the figure-of-8 hop and side hop tests. There were significant correlations between the FAI index and the side hop ($r = .35$) and FAI index and the figure-of-8 hop ($r = .31$). There was a correlation between the FAI index and the presence of perceived instability during the FPTs ($r = .43$).</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Comments</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
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</tr>
<tr>
<td>Eechaute C, et al. 2012.43</td>
<td>29 adults who participate in recreational or competitive sports with CAI vs. 29 controls</td>
<td>Not reported.</td>
<td>Multiple hop test for agility (for Agility) (with balance error scoring system)</td>
<td>Multiple hop test might be appropriate as a discriminative tool for CAI.</td>
</tr>
<tr>
<td>Eechaute C, et al. 2008.45</td>
<td>29 adults who participate in recreational or competitive sports with CAI vs. 29 controls</td>
<td>Not reported.</td>
<td>Multiple hop test for agility (for Agility) (with balance error scoring system)</td>
<td>The individuals with CAI needed significantly longer time to complete the test. VAS scores of difficulty with Multiple hop test of CAI were significantly higher when compared with contralateral side.</td>
</tr>
<tr>
<td>Eechaute C, et al. 2009.44</td>
<td>29 adults who participate in recreational or competitive sports with CAI vs. 29 controls</td>
<td>Not reported.</td>
<td>Multiple hop test for agility (for Agility) (with balance error scoring system)</td>
<td>CAI used significantly more a change-in-support strategy. The number of balance errors was significantly correlated with the time to complete the test and VAS score of perceived difficulty of the test.</td>
</tr>
<tr>
<td>Gerber JP, et al. 1998.58</td>
<td>96 young adults (cadets) with various degree of ankle sprains</td>
<td>Formal Rehabilitation</td>
<td>Lateral Hop (for Distance) Forward Hop Test (for Distance)</td>
<td>At 6 week post injury, 23% had &gt; 20% deficits in the FPTs when compared uninjured limbs. Subjects regained forward hopping ability sooner than lateral hop ability.</td>
</tr>
<tr>
<td>Johnson MR, et al. 2007.56</td>
<td>29 young adults (cadets) with lateral sprain within 5 days from the injury</td>
<td>Formal Rehabilitation</td>
<td>Sports Ankle Rating System</td>
<td>Lateral Hop (for Distance) Forward Hop Test (for Distance)</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Methods</td>
<td>Results</td>
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<td></td>
</tr>
<tr>
<td>Monteleone BJ, et al. 2012.119</td>
<td>12 young adults with no history of previous ankle injury</td>
<td>Not reported.</td>
<td>Not reported.</td>
<td>Side hop test</td>
</tr>
<tr>
<td>Sekir U, et al. 2008.142</td>
<td>24 healthy, male recreational athletes</td>
<td>Not receiving formal rehabilitation at the time of testing</td>
<td>Not reported.</td>
<td>Single limb hopping course Single legged Lateral hop for distance Triple legged hop for distance 6 meter hop for time Cross 6 meter hop for time</td>
</tr>
<tr>
<td>Wikstrom EA et al, 2009.176</td>
<td>24 young adult copers, 24 with CAI, vs. 24 controls</td>
<td>No formal habilitation allowed</td>
<td>FADI</td>
<td>Figure-8 hop (for Agility) Side-to-side hop (for Agility) Triple-crossover hop (for Agility) Single-leg hop (for Distance)</td>
</tr>
<tr>
<td>Study: Witchalls JB, et al. 2013.</td>
<td>Participants: 18 young adults with varying degrees of the ligament laxity with the anterior drawer test (unspecified ankle sprain history)</td>
<td>Methods: Not reported. Single hop (for Distance) Hexagon hop test (for Agility) Hop-and-hold test</td>
<td>Findings: A significant difference between lax and stable ankles in the hexagon hop test. Although non-significant, the legs with ligament laxity scored approximately 10% less distance than healthy legs in the single hop for distance.</td>
<td></td>
</tr>
</tbody>
</table>
Prognosis of Ankle Sprains

Traumatic lateral ankle sprains are typically classified as mild, moderate, or severe, which correspond to first, second and third degree sprains. Traditionally, those classifications are based upon various clinician-rated measures, and are vaguely determined.\textsuperscript{8,58} These measures typically include swelling, range of motion, muscle strength, palpation, and ligamentous laxity.\textsuperscript{3,147} However, there is relatively limited evidence to support such classification system’s prognostic ability, which guides the treatment and rehabilitation process.\textsuperscript{23,161} This is detrimental to the quality of care as successful RTP with minimal symptoms is the primary concern of the injured athlete and the goal of the athletic rehabilitation process.\textsuperscript{163} If clinicians can provide athletes with a more realistic estimation of RTP, and expectations and requirements of the rehabilitation process, athletes will follow the rehabilitation program better, which will subsequently result in a better outcome.\textsuperscript{60,69}

Furthermore, clinical evaluation and RTP decisions have been criticized as being predominantly based upon clinician-rated measures in sport rehabilitation fields.\textsuperscript{19,50,115,144,159} In fact, it has been reported that prediction of RTP after traumatic lateral ankle sprains is more accurate and valid when it is
based upon patient-rated measures in addition to clinician-rated measures.\textsuperscript{23,178,179}

Cross et al reported that global function question, the SF-36 Health Survey Physical Function scale as well as the athlete’s ambulation status, measured within 24 hours following injury, are valid in predicting the duration of the time to RTP following traumatic lateral ankle sprains among twenty NCAA Division II college athletes.\textsuperscript{23} On the other hand, visual analog pain scale, combination of plantarflexion and dorsiflexion AROM, dorsiflexion muscle strength, and plantarflexion muscle strength measures were not correlated with the duration of the time to RTP.\textsuperscript{23}

Similarly, Wilson and Gansneder reported that the impairment measures, which consisted of passive dorsiflexion range of motion and swelling, explained only one third of the variance in the disability duration ($r^2 = 0.34$) following traumatic lateral ankle sprains among twenty-one NCAA Division I college athletes.\textsuperscript{178} By combining the activity limitation measures with the impairment measures, it improved the prediction of disability duration ($r^2 = 0.67$). However, activity limitation measures alone explained nearly 66% ($r^2 = 0.66$) of the variance in the duration of the duration of the time to RTP.
In both of the studies by Cross\textsuperscript{23} and Wilson,\textsuperscript{178} the investigators made up the actability limitation measures on their own. It can reasonably be speculated that self-reported outcome instruments with higher construct validity, such as the FAAM, will have a better prognostic ability for the duration of disability following traumatic lateral ankle sprains.

**SECTION 1-4: Aims of this thesis**

The primary purposes of the following investigations were:

1. To provide the evidence of validity of the Japanese version of the Foot and Ankle Ability Measure.

2. To investigate self-reported functions and single-limb hop test performance at return-to-play phase following traumatic lateral ankle sprains among competitive college basketball players.

3. To investigate the prognostic ability of patient- and clinician-rated measures for traumatic lateral ankle sprains among competitive collegiate basketball players.
Chapter 2: 
Evidence of validity for the Japanese version of the 
Foot and Ankle Ability Measure

SECTION 2-1: ABSTRACT

Context: The Foot and Ankle Ability Measure (FAAM) is a valid and reliable, self-reported, outcome instrument for the foot and ankle region.

Objective: The aim of this study was to provide the evidence of translation, cross-cultural adaptation, validity, and reliability of the Japanese version of the FAAM (FAAM-J).

Design: Cross-sectional study.

Setting: Collegiate athletic training/sports medicine clinical setting.

Patients or Other Participants: Eighty-three collegiate athletes.

Main Outcome Measure(s): All participants completed the activities of daily living and sports subscales of the FAAM-J and the physical functioning and mental health subscales of the Japanese version of the short form-36v2 (SF-36). Also, 19 participants (23%), whose conditions were expected to be stable, completed another FAAM-J 2 to 6 days later for test-retest reliability. We
analyzed the scores of those subscales for the convergent and divergent validity, internal consistency, and test-retest reliability.

**Results:** Our results showed that the activities of daily living and sports subscales of the FAAM-J had 0.86 and 0.75 correlation coefficients with the physical functioning section of the SF-36 for convergent validity. For divergent validity, the correlation coefficients with mental health of the SF-36 were 0.29 and 0.27 for the activities of daily living and sports subscale. A 95% confidence interval with a single measure was +/- 8.1 and +/- 14.0 points for each subscale. The test-retest reliability measures revealed intraclass correlation coefficient values of 0.87 for the activities of daily living and 0.91 for the sports subscales with minimal detectable changes of +/- 6.8 and +/- 13.7 for respective subscale.

**Conclusions:** The FAAM was successfully translated for a Japanese version, and the FAAM-J was adapted cross-culturally. Thus, the FAAM-J can be used as a self-reported outcome measure for Japanese-speaking individuals; however, the scores must be interpreted with caution, especially when applied to different populations and other types of injury than those included in this study.
SECTION 2-2: INTRODUCTION

To the author’s knowledge, the FA translated for its use in German, Persian, and French. As of this writing, it has not been translated into Japanese. Thus, the primary objective of this study was to provide evidence of validity and reliability of the Japanese version of the FAAM (FAAM-J).

SECTION 2-3: METHODS

The Instrument

The FAAM, originally developed by Martin et al, has a total of 29 items on its questionnaire with 21 items in the ADL subscale and 8 items in the Sports subscale. Each item is scored on a 5-point Likert scale, 4 representing “no difficulty at all”, 3 “slight difficulty”, 2 “moderate difficulty”, 1 “extreme difficulty” and 0 “unable to do” respectively. Therefore, the highest possible scores are 84 for the ADL subscale and 32 for the Sports subscale. Unanswered items or N/A responses are not counted to the total score, and hence with every item without a response or N/A, 4 points are subtracted from the highest potential score. To get percentage values, each total subscale scores are divided by the highest potential scores. A higher score represents a higher level of physical function. At
the end of each subscale, global ratings of functions for ADL (GRF-ADL) and sports related activities (GRF-SP) are also rated with 0% indicating the inability to perform any of the usual daily activities and 100% indicating the level of function before injury. Additionally, at the end of the form, patients are asked to rate the current level of function with a 4-point Likert scale (normal, nearly normal, abnormal, or severely abnormal). The patients rate each item according to the difficulty they feel with each task due to their foot and ankle condition.

**SF-36**

The SF-36v2 Health Survey (SF-36) is a generic self-reported outcome instrument to measure a wide range of effects of a condition or disease on patients.\textsuperscript{170,171} It consists of 8 subscales, including Physical Functioning (PF), Role-Physical, Bodily Pain, General Health perception, Vitality, Social Functioning, Role-Emotional, and Mental Health (MH). Each subscale has a 0 to 100 score range and a higher score represents a better health status. The Japanese version of the SF-36 was validated by Fukuhara et al.\textsuperscript{56,57}

**Translation & Cross Cultural Adaptation process**

Translation and cross cultural adaptation process in the current study was conducted in accordance with the guidelines set by the International Society
The forward translation of the original version of the FAAM was conducted by two independent native Japanese translators (T1 & T2) with extensive English expertise without any medical background. In a consensus meeting, T1 and T2 discussed the discrepancies and agreed on the preliminary version of the FAAM-J. Translator 3, a native Japanese with medical expertise and broad experience in translating medical literature, rated the preliminary version of the FAAM-J in terms of clarity, common language use and conceptual equivalence, creating the forward-translation version of the FAAM-J. Translators 4 and 5, native Japanese with extensive translation experience, then translated the forward-translation version of the FAAM-J back into English (back-translation version of the FAAM-J). Translator 6, a native American English speaker with no medical background, compared the back-translation version of the FAAM-J with the original FAAM in terms of conceptual equivalence to make further adjustments as needed. A committee reviewed and discussed the disagreements and possible modifications, agreeing on the pre-final version of the FAAM-J. A pilot study of the pre-final version of the FAAM-J on 20 collegiate students was conducted for accuracy of wording and ease of understanding, and no difficulties were noted during this process.
Participants/Subjects

Eighty three competitive athletes (59 males and 24 females, 20.3 ±3.7 yoa) with foot and ankle pathologies from 7 competitive collegiate varsity teams (1 men’s basketball, 3 women’s basketball, 1 men’s rugby, 1 men’s soccer and 1 men’s gymnastics) from 3 institutions volunteered to participate in the study. Foot and ankle pathologies were included in the study if they were musculoskeletal in origin and sustained during their sport participation. Subjects were excluded if they had injuries to the lower back, hip, knee, lower leg, ankle or foot regions within the previous 6 months prior to the condition they were measured on. Other exclusion criteria were a history of surgery to the above mentioned areas, co-existing musculoskeletal injuries in other body parts, and chronic conditions such as systematic inflammatory rheumatic disease, neurological or vascular conditions, cancer, diabetes mellitus, alcohol abuse and psychiatric disorders.106

Injury Classification

The location and type of injury were categorized in a classification system, which was modified from the previous literature.87 The locations of injury included Achilles tendon, ankle, foot and toes. The types of injury were;
fracture (traumatic), stress fracture (overuse), other bone injuries, dislocation/subluxation, tendon rupture, sprain (injury of joint and/or ligaments), lesion of meniscus or cartilage, strain/muscle rupture/tear, contusion/hematoma/bruise, tendinosis/tendinopathy, bursitis, laceration/abrasion/skin lesion, muscle cramps or spasm, and others.\textsuperscript{87}

**Data Collection**

Prior to participating in the study, all subjects read and signed a consent form, approved by the Institutional Review Board of Waseda University. They were then given the FAAM-J and SF-36 and asked to complete the forms. The forms were given to the subject once they had a condition with an acute or chronic onset, and sought a medical attention from their respective team medical personnel while the nature of the conditions and the inclusion and exclusion criteria were confirmed. For reliability testing, 19 participants, whose conditions were expected to remain stable (i.e. chronic state, no treatments), were requested to fill out the forms again 2 to 6 days after the initial recording. This study was approved by the institutional review board of Waseda University.

**Statistical Analysis**

To examine the convergent validity, the correlations between the ADL
and Sports subscales of the FAAM-J, and the PF subscale of the SF-36 were analyzed with Pearson correlation coefficients. Likewise, the correlations between the ADL and Sports subscales of the FAAM-J and the MH Subscale of the SF-36 were analyzed to acquire the divergent validity. The a priori alpha level for this analysis was set at 0.05. Also, Pearson Correlation Coefficients between the ADL Subscale of the FAAM-J and the GRF-ADL, and the Sports subscale of the FAAM-J and the GRF-SP, were calculated.

Cronbach’s coefficient alpha was acquired for the assessment of the internal consistency. The Standard Error of Measurement (SEM) of each subscale scores were calculated as \( SEM = \sigma \sqrt{1 - r} \) where \( \sigma \) was the standard deviation of the scores and \( r \) was the coefficient alpha. The error associated with a score at a single point in time was acquired by calculating a 95% Confidence Interval (CI).

Test-retest reliability was examined with Intra-class correlation coefficients (ICC 2,1). To confirm there was no systemic bias between the test and retest sessions, paired t-test was performed. We determined the SEM using the ICC test retest reliability coefficient. The SEM was multiplied by \( \sqrt{2} \) and a 95% CI was calculated to determine the minimal detectable change (MDC). All
statistical analyses were performed using the SPSS 20.0 (SPSS Japan Inc., Tokyo, Japan).

SECTION 2-4: RESULTS

Participants/Subjects

The demographic information, injury types, and locations are presented in TABLE 2-1. While the predominant body part involved was the ankle, the most frequent injury type was a sprain.
TABLE 2-1. Demographic Information of the Subjects, and the Types and Locations of the Injury

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, y</strong></td>
<td>20.3</td>
</tr>
<tr>
<td>(range = 18-24, SD = ± 3.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>59/83 (71 %)</td>
</tr>
<tr>
<td>Female</td>
<td>24/83 (29 %)</td>
</tr>
<tr>
<td><strong>FAAM Score (%)</strong></td>
<td></td>
</tr>
<tr>
<td>ADL Subscale</td>
<td>74.2% (range = 0-100, SD = ± 29.4%)</td>
</tr>
<tr>
<td>Sports Subscale</td>
<td>52.1% (range = 0-100, SD = ± 35.7%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
</tr>
<tr>
<td>Ankle</td>
<td>63/83 (76%)</td>
</tr>
<tr>
<td>Foot</td>
<td>19/83 (23%)</td>
</tr>
<tr>
<td>Toe</td>
<td>1/83 (1%)</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td></td>
</tr>
<tr>
<td>Sprain (injury of joint and/or ligaments)</td>
<td>71</td>
</tr>
<tr>
<td>Fracture (traumatic)</td>
<td>2</td>
</tr>
<tr>
<td>Lesion of meniscus or cartilage</td>
<td>2</td>
</tr>
<tr>
<td>Other bone injuries</td>
<td>2</td>
</tr>
<tr>
<td>Stress fracture (overuse)</td>
<td>2</td>
</tr>
<tr>
<td>Tendinosis/tendinopathy</td>
<td>2</td>
</tr>
<tr>
<td>Contusion/hematoma/bruise</td>
<td>1</td>
</tr>
<tr>
<td>Others</td>
<td>1</td>
</tr>
</tbody>
</table>
Translation and Cross Cultural Adaptation

No major difficulties were encountered during the translation and cross cultural adaptation process. As expected, a few minor discrepancies were found during the forward translation process, however, the translators could decide on the agreements without any difficulties. In item 5 of the Sports subscale, “Cutting” was translated as “Katteinngu” in katakana (a set of Japanese alphabets for foreign words) by one translator and as “Houkoutenkan”, (literally “change of direction” in Japanese) by the other translator. We decided to use “Houkoutenkan” rather than “Katteinngu” as we thought “Katteinngu” is a sport specific maneuver and appropriate if the FAAM was intended to be used only on athletes and physically active individuals. Furthermore, “Katteinngu” seemed too technical a term for the general population in Japanese and therefore may be misinterpreted by many individuals who do not understand the meaning of the word. Also, we thought that as “Houkoutenkan” is listed in the Sports subscale, people will take the word “Houkoutenkan” in the sport activity context. Therefore, “Houkoutenkan” is more correctly interpreted by respondents. In contrast, in item 7 of Sports subscale, the word “Technique” was translated as “Gihou” by one translator, yet we agreed to use “Tekunikku”, literally written as “technique” in
After initial corrections of the minor discrepancies, no further difficulties were noted during the translation, evaluation or pilot testing processes.

**Convergent and Divergent Validity**

Statistical analysis revealed correlation coefficients of 0.86 between the ADL Subscale and PF of the SF-36 (p < .001), and 0.75 between the Sports Subscale and PF of the SF-36 (p < .001). On the other hand, the ADL Subscale had a correlation coefficient of 0.29 with MH of the SF-36 (p = .007) and the Sports Subscale had a correlation coefficient of 0.27 with MH of the SF-36 (p = .013). Also, the ADL Subscale showed a correlation coefficient of 0.89 (p < .001) and 0.80 (p < .001) with the GRF ADL and SP respectively while the Sports Subscale had 0.80 (p < .001) and 0.87 (p < .001) correspondingly.

**Internal consistency**

Cronbach’s alpha for internal consistency was 0.99 for the ADL Subscale (p < .001) and 0.98 for the Sports subscale (p < .001). The SEM for the ADL Subscale was 2.9 with a 95% CI of +/- 8.1 whereas the SEM for the Sports Subscale was 5.0 with a 95% CI of +/- 14.0.

katakana, as it is more commonly used in the Japanese language than "Gihou".
**Test-Retest Reliability**

Paired t-test revealed no systemic bias between the test and retest scores for both ADL (p = .096) and Sports (p = .848) Subscales. Both subscales were shown to have an excellent reliability. The MDC at 95% CI was +/- 6.8 for the ADL Subscale, and +/- 13.7 for the Sports subscale.

**SECTION 2-5: DISCUSSION**

Clinician-rated measures relate to impairment-oriented data such as strength, pain, swelling and ROM, and provide information of an uncertain clinical utility.\(^{78,83}\) Though valuable in many ways, they should not be used as the sole outcome measure.\(^{115}\) On the other hand, patient-rated measures reflect on patient's values, perceptions of the condition they suffer\(^ {53,159}\) and provide the patient-oriented evidence that is directly related to the interest of patients. Moreover, a recent study indicates that clinician- and patient-rated outcome measures assess two different aspects of health status.\(^ {137}\) Thus, it is important to incorporate both types of outcome measures into the clinical decision making process.

The current study provided the evidence of translation and cross cultural
adaption as well as the evidence of convergent validity, divergent validity, internal consistency and test-retest reliability of both subscales of the FAAM-J. Therefore, the use of the FAAM-J as a self-reported outcome measure for the foot and ankle region was validated with some limitations.

Although interrelated, face validity relates more to whether an instrument is measuring what it is designed to measure, whereas content validity is concerned with adequacy, or the extent to which the items in an instrument measure the domain of interest.\textsuperscript{63,133} It is important that not only the experts, but also the patients, participate in developing an instrument.\textsuperscript{53,101} The original version of the FAAM went through a rigorous item selection process in which both of the expert clinicians and patients participated, utilizing the item reduction theory (IRT).\textsuperscript{106} Although the evaluation of face and content validity is qualitative and subjective in nature, this meticulous process in the original version of the FAAM, which incorporated both of the expert clinicians' and the patients' values and opinions, provided the evidence of the face and content validity of the FAAM.

Construct validity relates to the ability of an instrument to measure a construct, an unobservable, abstract concept.\textsuperscript{53,133}

The construct validity of an instrument is acquired by evaluating the
correlation between the tested instrument and other measures, which is logically hypothesized from a relationship between the patient’s health status and the construct. Also, there are two types of construct validity; convergent and discriminant, or divergent. Evidence of convergent validity is provided when the instrument being tested, is shown to have a strong correlation with other measures of the same construct. Whereas, divergent validity is granted when there is shown to be a weaker or no relationship at all between the score on the tested instrument and measures of a different construct. The constructs that the FAAM is intended to measure are functional limitations to the foot and ankle region, and activity restrictions. In the current study, as expected, both subscales of the FAAM-J were shown to have high correlations with PF and low correlations with MH of the SF-36. The correlation coefficients with PF were 0.86 for the ADL subscale and 0.75 for the Sports subscale while those with MH were 0.29 for the ADL Subscale and 0.27 for the Sports Subscale. Furthermore, the results of the current study were in accordance with the original and French versions of the FAAM. Thus, the subscales of the FAAM-J were correlated with the physical functioning aspect of the patients’ health status, but not the mental health aspect, granting the evidence of the convergent and divergent
validity of the FAAM-J.

The extent to which the items in an instrument are measuring different aspects of the construct is referred as internal consistency and associated with an error within a single measure. Internal consistency is commonly assessed with the correlation between all items in the instrument. In this study, Cronbach’s alphas for the internal consistency were found to be 0.99 with a SEM of 2.9 for the ADL subscale, and 0.98 with a SEM of 5.0 for the Sports subscale. The 95% CI with a single measure was +/- 8.1 and +/- 14.0 for respective subscales. The 95% CI value for the Sports subscale of the FAAM-J was found to be different from the values in the original version and French version. Although speculative, a couple sources of the discrepancy were conceivable. First, the patient population could be a source of the discrepancy; general adults (41.2 ± 16.3 years for the original version and 50.5 ± 14.6 years for the French version) were the subjects of the other two studies whereas the young, competitive athletes (20.3 ± 3.7 years) were the subjects of the current study. Second, the proportions of the injury location and type varied among the studies. Especially in the current study, the location and type of injury were largely acute ankle sprains. This was, however, expected considering the nature of the population in
the current study, which were competitive collegiate athletes. Reliability relates to the stability of the scores at repeated measures when no change to the health status is expected. It is assessed by the test retest measure. The evidence of the reliability of the FAAM-J was provided with the excellent ICCs for the ADL and Sports subscales. The MDC value for the Sports Subscale was substantially smaller in this study compared with those of the original and French versions. A possible explanation, along with the above-mentioned sources of the discrepancies, may be the time period between the test and retest; it was 4 weeks in the original version and 2 days in the French version while it was 2-6 days in this study.

The FAAM has been widely utilized as a self-reported outcome measure to assess functional limitations and activity restrictions caused by various pathological conditions to the foot and ankle region, and to assess the effectiveness of interventions that clinicians provide. Such conditions include foot and ankle trauma, acute ankle sprain, plantar heel pain, plantar fasciitis, ankle arthrodesis, ankle arthritis, chronic ankle instability, recurrent peroneal subluxation, and diabetes. The original version of the FAAM, along with three other questionnaires, provided evidence of content
validity, construct validity, reliability and responsiveness to support its use. Also, the FAAM and the Foot and Ankle Disability Index, a prototype of the FAAM, were considered to be the most suitable self-reported outcome instrument for the chronic ankle instability by a systemic review. Therefore, it was deemed appropriate and valuable to cross-culturally adapt and translate the FAAM for its use in Japanese.

Furthermore, a standard method of assessment allows comparisons of different treatment methods. The prevalent use of the FAAM allows clinicians to make such comparisons for better clinical decisions. Thus, a cross-culturally adapted version of the FAAM is beneficial not only for those individuals who speak that language, but also for those who use the other language versions of the FAAM.

A recent study showed that the individuals with functionally ankle instability (FAI) had significantly lower FAAM scores and SF-36 Physical Component Summary (PCS). In addition, both ADL and Sports subscales of the FAAM of the FAI were positively correlated with the SF-36 PCS and related subscales, but not with Mental Component Summary (MCS). Furthermore, the scores of the FAAM were correlated with the PF subscale to a greater degree.
than with the PCS itself or other subscales of the PCS. Therefore, although the functional limitations caused by FAI contributes to the Health Related Quality of life (HR-QOL), the FAAM primarily captured and was more specific to a physical dimension, and other factors contributed to the overall HR-QOL. Therefore, clinicians need to be careful with the dimensions they intended to capture with the FAAM.

There are some limitations in the current study. Firstly, although our translation process was in accordance with the guideline in the previous literature, there were limitations to our validation process with the classical test theory. Namely, the classical test theory focuses only on the whole test score and disregards the interaction between a respondent's ability and the characteristics of the item, such as difficulty, and each item's sensitivity to the respondent's ability level while the IRT can account for these factors. A study utilizing the IRT indicated that some items in a self-reported outcome instrument are more culture specific than others, while the current study did not address this issue as the classical test theory was applied. Additionally, the FAAM-J was compared with the original version of the FAAM and SF-36 in our method, and hence the reliability and validity of the FAAM-J was confined to those of the
instruments. Therefore, though our method was similar to that of the French version of the FAAM, future research needs to address these limitations with the FAAM-J.

Secondly, the characteristics of the subjects of the current study were different from those of the original and French version of the FAAM. Specifically, the current study was conducted on young, competitive athletes while the previous two studies were on regular adults in a general population. A previous study showed that the scores of SF-36 of noninjured elite athletes slightly differed from the age matched norm values and this trend was more substantial among females. Another study on physically active individuals showed that the uninjured control individuals, as well as those with FAI, had better PF subscale scores than the general population, while only the uninjured control had better PF scores than the age-matched population. On the other hand, both control and FAI groups had similar MCS scores with the general population although they were below the age-matched population. Furthermore, the magnitudes of functional limitations, participation restrictions, and disabilities experienced by injured individuals might vary according to the expected normal levels for each individuals. Therefore, further evidence is needed on this aspect of the
FAAM-J and the scores of the FAAM-J must be interpreted with caution when applied to a general population.

**SECTION 2-6: CONCULUSION**

This study provides the evidence of cross-cultural adaptation and translation along with convergent and divergent validity, internal consistency, and test-retest reliability of the FAAM-J. Thus, the FAAM-J can be used as a self-reported outcome measure of an athletic population of Japanese-speaking individuals with acute ankle injuries; however, the scores of the FAAM-J must be interpreted with caution especially when applied to a different population and other types of injury.
Chapter 3:
Self-reported functions and single-limb hop test performance at return-to-play phase following traumatic lateral ankle sprains among competitive college basketball players.

SECTION 3-1: ABSTRACT

STUDY DESIGN: Prospective case control study.

OBJECTIVES: To determine if functional deficits are present in college basketball players at RTP phase following traumatic lateral ankle sprain in the activities of daily living (ADL) and Sports subscale of the FAAM-J (FAAM-J ADL, FAAM-J SP) as well as in single-limb hop tests (SLHTs).

BACKGROUND: Literature suggests an absence of self-reported outcome measures in the field of sports medicine. Little evidence is available to show functional performance deficits are present in college basketball players following traumatic lateral ankle sprains.

METHODS: Thirty-one college basketball players with traumatic lateral ankle sprains and Thirty-one healthy controls participated in the study. Upon a
successful RTP, subjects completed the FAAM-J ADL and SP. Also, subjects performed two SLHTs; side hop and square hop tests, and rated the instability and pain they felt while performing the SLHTs on the visual analogue scale. The involved limbs were compared with the contralateral, healthy, and control limbs.

**RESULTS:** Significantly lower FAAM-J ADL and SP scores were found with the involved limbs compared with the contralateral limbs, and control group (p<.05). A significant finding was found only with the time measures of the side hop test. Subjects felt significantly higher instability and stronger pain with the SLHTs on the involved limbs than the contralateral, and control limbs (p<.01).

**CONCLUSION:** Based upon the scores of FAAM-J ADL and SP, collegiate basketball players were cleared for RTP without full recovery following traumatic lateral ankle sprains. Subjects had significantly higher perceived instability and greater pain with the SLHTs with the involved limbs.

**SECTION 3-2: INTRODUCTION**

To date, no study has shown that functional deficits in self-reported outcome measures as well as single-limb hop tests (SLHTs) are present among college basketball players at RTP phase following traumatic lateral ankle sprains
Despite that the use of those examinations are recommended to be included in RTP decision making process. Therefore, the purpose of this study was to elucidate if the ADL and Sports subscale of the FAAM-J (FAAM-J ADL, FAAM-J SP) as well as SLHTs can demonstrate functional deficits in the injured limbs of those subjects when compared to their contralateral uninjured limb and healthy control subjects.

SECTION 3-3: METHODS

Thirty-one Japanese college basketball players of four small institutions (21 males, 10 females, height 175.8 ±9.8 cm, weight 68.9 ±9.0 kg, age 19.0 ±3.7 yoa, 9.5 ±1.8 years of experience in competitive basketball), who sustained a traumatic lateral ankle sprain during a game or practice session, participated in the study. A traumatic lateral ankle sprain was defined as an ankle sprain that was sustained with inversion mechanism, resulting in at least one day of absence from game or practice participation (“time loss” definition of injury). The exclusion criteria for the study were: concurrent fractures, a history of surgery to the lower extremity or lower back, any preexisting athletic injury requiring medical attention at the time of the ankle injury, any injury to either foot,
ankle, knee, hip or lower back region that resulted in any restrictions from practice/game participation in the previous six months. Additionally, ankle sprains were not included in the study when clinical evaluation revealed that signs and symptoms were not limited to the lateral aspect of the joint, but also present in other areas such as metatarsal bones, medial aspect of the joint, and anterior tibiofibular ligament.

Thirty-one gender, dominance matched, healthy college basketball players (height 173.9 ±11.1 cm, weight 67.7 ±12.1kg, age 19.5 ±3.8 yoa, 10.1 ±2.0 years of participation in competitive basketball) also participated in the study. Subjects in the control group had not sustained any injury to the lower extremity or lower back region resulting in restriction from participation in the previous six months, had no prior history of surgery to the lower extremity or lower back region, and had no conditions that required medical attention at the time of participation. Prior to participating in the study, all subjects read and signed the consent form approved by the Institutional Review Board of Waseda University. This was a part of a larger investigation on the effects of traumatic lateral ankle sprains among college athletes.

Rehabilitation/RTP decisions
Rehabilitation was supervised by medical personnel of respective teams. After acute inflammation signs and symptoms subsided, rehabilitation and treatment were intended to restore range of motion, muscle strength, proprioception, static and dynamic balance, and ambulatory status, following conventional guidelines.\textsuperscript{12} Once subjects were judged to have achieved normal ranges in those variables based upon conventional clinical evaluations, subjects were progressed to perform generic athletic movements, and gradually allowed restricted sport participation. When subjects did not aggravate signs and symptoms during restricted sport participation and gained confidence to resume full participation, subjects were allowed RTP. All subjects achieved RTP with athletic taping on the injured ankle.\textsuperscript{89} RTP was operationally defined as medically cleared participation in a practice or game session without any restriction, in which decisions are made by medical personnel of respective teams.\textsuperscript{21} RTP was confirmed on the following day by verifying subjects could complete the practice or game session without any restrictions. The mean number of days the subjects were restricted from full participation was 13.7 ±9.3 days. Once successful RTP was confirmed, subjects were scheduled to participate in a testing session at the subject's earliest convenience. The mean
duration between the date of RTP and the testing session was 4.8 ±3.8 days. At
three months post-RTP, it was confirmed that subjects were able to continue to
participate in game and practice sessions without reinjury or restrictions after
RTP.¹⁶⁰

SLHTs

In the Side Hop (SH) test, subjects were instructed to hop laterally 30 cm
and back for a total of 10 repetitions as quickly as possible (FIGURE 3-1). In the
Square Hop (SQ) test, from the starting position, subjects were instructed to hop
in and out around a 40 x 40 cm square back to the starting position, which
constitutes one repetition (FIGURE 3-1). Subjects completed 5 repetitions as
quickly as possible. Using the right limb, subjects hopped in a clockwise
direction; subjects hopped in a counter clockwise direction using the left limb.
With both tests, subjects were required to repeat the trial if they stepped on the
line, missed the stopwatch pad, or touched down with the opposite limb. Detailed
descriptions of the SH and SQ tests are available in previous literature.¹⁴,³⁷

Based upon a pilot study on healthy college students, the reliability of the SH
and SQ tests is excellent with ICC₂,₁ of .94 and .93 respectively. The SEM and
minimal detectable change (MDC₉₅) are: .8 sec and 2.3 sec for the SH test and
1.6 sec and 4.3 sec for the SQ test. Furthermore, the dominant and non-dominant limbs were analyzed with paired $t$ test. Likewise, the perceived instability and pain with the SLHTs was analyzed with the Mann–Whitney U test. Limb dominance was defined as the limb used to kick a ball. We found no significant differences between the dominant and non-dominant limbs for all variables. (TABLE 4-1)

FIGURE 3-1. Single Leg Hop Tests
TABLE 3-1. Comparison between the dominant and non-dominant limbs of the control group

<table>
<thead>
<tr>
<th></th>
<th>Dominant</th>
<th>Non-Dominant</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>SH Time (sec)</td>
<td>8.1 ± 1.2</td>
<td>8.1 ± 1.1</td>
<td>.96</td>
</tr>
<tr>
<td>SQ Time (sec)</td>
<td>14.9 ± 2.4</td>
<td>14.9 ± 2.4</td>
<td>.64</td>
</tr>
<tr>
<td>SH Instability (cm)</td>
<td>0.6 ± 1.6</td>
<td>0.5 ± 1.2</td>
<td>.87</td>
</tr>
<tr>
<td>SH Pain (cm)</td>
<td>0.1 ± 0.4</td>
<td>0.1 ± 0.5</td>
<td>.59</td>
</tr>
<tr>
<td>SQ Instability (cm)</td>
<td>0.3 ± 1.2</td>
<td>0.4 ± 1.1</td>
<td>.47</td>
</tr>
<tr>
<td>SQ Pain (cm)</td>
<td>0.1 ± 0.3</td>
<td>0.0 ± 0.0</td>
<td>.18</td>
</tr>
</tbody>
</table>

Abbreviations: SH; Side hop test, SQ; Square hop test, SH Time; Time measures of the SH test, SQ Time; Time measures of the SQ test, SH Instability: VAS score of the perceived instability with the SH test, SH Pain; VAS score of the pain with SH test, SQ Instability; VAS score of the perceived instability with the SQ test, SQ Pain; VAS score of the pain with SQ test.

Procedures

After signing a consent form, subjects completed both subscales of the FAAM-J. Subjects were also asked to “please rate your current level of pain with activities of daily living on the line below” and “please rate your current level of pain with your sports activities on the line below” on the VAS scales. The left end of the 10 cm VAS was labeled as “no pain at all” and the right end was labeled as “unbearable pain.”

After the five minute warm-up session, subjects were given verbal instructions as well as demonstrations by the investigators, and asked to
perform a maximum of two practice trials of each SLHT to familiarize themselves with the SLHTs. A 30-second rest period between trials was included to prevent fatigue. Subjects with a traumatic lateral ankle sprain performed the SLHTs with the injured (Involved) and healthy, uninjured (Uninvolved) limbs. The order in which subjects performed the two SLHTs was counterbalanced. All SLHTs were performed barefoot. The time to complete the SLHTs was recorded with an electronic timer (Speedtrap 2, Brower Timing Systems, Draper, UT). The means of the two successful trials for each SLHT were used in statistical analysis.

After successfully completing two testing trials of each SLHT, subjects were asked if they felt instability and pain while performing each SLHT. When subjects indicated “yes” to the questions, they were required to rate the extent of their instability and pain on the 10 cm VAS, respectively. On the instability VAS, the left end of the scale was labeled as “Not unstable at all” while the right end was labeled as “Too unstable to complete the task”. On the pain VAS, the left end of the scale was labeled as “No pain at all” while the right end of the scale was labeled as “Unbearable pain”.

STATISTICAL ANALYSIS

For the time measures of the SLHTs, the one way ANOVA with Tukey's
post hoc analysis was performed to find any significant differences among the Involved, Uninvolved, and control groups. In addition, a subgroup was formed with those individuals who felt instability with the SLHTs, and separately analyzed with Uninvolved and control limbs.

The Welch ANOVA was performed on the scores of the FAAM-J ADL and SP, and all the VAS scores for any significant differences among the limbs. Games-Howell post-hoc test was conducted on any significant findings.

Spearman's correlation coefficients between the perceived instability and pain with SLHTs and the FAAM-J ADL and SP of the Involved limbs were acquired. All statistical analyses were performed with SPSS 22.0 (SPSS Japan Inc., Tokyo, Japan). The alpha level was set at p < .05 for all analysis.

SECTION 3-4: RESULTS

Self-Reported Outcome Measures

The Welch ANOVA analysis revealed significant differences among the groups for the FAAM-J ADL (F = 10.85, p< .01), FAAM-J SP (F = 19.94, p< .01), Pain ADL (F = 15.63, p < .01), and Pain SP (F = 24.59, p < .01). For the FAAM-J ADL, FAAM-J SP, Pain ADL, and Pain SP, Games-Howell post-hoc analysis
found significant differences between the Involved and Uninvolved limbs, and between the Involved and control limbs. (TABLE 3-2)

**SLHTs**

With time measures, the one way ANOVA found a significant differences among the limbs for the SH test ($F = 3.30, p < .05$), but not with the SQ test ($F = 1.50, p = .23$). Games-Howell post-hoc analysis found a significant difference between the Involved and control limbs with SH test ($p < .05$). (TABLE 3-3) The secondary analysis, in which those who indicated “yes” to the perceived instability question with each SLHT were separately compared with the Uninvolved and control limbs, revealed the same results; a significant difference with time measures of the SH ($F = 3.62, p < .05$), but not with the SQ test ($F = 1.26, p < .05$). (TABLE 3-3) Games-Howell post-hoc analysis found a significant difference between the Involved and control limbs with SH test ($p < .05$).

For the subjective evaluation of the SLHTs, we found significant differences among the limbs with the Perceived Instability with the SH test ($F = 14.29, p < .01$) and the SQ test ($F = 7.13, p < .01$). Similarly, we found significant differences among the limbs for Pain with the SH test ($F = 9.61, p < .01$) and the SQ test ($F = 4.94, p < .01$). (TABLE 3-4) The results of the post hoc analyses are
presented in TABLE 3-4.

Spearman's rank rho revealed significant associations between Perceived Instability with the SH test and the FAAM-J ADL and SP scores, respectively. However, no significant associations were found with the SQ test. (TABLE 3-5)
<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>S.D.</th>
<th>CI&lt;sup&gt;95&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FAAM ADL</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Involved</td>
<td>82.0</td>
<td>3.2</td>
<td>80.9 83.2</td>
</tr>
<tr>
<td>Uninvolved</td>
<td>84.0</td>
<td>0.2</td>
<td>83.9 84.0</td>
</tr>
<tr>
<td>Control</td>
<td>83.9</td>
<td>0.4</td>
<td>83.8 84.0</td>
</tr>
<tr>
<td><strong>FAAM SP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Involved</td>
<td>28.1</td>
<td>4.0</td>
<td>26.7 29.6</td>
</tr>
<tr>
<td>Uninvolved</td>
<td>31.7</td>
<td>0.9</td>
<td>31.3 32.0</td>
</tr>
<tr>
<td>Control</td>
<td>31.7</td>
<td>1.6</td>
<td>31.1 32.3</td>
</tr>
<tr>
<td><strong>Pain ADL</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Involved</td>
<td>0.3</td>
<td>0.3</td>
<td>0.1 0.4</td>
</tr>
<tr>
<td>Uninvolved</td>
<td>0.0</td>
<td>0.1</td>
<td>0.0 0.0</td>
</tr>
<tr>
<td>Control</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0 0.0</td>
</tr>
<tr>
<td><strong>Pain SP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Involved</td>
<td>1.4</td>
<td>1.5</td>
<td>0.9 2.0</td>
</tr>
<tr>
<td>Uninvolved</td>
<td>0.1</td>
<td>0.2</td>
<td>0.0 0.1</td>
</tr>
<tr>
<td>Control</td>
<td>0.1</td>
<td>0.4</td>
<td>-0.1 0.2</td>
</tr>
</tbody>
</table>

* indicates post hoc analysis revealed a significant difference between the Involved and Uninvolved groups (p < .05).
† indicates post hoc analysis revealed a significant difference between the Involved and control groups (p < .05).

Abbreviations: FAAM-J ADL; FAAM-J ADL subscale, FAAM-J SP; FAAM-J Sports subscale, Pain ADL; VAS scores of pain associated with ADL, Pain SP; VAS scores of pain associated with sports activities.
# TABLE 3-3. Time measures of the Single Leg Hop Tests (sec)

<table>
<thead>
<tr>
<th></th>
<th>SH</th>
<th>SQ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>S.D.</td>
</tr>
<tr>
<td>Involved</td>
<td>8.85</td>
<td>1.24</td>
</tr>
<tr>
<td>Uninvolved</td>
<td>8.74</td>
<td>1.21</td>
</tr>
<tr>
<td>Control</td>
<td>8.16</td>
<td>0.95</td>
</tr>
<tr>
<td>Involved with Instability (n=24)</td>
<td>8.94</td>
<td>1.26</td>
</tr>
</tbody>
</table>

Abbreviations: SH Time; the time measure for the Side hop test, SQ Time; the time measure for the Square hop test, Involved with instability; those individuals who felt instability with the single leg hop tests.
Table 3-4. Perceived Instability and pain of the Single Leg Hop Tests (cm)

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>S.D.</th>
<th>CI95</th>
</tr>
</thead>
<tbody>
<tr>
<td>SH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instability</td>
<td>Involved</td>
<td>1.9</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>Uninvolved</td>
<td>0.3</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Pain</td>
<td>Involved</td>
<td>1.1</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Uninvolved</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>SQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instability</td>
<td>Involved</td>
<td>0.8</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>Uninvolved</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Pain</td>
<td>Involved</td>
<td>1.7</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>Uninvolved</td>
<td>0.5</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.5</td>
<td>1.4</td>
</tr>
</tbody>
</table>

* indicates post hoc analysis revealed a significant difference between the Involved and Uninvolved groups. (p < .01)

† indicates post hoc analysis revealed a significant difference between the Involved and control groups. (p < .01)

Abbreviations: SH; Side hop test, SQ; Square hop test, Instability; the perceived instability with the single leg hop tests, Pain; the perceived pain with the single leg hop tests.
### Table 3-5. Spearman's rank correlation coefficients between Single Leg Hop Tests and the perceived instability

<table>
<thead>
<tr>
<th></th>
<th>SH Instability</th>
<th>SH Pain</th>
<th>SQ Instability</th>
<th>SQ Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAAM ADL</td>
<td>-.57*</td>
<td>-.26</td>
<td>-.25</td>
<td>-.31</td>
</tr>
<tr>
<td>FAAM SP</td>
<td>-.43†</td>
<td>-.25</td>
<td>-.10</td>
<td>-.14</td>
</tr>
</tbody>
</table>

SH; Side hop test, SQ; Square hop test,

* indicates the significant level is at $p < .01$.

† indicates the significant level is at $p < .05$. 
SECTION 3-5: DISCUSSION

Self-Reported Outcome Measure

The results of this study provide evidence that functional deficits were present in both of the subscales of the FAAM-J with injured limbs of college basketball players at the RTP phase following traumatic lateral ankle sprains. In fact, the mean differences between the Involved and Uninvolved limbs, and between the Involved and control limbs were larger than MDC of the FAAM-J SP.\textsuperscript{158} Furthermore, the lower bounds of confidence intervals of the FAAM-J ADL and SP of the Uninvolved and control limbs were higher than the upper bounds of those of the Involved limbs. Therefore, it is unlikely that the mean differences in this study were caused by chance.

The literature reveals a paucity of self-reported outcome measures in the sports medicine field despite that they are integral to patient-centered medical practice.\textsuperscript{19,34,50,115} Furthermore, the literature has suggested patient- and clinician-rated measures assess different aspects of health-related quality of life.\textsuperscript{96,137} Therefore, lack of patient-rated outcome measures will significantly diminish the quality of outcome measures as assessed by health care professionals in the sports medicine field.
Additionally, there have been few studies to show that athletes are in fact achieving RTP with functional deficits although premature RTP has been implicated as one of the causes for the development of CAI.\textsuperscript{113} To the authors’ knowledge, this study was the first to provide the self-reported outcome scores of competitive college basketball players at the RTP phase following traumatic lateral ankle sprains. Based upon the self-reported outcome scores in this study, competitive college basketball players were indeed cleared for RTP without full recoveries.

Of the four studies that utilized the SLHTs similar to the current study,\textsuperscript{13,14,37,176} only one study reported the scores of a self-reported outcome instrument.\textsuperscript{176} In agreement with the results of the current investigation, the previous study on young adults reported that the time measure of the SLHTs could not demonstrate a difference of functional performance among the CAI, coper, and control groups whereas the Foot Ankle Ability Index, a former version of the FAAM, was able to identify functional deficits of the CAI.\textsuperscript{176}

There is little evidence available for RTP guidelines for self-reported outcome scores following traumatic lateral ankle sprains in the literature\textsuperscript{19} although the use of self-reported outcome scores is recommended to be
included in the RTP decision making process. Cosby and Hertel recommended that basketball players should achieve scores of 95% or better on the FAAM ADL and 80 % or better on the FAAM Sports subscale at RTP. In contrast, a previous study on National Collegiate Athletic Association Division II athletes reported subjects with CAI had scores of 88 ± 7.7 % and 76 ± 12.7 % of the FAAM ADL and Sports subscales, respectively. Indeed, the mean scores of both subscales of the FAAM-J in this study were above those values. (TABLE 3-2) However, cross-sectional design of the current study cannot elucidate whether or not subjects in the current study would develop CAI or become copers following RTP. Furthermore, whether or not RTP with higher self-reported outcome scores will prevent subsequent recurrent sprains and development of CAI needs to be addressed in future research.

SLHTs

One of the primary purposes of this study was to reveal that functional performance deficits are present in college basketball players at RTP phase following traumatic lateral ankle sprain in the SLHTs. Based upon the time measure of the SLHTs in this study, functional performance deficits were found in the involved limbs only with the SH test when compared with healthy control
limbs, but not with their contralateral uninjured limbs. Furthermore, when the involved limbs were divided into the subgroups according to the presence of unstable feeling while performing the SLHTs, the results remained the same; only the SH test produced a significant difference between the involved and control limbs (p < .05) with the mean differences of .8 sec. (TABLE 3-3) However, MDC of the SH test (2.3 sec) was far larger than this value. Therefore, even though it reached a significant level, it may have a limited clinical value.

Literature has shown the effectiveness of FPTs that specifically involve single-limb hop with agility maneuvers.\textsuperscript{13,14,37,176} The findings of the current study only partly supported the results of these studies. Possible explanations for this discrepancy might include the nature and state of subjects. Specifically, recreational athletes or physically active individuals were the subjects in previous studies.\textsuperscript{13,14,37,176} Since subjects did not go through a formal rehabilitation process in one study\textsuperscript{176} and such information was not provided in the other studies,\textsuperscript{25-27} subjects with CAI in those studies might have residual symptoms and have not completed rehabilitation to perform demanding activities like SLHTs. Subjects of this study, on the other hand, were competitive collegiate athletes who participated in the formal rehabilitation process supervised by
respective medical personnel immediately after the injury until they achieved RTP. Therefore, subjects in this study, despite their lower self-reported outcome scores, might have been able to create compensation patterns to execute the task. In fact, the mean time measures of the FPTs in this study were faster than those in the previous studies.\textsuperscript{13,14,37,176}

Furthermore, there was a tendency for the contralateral, healthy limbs to take longer to complete the SLHT than the control group. Although hypothetical, this may be because the contralateral, healthy limbs might have had postural balance deficits as bilateral balance impairments may develop after lateral ankle trauma.\textsuperscript{174} Therefore, it may not be recommended that the SLHTs in the current study be used clinically for competitive athletes solely based upon the time values.\textsuperscript{14}

In contrast, subjects felt significantly greater pain and higher instability performing the SLHTs with the Involved limbs when compared with Uninvolved and control. A greater percentage of the subjects in this study reported perceived instability of the involved limbs with the SLHTs. With the SH test, 77\% (24 of 31) reported feelings of instability, compared with 47\% (14 / 30),\textsuperscript{14} 60\% (25 / 42),\textsuperscript{37} 71\% (17 / 24),\textsuperscript{176} 38\% (9 / 24)\textsuperscript{176}, and 50\% (10 / 20)\textsuperscript{13} among the individuals with
CAI in previous literature. With SQ test, 65% (20/31) of subjects reported feelings of instability, compared with 33% (11/30) of the previous study on CAI.¹⁴

Although speculative, this may be because subjects of this study might have had a greater fear of reinjury as the feeling of ankle instability is generally associated with fear of reinjury²⁸ and the testing sessions were immediately after RTP (4.8 ±3.8 days). Research has shown that pain-related fear of movement, or kinesiophobia, is associated with RTP and disabilities of various musculoskeletal disorders.²,²⁶,⁹⁷,¹³⁴ A previous study on various foot and ankle pathologies, including lateral ankle sprains, suggested that kinesiophobia and intensity of pain were associated with self-reported functions and disabilities of patients.⁹⁷ Similarly, a previous study of general adults reported that patients continued to have a fear of re-injury at the time of discharge and the patient’s judgment of their functional recovery was lower than that of the clinician’s.⁹⁶ Furthermore, patients continued to have a fear of re-injury until they actually performed tasks that they deemed as difficult.⁹⁶ Therefore, it is important that patients go through high demand activities and tasks such as the SLHTs in the current study so that not only clinicians but also patients can evaluate how the injured ankle functions with those activities in a controlled situation, and estimate
their own functional recovery. This process will help patients to conquer a fear of re-injury.\textsuperscript{96}

The concept of the feeling of instability has not been well defined in previous studies. Various terms, such as giving-way, functional instability, recurrent sprains, and perceived instability, have been used to express the concept.\textsuperscript{28,68,111} This has contributed to the difficulty in comparing studies and inconsistent results.\textsuperscript{28} The term “giving way” has been the most commonly used term, however, it can be either perceived or actual twisting of the ankle.\textsuperscript{68} Therefore, the term “perceived instability” was used in this study.\textsuperscript{28} Additionally, to the authors’ knowledge, this was the first attempt to quantify the perceived instability with the SLHTs whereas previous studies reported only about the presence or absence of such feeling among CAI.

A previous study reported a significant association between self-reported recovery and the sensation of “giving way" as well as pain intensity during high ankle load activities at a short-term follow up after acute ankle sprain.\textsuperscript{162} Another study on CAI subjects reported a significant correlation between the functional ankle instability index and presence of feelings of instability during FPTs.\textsuperscript{37} Similarly, there were significant associations between the intensity of perceived
instability with the SH test and the scores of the FAAM-J ADL and SP in this study this was not the case with the SQ test. The authors believe this was because the SH test more strongly challenges the lateral aspect of the ankle complex and exposed the functional deficits that subjects had. Although it is speculated that the FAAM-J SP has a higher association with perceived instability with the SLHTs, it is unknown why the FAAM-J ADL had a stronger association in this study.

The use of FPTs is recommended to be a component of the RTP decision making process by the literature.\textsuperscript{89,103} To the authors’ knowledge, this was the first study in which the FPTs were utilized at the RTP phase of traumatic lateral ankle sprains whereas the previous studies were on CAI.\textsuperscript{13,14,37,176} Based upon the results of this study, clinicians can discriminate the acutely sprained ankle at RTP phase against the opposite healthy limbs and control limbs based upon perceived instability with the SH and SQ tests.

**Limitations**

Several limitations with the current study should be noted. First, RTP decisions were made by respective team medical personnel without a uniform objective guideline. Clinician-rated data such as ROM, muscle strength, and
swelling were not included in the study. Therefore, it is unknown if this might have influenced the results of the current study.

Second, a successful RTP is not well defined in the literature and various factors can influence the decision.\textsuperscript{21,153} Furthermore, length of full participation before it is considered a successful RTP can vary.\textsuperscript{153} In this study, successful RTP was determined on the following day that subjects achieved full participation. This was necessary because the primary purposes of this study were to evaluate if functional deficits are present among college basketball players at RTP phase following traumatic lateral ankle sprains. To counter this constrains, it was confirmed at three months post-RTP that subjects were able to maintain full participation without reinjury or any restrictions to their participations following RTP.

Third, the time between RTP and the testing session was not consistent. This was because the subjects were competitive athletes as well as college students with very limited schedule flexibility due to the team’s practice schedule and academic duties. Therefore, the flexibility of scheduling the testing session was necessary.

Lastly, although all subjects did not have injuries or conditions in the six
months prior to their participation in the study or preexisting medical conditions that required medical treatment at the time of ankle sprain, previous history of ankle sprains was not among the exclusion criteria. Hence, the result of this study needs to be interpreted with caution as the effects of previous ankle sprains may extend over as long as one year. Nonetheless, this criteria was employed because history of ankle sprains is prevalent and common in competitive basketball players and it would have been extremely difficult to gather groups of subjects otherwise.

SECTION 3-6: CONCLUSION

We found that competitive college basketball players at RTP phase following traumatic lateral sprains had functional deficits in the ADL and Sports subscale of the FAAM-J when compared with contralateral healthy limbs and healthy controls. Subjects had significantly higher perceived instability and greater pain with the SLHTs whereas they had functional performance deficits with the SH test based upon the time measures. Results from this investigation support the use of a self-reported outcome measure and functional performance tests in RTP decision making process.
Chapter 4:
Prognostic ability of patient- and clinician-rated measures for traumatic lateral ankle sprains among collegiate basketball players

SECTION 4-1: ABSTRACT

**Context:** Patient-rated measures have been reported to be more valid in the prognosis of traumatic lateral ankle sprain among competitive athletes than clinician-rated measures.

**Objective:** The purpose of this study was to evaluate the prognostic ability of clinician-rated measures and the Japanese version of the Foot Ankle Ability Measure (FAAM-J) for the duration of disability after traumatic lateral ankle sprains among competitive, collegiate basketball players.

**Design:** Prospective cohort study.

**Setting:** Collegiate Athletic Training/Sports Medicine clinical setting.

**Patients or Other Participants:** Twenty one collegiate athletes.

**Main Outcome Measure(s):** Following a traumatic lateral ankle sprain, subjects completed the ADL and Sports subscales of the FAAM-J (FAAM-J ADL, SP). We
also measured pain associated with ADL and Sports (Pain ADL, SP), passive
dorsiflexion ROM (PROM), swelling, dorsiflexion strength, and eversion strength.

For clinician-rated measures, the values of injured limbs were normalized to
those of uninjured limbs for statistical analysis. Simple regression and multiple
regression analyses were performed to identify the correlations of all the
measures with the number of days subjects needed to the return-to-play (RTP).

Results: Simple regression analysis revealed a statistically significant
correlations of the FAAM-J SP ($r = -.69$, $p < .01$), Pain SP ($r = .50$, $p < .01$), and
PROM ($r = -.70$, $p < .01$) with the number of days to the RTP. A multiple
regression model of the FAAM-J, Pain SP and PROM produced a correlation
coefficient of .78 and explained 54.5 % of the variance of the number of days
needed to achieve RTP ($p < .01$).

Conclusions: The Sports subscale score of the FAAM-J, the VAS score of pain
associated sports activities and dorsiflexion PROM deficit were relevant in
predicting the number of days needed for competitive, collegiate basketball
players to achieve RTP after traumatic lateral ankle sprain.
Section 4-2: INTRODUCTION

The primary purpose of this study was to evaluate the prognostic ability of patient-rated measures and the FAAM-J for the duration of participation restriction following a traumatic lateral ankle sprain among competitive, collegiate basketball players. It was hypothesized that RTP following a traumatic lateral ankle sprain among collegiate basketball players is more valid and predictable when based upon the FAAM-J than clinician-rated measures. This was a part of a larger study which investigated patient-rated evaluation of traumatic lateral ankle sprain.

Section 4-3: METHODS

Subjects

Subjects (n= 36) were collegiate basketball players of a small Japanese college, who each sustained a traumatic lateral ankle sprain during a game or practice participation. (FIGURE 4-1) A traumatic lateral ankle sprain was defined as a sprain that occurred with inversion mechanism, resulting in at least one day of restriction from a game or practice participation (“time loss” definition of injury). The exclusion criteria for the study were; concurrent fractures, a history of surgery to the lower extremity or lower back, any preexisting athletic injury.
requiring medical attention at the time of the ankle injury, any injury to either foot, ankle, knee, hip, or lower back region that resulted in any restrictions from practice/game participation in the previous 6 months. Those who were unable to schedule a testing session within 72 hours post injury due to scheduling difficulties were also excluded. Additionally, ankle sprains were not included in the study when clinical evaluation revealed that signs and symptoms were not limited to the lateral aspect of the joint, but also present in other areas such as metatarsal bones, medial aspect of the joint, and anterior tibiofibular ligament, or syndesmosis sprains. Thirty-six subjects sustained a traumatic lateral ankle sprain during the study period. Fifteen subjects were excluded from the study due to; scheduling difficulties (n = 5), a history of injury within previous 6 months (n = 4), history of surgery (n = 2), syndesmosis ankle sprain (n = 1), and symptoms not limited to the lateral aspect of the joint (n = 3). Thus, 21 subjects (18 males, 3 females, height = 177.2 ± 9.1 cm, mass = 70.9 ± 7.9 kg, 19.2 ± 1.2 yoa) entered the study, two of whom were not available for the RTP testing session. (FIGURE 4-1) This was a prospective cohort study.
FIGURE 4-1. Flow of participants

Procedure

Following a lateral ankle sprain, subjects were evaluated by the primary author (D.U.), an ATC with 9 years of clinical experience, to confirm eligibility and exclusion criteria. No subjects showed signs or symptoms of concurrent fractures. The initial testing session was scheduled within 72 hours post injury with subjects' earliest convenience. The RTP testing session was scheduled once subjects achieved a successful RTP, defined as participation in a practice or game session without any restriction. Successful RTP was confirmed on the following day by ensuring that subjects could maintain their participation status.
Prior to participating in the study, all subjects read and signed a consent form, approved by the Institutional Review Board of Waseda University.

Outcome Measure

The primary outcome measure was the number of days that subjects needed to achieve RTP.

Patient-Rated Measures

Self-Reported Function

Subjects completed both the ADL and Sports subscales of the FAAM-J\textsuperscript{158} (FAAM-J ADL and SP) at the testing sessions.

Pain

Subjects rated their pain on the 10 cm visual analogue scale (VAS).\textsuperscript{177} Each subject was asked to “please rate your current level of pain with activities of daily living on the line below” and “please rate your current level of pain with your sports activities on the line below”. The left end of the VAS was labeled as “no pain at all” and the right end was labeled as “unbearable pain”.

Clinician-Rated Measures

Swelling

Swelling was measured using the figure-8 method, in which subjects
were asked to lie supine on the table with ankles to 20° plantar-flexed with a custom-made device. A tape measure was placed from the midpoint between the lateral malleolus and the tibialis anterior to the navicular tuberosity, the base of fifth metatarsal, the medial malleolus, the lateral malleolus, and the starting point in a figure-8 manner. A mark was placed on each anatomic landmark prior to tape measurements for reliability. The length was recorded in millimeters. The mean of 3 measurements was used for the analysis.

Ankle dorsiflexion range of motion

Ankle dorsiflexion passive ROM (PROM) was measured with a generic plastic goniometer. Subjects were prone on the table with the knee joint flexed to 90°. The axis of the goniometer was placed on the lateral aspect of the calcaneus while the stationary arm of the goniometer was aligned with the fibular head and the moving arm was aligned with the fifth metatarsal. The examiner passively moved the ankle into dorsiflexion while minimizing the subject’s ankle motion in the frontal plane to avoid pronation or supination motion. Subjects were instructed to notify the examiner of any pain they experienced during the measurement. If pain was felt during dorsiflexion, the range of motion prior to pain onset was used for measurement. If no pain was felt, the examiner
passively dorsiflexed the ankle until a firm end point was felt. The mean of 3 measurements was used for the analysis.

**Strength**

Ankle dorsiflexion (DF) and eversion (EV) isometric strength tests, or make tests, were conducted with a hand held dynamometer (HHD) (PowerTrack II Commander, JTECH Medical, Salt lake City, Utah). Assessment of muscle strength with the HHD is regarded as reliable and valid for muscle strength assessment in the clinical setting.\textsuperscript{145,146} Subjects were asked to lie supine on the table, holding on to the sides of the table with their hands for stability. The HHD was placed against the lateral aspect of the 5th metatarsal for EV and the dorsum of the navicular for DF.\textsuperscript{168} The ankle joint was kept in the neutral position for both of EV and DF testing. Subjects were instructed to exert 5-second isometric maximum voluntary contractions against the stationary resistance applied by the investigator.\textsuperscript{151} A standard verbal instruction of "go ahead-push-push-push-push and relax" was given to subjects.\textsuperscript{155} To reduce a possible learning effect, subjects were asked to perform one sub-maximal practice trial prior to the four testing trials in each direction. Measurements of the injured limb were taken within subjects' pain tolerance. The obtained data (in
Newton, or N) were divided by subjects’ body weights. The mean of the best three of four testing trials was used for the statistical analysis.

We recorded all clinician-rated measurements on the injured and uninjured limb of each subject. The order of the measurements was randomized. The FAAM-J ADL and SP as well as Pain ADL and SP were recorded only on the injured limb. The primary author (D.U.) collected all the data to ensure reliability. The intersession test-retest reliabilities for all clinician-rated measures were determined by calculating the intraclass correlation coefficients (ICC) based upon a pilot study of 16 healthy college students. Standard Error of Measurement (SEM) was calculated as $SEM = \alpha \sqrt{1 - ICC}$, where $\alpha$ was the standard deviation of the measurements. The minimal detectable change, using 95% confidence intervals (MDC$_{95}$), was calculated with the equation of $1.96 \times SEM \times \sqrt{2}$. ICC, SEM, and MDC for all clinician-rated measures were; ICC = .89, SEM = 2.7°, MDC = 7.4° for PROM; ICC = .99, SEM = .3 cm, MDC = .7 cm for swelling; ICC = .81, SEM = .2 N/bw, MDC = .7 N/bw, for DF; and ICC = .92, SEM = .2 N/bw, MDC = .5 N/bw, for EV. There was one week between the two measurement sessions. SEM for the FAAM-J ADL and SP were 2.9 and 5.0 points, respectively whereas the MDC at 95% confidence interval was +/- 8.1
point for the ADL Subscale, and +/- 14.0 point for the Sports subscale.  

**Athletic Rehabilitation**

The secondary author (H.S.), an ATC with 9 years of clinical experience, supervised the athletic rehabilitation of subjects and made the RTP decisions. The treatment and rehabilitation process followed conventional guidelines. Subjects participated in rehabilitation for approximately 90 minutes once a day, 6 days per week. In the acute phase, the injured ankle was immobilized and subjects were instructed to apply ice, compression, and elevation for 30 minutes several times throughout the day until acute inflammation signs and symptoms subsided. Ambulatory assistance such as crutches was given to the subjects as needed. Once acute inflammation signs and symptoms diminished, therapeutic exercises were initiated to restore range of motion, muscle strength, proprioception, static and dynamic postural control, and weight bearing and ambulatory status while utilizing various therapeutic modalities. In the advanced phase, more dynamic and generic athletic movements such as jumping, change of direction, cutting, sprinting, and stopping were performed. Then, the rehabilitation was gradually progressed and more sport specific movements were incorporated according to subjects’ recovery levels while swelling and pain...
were minimized. Restricted sport participation was allowed once clinical examinations revealed subjects achieved good ankle strength, pain-free full ROM, and static and dynamic postural controls compared uninjured limbs, and could perform sport specific movements safely. RTP was allowed by the ATC when subjects a) did not aggravate signs and symptoms during restricted sport participation and b) gained confidence to resume full athletic participation. RTP was confirmed on the following day of full participation.

**STATISTICAL ANALYSIS**

All clinician-rated data from subjects’ injured limbs were normalized to the opposite healthy limbs (injured / healthy x 100). Subscales of the FAAM-J were divided by the highest possible scores to calculate percentage values. A simple regression analysis was performed to determine the correlation coefficients between the dependent variables and the number of days to RTP. A multiple regression analysis was performed on the variables that were found to be statistically significant. The level of significance was set at p < .05 for all statistical analysis. Additionally, for the 19 subjects who were measured after RTP, the effect sizes were calculated with the equation of (post – pre score) / pooled standard deviation.²²,¹⁶⁷
Section 4-4: RESULTS

The number of days needed to achieve RTP was 11.7 ±6.4 days. The descriptive statistics are presented in the TABLE 4-1. The mean difference values exceeded the MDCs for all of the clinician rated measures except for PROM. Simple regression analysis revealed that PROM (r = -.70, p < .01), Pain SP (r = .50, p = .01) and the FAAM-J SP (r = -.69, p < .01) had significant correlations with the number of days to RTP. The FAAM-J ADL (r = -.04, p = .43), Pain ADL (r = .09, p = .34), swelling (r = .23, p = .16), DF (r = -.25, p = .13), and EV (r = .23, p = .16) did not have significant relationships with the number of days to RTP. The multiple regression model of the FAAM-J SP, Pain SP, and PROM produced a correlation efficient of .78 with adjusted $r^2$ of .545 with the number of days needed to achieve RTP (p < .01). (TABLE 4-2) A comparison of the initial and RTP testing sessions of the injured ankle as well as corresponding effect sizes are presented in TABLE 4-3. The mean duration between the date of injury and the initial testing session was 1.5 ±0.9 days whereas the mean duration between the date of RTP and the RTP testing session was 4.9 ±4.0.
TABLE 4-1. Descriptive Statistics at the Acute Testing Session

<table>
<thead>
<tr>
<th></th>
<th>Injured</th>
<th>Uninjured</th>
<th>Mean Difference</th>
<th>Symmetry</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAAM ADL</td>
<td>60.1 ± 13.6</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>FAAM SP</td>
<td>14.3 ± 7.3</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Pain ADL (cm)</td>
<td>3.0 ± 1.9</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Pain SP (cm)</td>
<td>6.0 ± 2.6</td>
<td>na</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>PROM (deg.)</td>
<td>16.9 ± 5.8</td>
<td>20.4 ± 6.1</td>
<td>3.5 ± 4.9</td>
<td>0.83 ± 0.28</td>
</tr>
<tr>
<td>Swelling (cm)</td>
<td>53.1 ± 2.5</td>
<td>52.1 ± 2.7</td>
<td>-1.0 ± 0.7</td>
<td>1.02 ± 0.01</td>
</tr>
<tr>
<td>DF (N/bw)</td>
<td>2.2 ± 0.7</td>
<td>3.0 ± 0.5</td>
<td>0.8 ± 0.6</td>
<td>0.73 ± 0.21</td>
</tr>
<tr>
<td>EV (N/bw)</td>
<td>2.1 ± 0.9</td>
<td>3.0 ± 0.8</td>
<td>0.9 ± 0.8</td>
<td>0.71 ± 0.25</td>
</tr>
</tbody>
</table>
### TABLE 4-2. Correlation Values from the Multiple Regression Analysis

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>Adjusted r²</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM</td>
<td>-.70</td>
<td>.465</td>
<td>p &lt; .01</td>
</tr>
<tr>
<td>FAAM-J SP</td>
<td>-.69</td>
<td>.453</td>
<td>p &lt; .01</td>
</tr>
<tr>
<td>Pain SP</td>
<td>.50</td>
<td>.214</td>
<td>p = .02</td>
</tr>
<tr>
<td>Combination of the FAAM-J SP, Pain SP and PROM</td>
<td>.78</td>
<td>.545</td>
<td>p &lt; .01</td>
</tr>
</tbody>
</table>
TABLE 4-3. Values at the Acute and RTP Testing Sessions and Effect Sizes

<table>
<thead>
<tr>
<th></th>
<th>Acute</th>
<th>RTP</th>
<th>Mean Difference</th>
<th>Effect Size(_CI&lt;sub&gt;95&lt;/sub&gt;)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAAM ADL</td>
<td>59.7 ± 14.3</td>
<td>81.9 ± 3.5</td>
<td>-22.2 ± 13.9</td>
<td>1.5 (1.0, 1.9)</td>
</tr>
<tr>
<td>FAAM SP</td>
<td>14.1 ± 3.5</td>
<td>28.3 ± 3.9</td>
<td>-14.2 ± 7.9</td>
<td>1.5 (1.1, 2.0)</td>
</tr>
<tr>
<td>Pain ADL (cm)</td>
<td>3.0 ± 1.9</td>
<td>0.3 ± 0.4</td>
<td>-2.7 ± 1.8</td>
<td>1.4 (1.0, 1.9)</td>
</tr>
<tr>
<td>Pain SP (cm)</td>
<td>6.1 ± 2.7</td>
<td>1.3 ± 1.5</td>
<td>-4.7 ± 3.0</td>
<td>1.5 (1.0, 1.9)</td>
</tr>
<tr>
<td>PROM (deg.)</td>
<td>16.7 ± 5.9</td>
<td>22.2 ± 6.2</td>
<td>5.5 ± 4.9</td>
<td>0.8 (0.5, 1.2)</td>
</tr>
<tr>
<td>Swelling (cm)</td>
<td>53.2 ± 2.2</td>
<td>52.5 ± 2.4</td>
<td>-0.7 ± 0.5</td>
<td>0.3 (0.2, 0.4)</td>
</tr>
<tr>
<td>DF (N/bw)</td>
<td>2.2 ± 0.6</td>
<td>3.2 ± 0.6</td>
<td>1.0 ± 0.5</td>
<td>1.3 (1.0, 1.6)</td>
</tr>
<tr>
<td>EV (N/bw)</td>
<td>2.1 ± 0.9</td>
<td>3.2 ± 0.8</td>
<td>1.1 ± 0.7</td>
<td>1.1 (0.7, 1.4)</td>
</tr>
</tbody>
</table>

The values were from 19 subjects who were available for both of the acute and RTP testing sessions.
Section 4-5: DISCUSSION

In the current study, we found that only the FAAM-J SP, Pain SP and PROM had significant correlations with the duration of participation restriction after a traumatic lateral ankle sprain among collegiate basketball players. A combination of the FAAM-J SP, Pain SP, and PROM explained 54.5 % of the variance. The results of this study were compatible with previous reports that RTP following traumatic lateral ankle sprain is more valid and predictable when it is based upon patient-rated measures, or activity limitations, and participation restrictions.23,178

The FAAM-J SP had the second highest correlation, r = .69, with duration of the disability in this study. It is reasonable to see the FAAM-J SP had a high correlation with disability encountered in the current study because the FAAM-J SP was intended to be more specific to activity limitations and participation restrictions associated with sports activities.106 This finding provided evidence of the FAAM-J SP’s validity in predicting RTP following traumatic lateral ankle sprain among competitive basketball players. In fact, the mean difference between the acute and RTP testing sessions was 14.2 ±7.9, which was larger than the MDC of the FAAM-J SP, or 14.0 points.

Pain-related fear of movement, or kinesiophobia, has been reported to be associated with disabilities, or RTP, of various musculoskeletal disorders although this has been predominantly demonstrated in patients with Anterior Cruciate Ligament reconstruction.2,26,94 A previous report suggested that kinesiophobia and intensity of pain with various foot and ankle pathologies, including lateral ankle sprains, were associated with self-reported functions and
disabilities of patients while kinesiophobia was the strongest contributor to disability.\textsuperscript{97} Therefore, although pain intensity is not a direct measurement of kinesiophobia, our finding that Pain SP had a significant correlation with the duration of disability in the current study deemed reasonable.

The finding that PROM loss was correlated with the number of days to RTP was in agreement with a study by Wilson and Gansneder\textsuperscript{178} although the PROM loss at the acute testing session in the current study was smaller than MDC. Several literatures have reported that restricted dorsiflexion ROM is associated with traumatic lateral ankle sprain and chronic ankle instability.\textsuperscript{18,32,40,60,72,131,167,185} Furthermore, restricted dorsiflexion ROM has been reported to be associated with gross motor control alterations in various tasks\textsuperscript{29,54,143} and dynamic balance capabilities.\textsuperscript{5,71} Altered joint kinematics of the talocrural joint has been considered as a plausible mechanism for limited dorsiflexion ROM.\textsuperscript{32,167,172} Consequently, restoration of arthrokinematic movement of the talocrural joint after traumatic lateral ankle sprain has been shown to result in increased dorsiflexion ROM and improved function.\textsuperscript{18,20,24,60,70,130} Furthermore, dorsiflexion ROM reflects capsuloligamentous structures when measured with the knee flexed 90°.\textsuperscript{36,92,93} Therefore, it is plausible that PROM loss measured with the knee flexed 90° was correlated with the number of days to RTP in the current study. Nonetheless, clinicians need to interpret the result of the current study with caution as responsiveness of ankle joint ROM was questioned in a literature review.\textsuperscript{107}

That swelling did not correlate with the number days to RTP in the current study was in agreement with a previous study.\textsuperscript{178} Other literatures have also
reported that swelling does not correlate with self-reported functions.\textsuperscript{102,135} Although Figure-8 method may be a reliable and valid method to measure the extent of swelling and inflammation and the mean difference of swelling at the acute testing session matched the MDC of .7cm, it may not reflect the severity of perceived activity limitations and participation restrictions at the initial post-injury stage.\textsuperscript{135} And hence, it may not be suitable to predict the improvements of those variables. In fact, subjects in the current study went through a large change in their activity limitation and participation restriction status, from unable to continue sports activities with the FAAM-J SP of 14.1 ±3.5 to full participation with the FAAM-J SP of 28.3 ±3.9, however, the effect size of swelling was small. (TABLE 4-3)

Our finding that DF and EV strength loss did not correlate with the number days to RTP, was in agreement with a previous investigation.\textsuperscript{23} To the authors’ knowledge, the study by Cross et al\textsuperscript{23} is the only study which examined the prognostic ability of ankle joint strength measures for RTP after traumatic lateral ankle sprain. Although strength deficits have been reported following traumatic lateral ankle sprains,\textsuperscript{1,73} previous reports from various populations and settings conflict over the effects of traumatic lateral ankle sprains and simulated swelling on muscular function, or arthrogenic muscle response.\textsuperscript{65,91,126} Contrary to the common belief that periarticular muscles are inhibited by acute joint injuries,\textsuperscript{75,150} previous studies reported no effect or even facilitation of certain muscles surrounding the ankle joint, attributing it to the protective mechanism.\textsuperscript{91}

Furthermore, a previous investigation showed that VAS scores of current level of pain explained a large amount of variance in the motor-neuron pool
excitability of the tibialis anterior, however, the scores did not explain those of the soleus or peroneus longus muscles in the acutely sprained ankles. Although it is common to assume an adverse relationship between pain and muscle inhibition, a previous report showed muscle activation was not affected in the presence of pain after knee injury and little evidence is available for the acutely sprained ankle joint. Additionally, to the authors’ knowledge, few researches are available to show improvement in the ankle strength result in improvements in activity limitations and participation restrictions. Thus, although the DF and EV strength deficits at the acute testing session were larger than the respective MDC, they were not necessarily proportional to the duration of disability and may have little prognostic value after traumatic lateral ankle sprain. Further research is needed in this area.

The FAAM-J ADL did not have a significant correlation with the number of days to RTP in this study although the mean differences at the acute testing session as well as the improvement from the acute testing to the RTP testing sessions were larger than the MDC of the FAAM-J ADL. (TABLE 4-1 & 4-3) Because the FAAM-J ADL is not specific to sports activity limitations and participation restrictions, it may not be effective in predicting the number of days to RTP.

Based upon the measurements from 19 subjects who completed the RTP testing session, the effect sizes ranged from .3 to 1.5. In fact, the effect size for every measure except for swelling exceeded .8, showing large improvement during the course of the athletic rehabilitation process. (TABLE 4-3) The FAAM-J ADL and SP showed the largest improvement with the effect size of 1.5.
while swelling showed the least improvement with the effect size of .3.

Clinicians need to interpret the results of the current study with cautions. In the patient-centered medicine, where patient’s values, preferences, and needs are respected, patient-oriented outcome measures are considered as the gold-standard in the assessment of musculoskeletal conditions. However, they should not be considered the sole outcome measures, nor the significance of clinician-rated measures should be underestimated as clinician-rated measures are valuable in many aspects. Therefore, the FAAM-J SP should be considered a necessary but not sufficient measure in the assessment of traumatic lateral ankle sprains.

There were a couple limitations to be noted in this study. First, the rehabilitation process and RTP decisions in this study were not strictly controlled. Although the purpose of this study was not to evaluate the effectiveness of a specific rehabilitation protocol or RTP guidelines, this might have influenced the results of the current study.

Second, the subject pool consisted only of a small number of competitive collegiate basketball players although the number of subjects in the current study is comparable to those in previous studies, n= 21 and 20. This was necessitated because a relative large percentage of potential subjects (41.6%) were excluded from the study. We performed a post hoc power analysis with a statistical software. The variance of the duration of disability explained by valid three measures was .545 with $\alpha$ set at 0.05. The analysis produced a power of .958. Therefore, we believe the subject pool of the current study is sufficient although the results of the current study are only applicable to the
specific population of the current study.

Furthermore, an injury can have different effects on the HR-QOL of physically active individuals and athletes than on that of the general population.\textsuperscript{109,159,163} Therefore, clinicians need to be cautious to apply the results of the current study to different populations such general and/or youth populations. Future research should address these limitations by including a larger number of subjects from various sports, ages and different competitive levels.

Third, based upon the number of days to RTP, 11.7 ±6.4 days, majority of the traumatic lateral ankle sprains in the study are considered relatively minor. Therefore, clinicians need to be careful in applying the results of the current study to relatively severe traumatic lateral ankle sprains.

\textbf{Section 4-6: CONCLUSION}

The results of this study provide evidence of the prognostic values of the Sports subscale score of the FAAM-J, the VAS score of pain associated sports activities, and dorsiflexion PROM deficit measured with the knee flexed 90° to predict the duration of disability following traumatic lateral ankle sprain among competitive collegiate basketball players.
Chapter 5:

Discussions

Crucial to EBP and patient-centered medicine, POEMs can be provided only through studies that include patient-rated outcome measures.\textsuperscript{159} However, the lack of such approaches in the profession of athletic training and in the sports medicine field has been reported in the literature.\textsuperscript{50,127,128,144,159} This is detrimental to the quality of care provided to the athlete as POEMs directly relate to the HR-QOL of the athletes. Contrary to the POEM, DOE is of uncertain clinical utility unless evidence of how it contributes to the overall activity limitations and disabilities is provided.\textsuperscript{78,83}

Furthermore, physically active individuals and athletes have been reported to perceive activity limitations and disabilities from a health condition differently than general populations as they have different expectations on their normal functions and social roles.\textsuperscript{4,109,163,164} Therefore, POEMs specific to the athletic population need to be provided by those who are involved in the care of such population. The primary purpose of this dissertation was to provide POEMs to guide the treatment and rehabilitation process as well as RTP decisions following traumatic lateral ankle sprain in competitive college athletes.

Patient-rated outcome measures allow clinicians to assess the outcome of the intervention through the patient’s eyes.\textsuperscript{53} They are the primary outcome measures in patient-centered medicine as the patient provides the information that he or she perceives to be most important.\textsuperscript{140}

The first part of this series of investigations provide evidence of cross
cultural adaptation, translation, convergent and divergent validity, internal consistency, and test-retest reliability of the FAAM-J based upon various collegiate competitive athletes. The original version of the FAAM is a self-reported outcome instrument which measures activity and participation limitations caused by a condition of the foot and ankle region.\textsuperscript{106}

No major difficulties were encountered during the translation and cross cultural adaptation process in this investigation. For convergent validity, the results showed that the ADL and Sports Subscales of the FAAM-J had 0.86 and 0.75 correlation coefficients with Physical functioning of the Short Form-36 (SF36). For divergent validity, correlation coefficients with MH of the SF-36 were 0.29 and 0.27 for each subscale. Cronbach’s alpha for internal consistency was 0.99 for the ADL and 0.98 for the Sports Subscale. The SEM for the ADL Subscale was 2.9 and the MDC at 95% CI was +/- 8.1 while the SEM for the Sports Subscale was 5.0 and the MDC at 95% CI of +/- 14. Test retest reliability measures revealed the ICC values of 0.87 for the ADL and 0.90 for the Sports Subscales. The MDC at 95% confidence was +/- 6.8 for the ADL Subscale, and +/- 13.7 for the Sports subscale.

In the literature, the FAAM has been validated for its use in a variety of health conditions. Furthermore, the FAAM has been translated into French, German, and Persian.\textsuperscript{9,108,124} Therefore this study will allow Japanese speaking clinicians and researchers to assess the outcome of their interventions and clinical decisions based upon studies that used other language versions of the FAAM, and vice versa.\textsuperscript{80}

Following traumatic athletic injuries, the most important outcome is full
RTP with minimal symptoms.\textsuperscript{163} In particular this is the case for traumatic lateral ankle sprains as premature RTP has been indicated as one of the causes for re-injury and subsequent development of CAI.\textsuperscript{113,160} However, there are few studies that show athletes are in fact allowed RTP with functional deficits. Therefore, in the second investigation, we investigated if functional deficits are present in college basketball players at RTP phase following traumatic lateral ankle sprains with the FAAM-J ADL and SP, and the SLHTs.

Significantly lower FAAM-J ADL and SP scores were found among the involved limbs. Subjects had significantly higher perceived instability and greater pain on SLHTs with the involved limbs although no significant findings were found among the time measures of the SLHTs. Furthermore, there are significant correlations between perceived instability and scores on the FAAM-J subscales.

Based upon the results of the current study, collegiate basketball players were in fact cleared for RTP without full recovery following traumatic lateral ankle sprain. This investigation was the first to show college basketball players are achieving RTP with functional deficits. Whether RTP without full recovery in fact leads to re-injury or development of CAI needs to be investigated in future research.

In the third investigation, we examined the prognostic values of the FAAM-J as well as other clinical impairment measures with traumatic lateral ankle sprain. This is crucial as successful RTP is the primary concern of the injured athlete and the goal of the athletic rehabilitation process.\textsuperscript{163} Also, this will provide information on the degree to which the FAAM-J and other impairment measures relate to the severity of the disability caused by traumatic lateral ankle
sprains. With this evidence provided, these measures can be validated to be used to predict RTP.

Following a traumatic lateral ankle sprain, 21 collegiate basketball players completed the FAAM-J ADL and SP. We also measured Pain ADL and SP, PROM, swelling, dorsiflexion strength, and eversion strength. The values of injured limbs were normalized to those of uninjured limbs for statistical analysis. The results indicated a statistically significant correlations of PROM (r = -.70, p < .01), Pain SP (r = .50, p = .02) and FAAM-J SP (r = -.69, p < .01) with the number of days to RTP. A multiple regression model of the FAAM-J, Pain SP and PROM produced a correlation coefficient of .78 and explained 54.5 % of the variance of the number of days needed to achieve RTP (p < .01). The FAAM-J SP, Pain SP, and dorsiflexion PROM were relevant in predicting the number of days needed for competitive, collegiate basketball players to achieve RTP after traumatic lateral ankle sprains. On the other hand, other impairment measures were questioned for their prognostic values although they are reliable impairment measures.

To the author’s knowledge, there are only a few studies that compared the effectiveness of clinician-rated measures and patient-rated measures in predicting the duration of disability following traumatic lateral ankle sprains, which also reported prognostic abilities of patient-rated measures following traumatic lateral ankle sprains. The results of this study further emphasize the importance of patient-rated measures.

Collectively, these investigations showed the effectiveness of patient-rated measures as prognostic and outcome evaluation tools of collegiate
basketball players following traumatic lateral ankle sprains, providing the POEM for such population and condition. An emerging concept in recent years is that clinician-rated measures and patient-rated measures portray different aspects of HR-QOL. In the patient-center medicine, patient oriented outcome measures are considered as the gold-standard in the assessment of musculoskeletal conditions.\textsuperscript{27,129}

However, patient oriented outcome measures should not be considered the sole outcome measure, nor the significance of clinician-rated measures should be underestimated as clinician-rated measures are valuable in many aspects. Therefore, the FAAM-J SP should be considered a necessary but not sufficient measure in the assessment of traumatic lateral ankle sprains. The results of the current studies provided further evidence, emphasizing the importance of incorporating patient's perspectives in assessment of traumatic lateral ankle sprains in addition to more prevalent clinician-rated measures.

This series of investigations have limitations. First of all, the subjects of these investigations were competitive, collegiate athlete of relatively small sample. It is reported in the literature that an injury can have different effects on the HR-QOL of physically active individuals and athletes than on those of the general population.\textsuperscript{109,159,163} Therefore, clinicians need to be cautious to apply the results of the current investigations to different populations such as general and/or youth populations.

Second, in the second and third investigations, majority of the traumatic lateral ankle sprains in the study were considered relatively minor. Therefore, the results of this these studies are only relevant to those minor traumatic lateral
ankle sprains. Clinicians need to be careful in relating the results of the current investigations to relatively severe traumatic lateral ankle sprains.

Future research should address these limitations by including a larger number of subjects from various sports, ages, as well as different competitive levels.
Chapter 6: Conclusions

The followings are the conclusions;

1. The Japanese version of the Foot Ankle Ability Measure (FAAM-J) is a valid, reliable self-reported outcome instrument for the young, competitive athlete with acute foot and ankle lesions.

2. Based upon the scores of FAAM-J ADL and SP, collegiate basketball players were cleared for RTP without full recovery following traumatic lateral ankle sprains. There is a significant association between the severity of the perceived instability with a functional performance test and the scores of the subscales of the FAAM-J.

3. The FAAM-J, intensity of pain associated with sports activities, and ankle dorsiflexion passive range of motion limitations had prognostic values of, and hence validity in estimating, the severity of disability caused by the traumatic lateral ankle sprain among collegiate basketball players while swelling, ankle eversion strength, and ankle dorsiflexion strength did not.
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115


Appendix


The Original Version of the Foot and Ankle Ability Measure

The Japanese Version of the Foot and Ankle Ability Measure

The Japanese Version of the SF-36
Evidence of Validity for the Japanese Version of the Foot and Ankle Ability Measure

Daisuke Uematsu, MS, ATC*; Hidetomo Suzuki, MEd, ATC, CSCS†; Shogo Sasaki, PhD‡; Yasuharu Nagano, PhD, PT, JASA-ATS§; Nobuyuki Shinozuka, MS, JASA-AT*; Norihiko Sunagawa, MS, JASA-AT*; Toru Fukubayashi, MD, PhD*

*Faculty of Sport Sciences, Waseda University, Tokorozawa City, Saitama, Japan; †Niigata University of Management, Kamo City, Japan; ‡Tokyo Ariake University of Medical and Health Sciences, Japan; §Niigata University of Health and Welfare, Niigata City, Japan

Context: The Foot and Ankle Ability Measure (FAAM) is a valid, reliable, and self-reported outcome instrument for the foot and ankle region.

Objective: To provide evidence for translation, cross-cultural adaptation, validity, and reliability of the Japanese version of the FAAM (FAAM-J).

Design: Cross-sectional study.

Setting: Collegiate athletic training/sports medicine clinical setting.

Patients or Other Participants: Eighty-three collegiate athletes.

Main Outcome Measure(s): All participants completed the Activities of Daily Living and Sports subscales of the FAAM-J and the Physical Functioning and Mental Health subscales of the Japanese version of the Short Form-36v2 (SF-36). Also, 19 participants (23%) whose conditions were expected to be stable completed another FAAM-J 2 to 6 days later for test-retest reliability. We analyzed the scores of those subscales for convergent and divergent validity, internal consistency, and test-retest reliability.

Results: The Activities of Daily Living and Sports subscales of the FAAM-J had correlation coefficients of 0.86 and 0.75, respectively, with the Physical Functioning section of the SF-36 for convergent validity. For divergent validity, the correlation coefficients with Mental Health of the SF-36 were 0.29 and 0.27 for each subscale, respectively. Cronbach’s α for internal consistency was 0.99 for the Activities of Daily Living and 0.98 for the Sports subscale. A 95% confidence interval with a single measure was ±5.1 and ±3.2 points for each subscale. The test-retest reliability measures revealed intraclass correlation coefficient values of 0.87 for the Activities of Daily Living and 0.90 for the Sports subscales with minimal detectable changes of ±4.9 and ±9.9 for the respective subscales.

Conclusions: The FAAM was successfully translated for a Japanese version, and the FAAM-J was adapted cross-culturally. Thus, the FAAM-J can be used as a self-reported outcome measure for Japanese-speaking individuals; however, the scores must be interpreted with caution, especially when applied to different populations and other types of injury than those included in this study.

Key Words: self-reported outcome measures, questionnaires, outcome assessments

Foot and ankle injuries are common in sport activities. Ankle sprains are the most frequent of all athletic injuries. The greatest risk factor for an ankle sprain is a previous ankle sprain, and chronic ankle instability is a concerning and common result of an initial ankle sprain. With recurrent injuries, such as ankle sprains, athletes frequently suffer from residual symptoms. Outcome measures are essential to evidence-based practice because they offer a basis for clinical decisions. There are 2 types of outcome measures: clinician rated and patient rated. Clinician-rated measures are acquired by clinicians and primarily collect information about the disease or injury. Clinician-rated measures address impairments. In contrast, patient-rated measures focus on the data provided by patients including information about how patients perceive the effect of the disease or injury on their function and participation in Activities of Daily Living (ADL) and sports. Incorporating patient-based outcome measures into health care is imperative to fully appreciate the effect of pathologic conditions on the patient’s overall health. A self-reported outcome instrument allows clinicians to incorporate a patient’s values into the medical treatment and to evaluate the effectiveness of interventions from the patient’s perspective.
Self-reported outcome instruments can be generic or specific. Specific self-reported outcome instruments address disease, body region, dimension, summary items, and individual measures. Clinicians need to choose a self-reported outcome instrument based on its intended use. However, before a self-reported outcome instrument is used for that purpose, evidence must be provided that includes, among other items, face validity, content validity, construct validity, internal consistency, and reliability. Furthermore, a self-reported outcome instrument needs to be translated and cross-culturally adapted if it is to be used in another culture or by speakers of another language.

More than a dozen self-reported outcome instruments have been developed for the foot and ankle region. The original version of the Foot and Ankle Ability Measure (FAAM) is 1 of the 4 instruments that provides evidence of content validity, construct validity, reliability, and responsiveness. To our knowledge, the FAAM has been translated into German, Persian, and French. Before this writing, it had not been translated into Japanese. Thus, the primary objective of our study was to provide evidence of the validity and reliability of the Japanese version of the FAAM (FAAM-J).

METHODS

The Instrument

The FAAM, originally developed by Martin et al. has 29 items in its questionnaire, with 21 items (72%) in the ADL subscale and 8 items (28%) in the Sports subscale. Each item is scored on a 5-point Likert scale, with 4 representing no difficulty at all; 3, slight difficulty; 2, moderate difficulty; 1, extreme difficulty; and 0, unable to do. Therefore, the highest possible score is 84 for the ADL subscale and 32 for the Sports subscale. Unanswered items or N/A responses are not counted in the total score, and for every item without a response or with an N/A, 4 points are subtracted from the highest potential score. To calculate percentage values, each total subscale score is divided by the highest potential score. A higher score represents a higher level of physical function. At the end of each subscale, global ratings of functions for ADL (GRF-ADL) and sport-related activities (GRF-SP) are also calculated, with 0% indicating the inability to perform any of the usual daily activities and 100% indicating the level of function before injury. Additionally, at the end of the form, patients are asked to rate the current level of function with a 4-point Likert scale (normal, nearly normal, abnormal, or severely abnormal). Patients rate each item according to the difficulty they encounter with each task because of their foot and ankle condition.

Short-Form 36, Version 2, Health Survey

The Short-Form 36, Version 2 (SF-36v2, commonly known as the SF-36) Health Survey is a generic, self-reported outcome instrument for measuring a range of the effects of a condition or disease on quality of life. The measure consists of 8 subscales: (1) Physical Functioning (PF), (2) Role-Physical, (3) Bodily Pain, (4) General Health Perception, (5) Vitality, (6) Social Functioning, (7) Role-Emotional, and (8) Mental Health (MH). Each subscale has a 0 to 100 score range, and a higher score represents a better health status. The Japanese version of the SF-36 was validated by Fukuura et al.

Translation and Cross-Cultural–Adaptation Process

We conducted the translation and cross-cultural–adaptation process in accordance with the guidelines set by the International Society for Quality of Life Assessment. The forward translation of the original version of the FAAM was performed by 2 independent, native Japanese translators (T1 and T2) with extensive English expertise, who had no medical background. In a consensus meeting, T1 and T2 discussed the discrepancies and agreed on the preliminary version of the FAAM-J. Translator 3, a native Japanese speaker with medical expertise and broad experience in translating medical literature, rated the preliminary version of the FAAM-J in terms of clarity, common language use, and conceptual equivalence, creating the forward-translation version of the FAAM-J. Translators 4 and 5, native Japanese speakers with extensive translation experience, then translated the forward-translation version of the FAAM-J back into English (back-translation version of the FAAM-J). Translator 6, a native American-English speaker with no medical background, compared the back-translation version of the FAAM-J with the original FAAM for conceptual equivalence to make further adjustments as needed. A committee reviewed and discussed the disagreements and possible modifications and agreed on the final version of the FAAM-J. We pilot tested the final version of the FAAM-J on 20 collegiate students for accuracy of wording and ease of understanding; no difficulties were noted during that process.

Participants

Competitive athletes with foot and ankle injuries, from 7 competitive, collegiate varsity teams (men’s basketball [n = 1; 14%], women’s basketball [n = 3; 43%], men’s rugby [n = 1; 14%], men’s soccer [n = 1; 14%], and men’s gymnastics [n = 1; 14%]) from 3 institutions participated in the study. Athletes’ foot and ankle injuries included in the study were musculoskeletal and originated during sports participation. Participants were excluded if they had injuries to the lower back, hip, knee, lower leg, ankle, or foot regions within the previous 6 months before the study. Other exclusion criteria were a history of surgery to the above-mentioned areas, coexisting musculoskeletal injuries in other body parts, and chronic conditions, such as systemic inflammatory rheumatic disease, neurologic or vascular conditions, cancer, diabetes mellitus, alcohol abuse, or psychiatric disorders.

Injury Classification

The locations and injury types were categorized in a system modified from previous literature. The locations of injury were the Achilles tendon, ankle, foot, and toes. The types of injuries included fractures (traumatic); stress fractures (overuse); other bone injuries, dislocations or subluxations; tendon ruptures, sprains (injury of joint ligaments or both); lesions of meniscus or cartilage; strains or muscle ruptures or tears; contusions, hematomas, or bruises; tendinosis or tendinopathy; bursitis; lacerations, abrasions, or skin lesions; and muscle cramps or spasms.
Table. Participants’ Demographic and Injury Information

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<tr>
<th>Participants</th>
<th>Values, No. (% or range, SD)</th>
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<tr>
<td>Age, y</td>
<td>20.3 (18-24, ±3.7)</td>
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<td>Sex, n = 83</td>
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<tr>
<td>Male</td>
<td>59 (71)</td>
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<tr>
<td>Female</td>
<td>24 (29)</td>
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<tr>
<td>Foot and Ankle Ability Measure score, %</td>
<td>Activities of Daily Living subscale 74.2 (0–100, ±28.4)</td>
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<tr>
<td>Sports subscale</td>
<td>52.1 (0–100, ±35.7)</td>
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<td>Injury location (n = 83)</td>
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<td>Ankle</td>
<td>63 (76)</td>
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<td>Foot</td>
<td>19 (23)</td>
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<td>Toe</td>
<td>1 (1)</td>
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<tr>
<td>Injury Classification (n = 83)</td>
<td>Sprain (injury of joint and/or ligaments) 71 (86)</td>
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<tr>
<td>Fracture (traumatic)</td>
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<td>Lesion of meniscus or cartilage</td>
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<tr>
<td>Other bone injuries</td>
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<tr>
<td>Stress fracture (avulsion)</td>
<td>2 (2)</td>
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<tr>
<td>Tendinosis/tendinopathy</td>
<td>2 (2)</td>
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<tr>
<td>Contusion/hematoma/bruise</td>
<td>1 (1)</td>
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<tr>
<td>Others</td>
<td>1 (1)</td>
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</tbody>
</table>

RESULTS

Participants

Eighty-three participants (59 men [71%] and 24 women [29%]) with foot and ankle injuries volunteered for the study. The demographic information, injury types, and injury location are presented in the Table. The predominant body part involved was the ankle, and the most frequent injury type was a sprain.

Translation and Cross-Cultural Adaptation

No major difficulties were encountered during the translation and cross-cultural adaptation process. As expected, we found a few minor discrepancies during the forward-translation process; however, the translators reached agreement. In item 5 of the Sports subscale, cutting was translated as kittingu in katakana (a Japanese alphabet for foreign words) by 1 translator and as houkutenkan (literally “change of direction” in Japanese) by the other translator. We decided to use houkutenkan rather than kittingu because we thought kittingu described a sport-specific maneuver and was appropriate if the FAAM was intended only for athletes and physically active individuals. Furthermore, kittingu seemed too technical a term in Japanese for the general population, which, therefore, might be misinterpreted by many individuals who did not understand the meaning of the word. In addition, we thought that because houkutenkan was listed in the Sports subscale, people would understand the word houkutenkan within a sports activity context. Therefore, houkutenkan would be correctly interpreted by respondents. In contrast, in item 7 of the Sports subscale, the word technique was translated as gihou by 1 translator, but we agreed to use teknunikku, literally written as teknunikku in katakana, because it is more often used in the Japanese language than gihou is. After initial corrections of the minor discrepancies, no further difficulties were noted during the translation, evaluation, or pilot-testing processes.

Convergent and Divergent Validity

Statistical analyses revealed correlation coefficients of 0.86 between the ADL subscale and the PF section of the SF-36 (P < .001) and 0.75 between the Sports subscale and the PF section of the SF-36 (P < .001). On the other hand, the ADL subscale had a correlation coefficient of 0.29 with the MH section of the SF-36 (P = .007), and the Sports subscale had a correlation coefficient of 0.27 with MH section of the SF-36 (P = .135). In addition, the ADL subscale showed correlation coefficients of 0.89 (P < .001) and 0.80 (P < .001) with the GRF-ADL and GRF-SP, respectively, whereas the Sports subscale correlation coefficients were 0.80 (P < .001) and 0.87 (P < .001), respectively.

Internal Consistency

The Cronbach α for internal consistency was 0.99 for the ADL subscale (P < .001) and 0.98 for the Sports subscale.
Test-Retest Reliability

A paired t test revealed no systemic bias between the test and retest scores for both ADL (P = .096) and sports (P = .848) subscales. Both subscales were shown to have excellent reliability. The MDC at 95% confidence was 4.1 for the ADL subscale and 4.9 for the Sports subscale.

DISCUSSION

Clinician-rated measures relate to impairment-oriented data, such as strength, pain, swelling, and range of motion, and provide information of an uncertain clinical utility.6,7 Although valuable in many ways, those measures should not be used alone. Patient-rated measures reflect patients’ values and their perceptions of the condition they suffer from, and they provide the patient-oriented evidence that is directly related to the interests of the patients. Moreover, a recent study8 indicated that clinician-rated and patient-rated outcome measures assess different aspects of health status. Thus, it is important to incorporate both types of outcome measures into the clinical decision-making process.

Our study provided evidence for translation, cross-cultural adaptation, convergent validity, divergent validity, internal consistency, and test-retest reliability for both subscales of the FAAM-J. Therefore, the use of the FAAM-J as a self-reported outcome measure for the foot and ankle region was validated with some limitations.

Although the concepts are related, face validity addresses whether an instrument is measuring what it is designed to measure, whereas content validity is concerned with adequacy, or the extent to which the items in an instrument measure the domain of interest.10,20 Not only experts but also patients need to participate in developing an instrument.10,11 The original version of the FAAM went through a rigorous item-selection process in which both expert clinicians and patients participated, using item-reduction theory.21 The evaluation of face and content validity is qualitative and subjective, but the meticulous process in the development of the original version of the FAAM, which incorporated both the expert clinicians’ and the patients’ values and opinions, provided evidence for its face and content validity.

The construct validity of an instrument is determined by evaluating the correlation between the tested instrument and other measures that are logically hypothesized from a relationship between the patient’s health status and the construct. Also, there are 2 types of construct validity: convergent and discriminant (divergent).13 Evidence for convergent validity is provided when the instrument is shown to have a strong correlation with other measures of the same construct. Divergent validity occurs when the relationship is weak or nonexistent between the score on the tested instrument and measures of a different construct. The constructs that the FAAM is intended to measure are functional limitations to the foot and ankle regions and activity restrictions. In this study, as expected, both subscales of the FAAM-J had high correlations with the PF and low correlations with the MH sections of the SF-36. The correlation coefficients with PF were 0.86 for the ADL subscale and 0.75 for the Sports subscale, whereas those with MH were 0.29 for the ADL subscale and 0.27 for the Sports subscale. Furthermore, our results were in accordance with the original and French versions of the FAAM.20,21 Thus, the subscales of the FAAM-J were correlated with the PF aspect of the patients’ health status but not with the MH aspect, providing evidence for the convergent and divergent validity of the FAAM-J.

Internal consistency is the extent to which the items in an instrument are measuring different aspects of the construct and is associated with an error within a single measure. Internal consistency is commonly assessed with correlations between all items in the instrument. In this study, the Cronbach x for internal consistency was 0.99, with an SEM of 0.56 for the ADL subscale, and 0.98, with an SEM of 1.58 for the Sports subscale. The 95% CI with a single measure was ±5.1 and ±3.2 for adult versions. The 95% CI value for the Sports subscale of the FAAM-J was considerably smaller than the values found for the original and French versions of the FAAM.20,21 Although speculative, several sources of the discrepancy were possible. First, the patient population could be a source of the discrepancy; adults (age = 41.2 ± 16.3 years for the original and French versions) were the participants in the other 2 studies, whereas young, competitive athletes (age = 20.3 ± 3.7 years) were the participants in this study. Second, the proportions of various injury locations and types varied among the studies. In our study, the locations and types of injuries were largely acute ankle sprains, which was expected because of the nature of the population in this study—competitive collegiate athletes.

Reliability relates to the stability of the scores with repeated measures when no change to the health status is expected and is assessed by the test-retest measure. The evidence for the reliability of the FAAM-J was provided with the high ICCs for the ADL and Sports subscales. The MDC value for the Sports subscale was substantially smaller in this study than it was in the original and French versions. A possible explanation, along with the above-mentioned sources of discrepancies, may be the time between the test and retest; it was 4 weeks in the original version and 2 days in the French version, whereas it was 2–6 days in this study.

The FAAM has been widely used as a self-reported outcome measure to assess (1) the functional limitations and activity restrictions caused by various pathologic conditions of the foot and ankle region and (2) the effectiveness of interventions that clinicians provide. Such conditions include foot and ankle trauma,1 acute ankle sprain,30 plantar heel pain,31 plantar fasciitis,32 ankle arthrodesis,33 ankle arthritis,34 chronic ankle instability,35–37 recurrent peroneal subluxation,34 and diabetes.38,39 The original version of the FAAM, along with 3 other questionnaires, provided evidence for construct validity, reliability, and responsiveness to support their use.16 Also, the FAAM and the Foot and Ankle Disability Index, a prototype of the FAAM, were considered to be the most suitable self-reported outcome instruments for chronic ankle instability during a systemic...
Therefore, we deemed it appropriate and valuable to translate and cross-culturally adapt the FAAM for its use in Japanese.

Furthermore, a standard method of assessment allows comparisons of different treatment methods. The prevalent use of the FAAM enables clinicians to make such comparisons for better clinical decisions. Thus, a cross-culturally adapted version of the FAAM is beneficial not only for the individuals who speak that language but also for those who speak the languages used in the other versions of the FAAM.

A recent study showed that people with functional ankle instability (FAI) had lower FAAM scores and SF-36 physical component summary scores. In addition, both the ADL and Sports subscales of the FAAM for FAI were positively correlated with the SF-36 Physical Component Summary and related subscales but not with the Mental Component Summary. Furthermore, the scores of the FAAM were correlated with the PF subscale to a greater degree than the Physical Component Summary or other subscales of the Physical Component Summary. Therefore, although the functional limitations caused by FAI contribute to the health-related quality-of-life score, the FAAM primarily captured, and was more specific to, a physical dimension, and other factors contributed to the overall health-related quality of life. Thus, clinicians need to be careful about the dimensions they intend to capture with the FAAM.

The current study had some limitations. First, although our translation process was in accordance with the guidelines in previous literature, there were limitations to our validation process with classic test theory; namely, classic test theory focuses only on the whole test score and disregards the interaction between a respondent’s ability and the characteristics of the item, such as difficulty, and each item’s sensitivity to the respondent’s ability level, whereas item-reduction theory can account for those factors. A study using item-reduction theory indicated that some items in a self-reported outcome instrument are more culture specific than others are, whereas our study did not address that issue because the classic test theory was applied. Additionally, the FAAM-J was compared with the original version of the FAAM and the SF-36, and hence, the reliability and validity of the FAAM-J were confined to those instruments. Therefore, although our method was similar to that of the development of the French version of the FAAM, future researchers need to address those limitations within the FAAM-J.

Second, the characteristics of our participants were different than those tested for the original and French versions of the FAAM. Specifically, this study was conducted on young, competitive athletes, whereas the previous 2 studies were of adults in a general population. A previous investigation showed that the SF-36 scores of uninjured, elite athletes differed slightly from the age-matched norm values, and that trend was more substantial among women. Another study of physically active individuals showed that the uninjured control group, as well as half of the FAI group, had better PF subscale scores than the general population did, whereas only the uninjured controls had better PF scores than the age-matched population. However, both the control and FAI groups had Mental Component Summary scores similar to those of the general population, although they were below those of the age-matched population. Furthermore, the magnitudes of functional limitations, participation restrictions, and disabilities experienced by injured individuals might vary according to the expected normal levels for each person. Therefore, further evidence is needed on this aspect of the FAAM-J, and the scores of the FAAM-J must be interpreted with caution when applied to a general population.

CONCLUSIONS
This study provides evidence for translation, cross-cultural adaptation, convergent and divergent validity, internal consistency, and test-retest reliability for the FAAM-J. Thus, the FAAM-J can be used as a self-reported outcome measure of an athletic population of Japanese-speaking individuals with acute ankle injuries; however, the scores of the FAAM-J must be interpreted with caution, especially when applied to different populations and other types of injury.

REFERENCES
足部・足関節能力評価票

この一週間のあなたの状態を表すにちっとも適当な苦ひとつに印をつけてください。質問の中の動作が足や足首以外のことで制限される場合は「該当なし」（N/A）をマークしてください。

日常生活について

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<tr>
<td>歩き始め</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5分以内の歩行</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>約10分間の歩行</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>約15分間の歩行</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

足・足首の状態のために、以下の動作にどのくらいの困難さがありますか。

<table>
<thead>
<tr>
<th></th>
<th>ぜんぜん難しくない</th>
<th>少し難しい</th>
<th>中くらいに難しい</th>
<th>非常に難しい</th>
<th>実行不能</th>
<th>該当なし（N/A）</th>
</tr>
</thead>
<tbody>
<tr>
<td>家事</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>日常生活動作</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>身の回りの世話</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>軽度から中程度の作業（立っていること、歩くこと）</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>きつい作業（押す/引くこと、登ること、運ぶこと）</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>余暇活動</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
日常生活動作に関する総合機能評価
通常の日常生活動作における現在の足・足首の機能レベルを0から100の数値で評価してください。あなたの足・足首の怪我をする前の機能レベルを100、一般的な日常生活を行うことが不可能なレベルを0とします。

スポーツ活動について
足・足首の状態のために、以下の動作にどのくらいの困難さがありますか。

<table>
<thead>
<tr>
<th></th>
<th>ぜんぜん難しくない</th>
<th>少し難しい</th>
<th>中くらいに難しい</th>
<th>非常に難しい</th>
<th>実行不能</th>
<th>該当なし (N/A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>走ること</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>リププすること</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>着地すること</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>素早く動いて、止まること</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>方向転換、横方向へ動くこと</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>衝撃の小さい動作</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>次段のテクニックで運動する能力</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>行おうとしているスポーツを好きなだけ続ける能力</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

スポーツ活動に関する総合機能評価
スポーツ関連の動作における現在の足・足首の機能レベルを0から100の数値で評価してください。あなたの足・足首の怪我をする前の機能レベルを100、一般的な日常生活を行うことが不可能なレベルを0とします。

全体的にあなたの足・足首の現在の機能レベルをどのように評価しますか？

□普通通り □ほぼ普通通り □異常 □極めて異常
**Foot and Ankle Ability Measure (FAAM)**  
Activities of Daily Living Subscale

Please Answer **every question** with **one response** that most closely describes your condition within the past week.  
If the activity in question is limited by something other than your foot or ankle mark “Not Applicable” (N/A).

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty</th>
<th>Slight Difficulty</th>
<th>Moderate Difficulty</th>
<th>Extreme Difficulty</th>
<th>Unable to do</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking on even Ground</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking on even ground without shoes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking up hills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking down hills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going up stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Going down stairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking on uneven ground</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stepping up and down curbs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Squatting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coming up on your toes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking initially</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking 5 minutes or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking approximately 10 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking 15 minutes or greater</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Because of your foot and ankle how much difficulty do you have with:

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty at all</th>
<th>Slight Difficulty</th>
<th>Moderate Difficulty</th>
<th>Extreme Difficulty</th>
<th>Unable to do</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home responsibilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activities of daily living</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal care</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Light to moderate work</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>(standing, walking)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy work</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(push/pulling, climbing, carrying)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recreational activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

__ ___ ___ . 0 %

**Foot and Ankle Ability Measure (FAAM)**  
**Sports Subscale**

Because of your foot and ankle how much difficulty do you have with:

<table>
<thead>
<tr>
<th>Activity</th>
<th>No Difficulty at all</th>
<th>Slight Difficulty</th>
<th>Moderate Difficulty</th>
<th>Extreme Difficulty</th>
<th>Unable to do</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Running</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jumping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starting and stopping quickly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cutting/lateral Movements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to perform Activity with your Normal technique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to participate In your desired sport As long as you like</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

__ __ __ . 0%

Overall, how would you rate your current level of function?

☐ Normal    ☐ Nearly Normal    ☐ Abnormal    ☐ Severely Abnormal

あなたの健康について

このアンケートはあなたがご自分の健康をどのように考えているかをおうかがいをするものです。あなたが毎日をどのように感じるか、日常の活動をどのくらい自由にできるかを知るうえで参考になります。お手数をおかけしますが、何卒ご協力のほど宜しくお願い申し上げます。

以下のそれぞれの質問について、一番よくあてはまるものに印（☑）をつけてください。

問1 あなたの健康状態は？（一番よくあてはまるものに☑印をつけて下さい）

<table>
<thead>
<tr>
<th>最高に良い</th>
<th>とても良い</th>
<th>良い</th>
<th>あまり良くない</th>
<th>良くない</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

問2 1年前と比べて、現在の健康状態はいかがですか。
（一番よくあてはまるものに☑印をつけて下さい）

<table>
<thead>
<tr>
<th>1年前より、はるかに良い</th>
<th>1年前よりは、やや良い</th>
<th>1年前と、ほぼ同じ</th>
<th>1年前ほど、良くない</th>
<th>1年前より、はるかに悪い</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>
問３ 以下の質問は、日常よく行われている活動です。あなたは健康上の理由で、こうした活動をするのがむずかしいと感じますか。むずかしいとすればどのくらいですか。
（ア～コまでのそれぞれの質問について、一番よくあてはまるものに☑印をつけて下さい）

ア）激しい活動、例えば、一生けんめい走る、
重い物を持ち上げる、激しいスポーツをするなど………□ 1 □ 2 □ 3

イ）適度の活動、例えば、家や庭のそうじをする、
1～2時間散歩するなど……………………………………□ 1 □ 2 □ 3

ウ）少し重い物を持ち上げたり、運んだりする
（例えば買い物袋など）……………………………………□ 1 □ 2 □ 3

エ）階段を数階上までのぼる………………………………□ 1 □ 2 □ 3

オ）階段を1階上までのぼる………………………………□ 1 □ 2 □ 3

カ）体を前に曲げる、ひざまずく、かがむ……………………□ 1 □ 2 □ 3

キ）1キロメートル以上歩く………………………………□ 1 □ 2 □ 3

ク）数百メートルくらい歩く………………………………□ 1 □ 2 □ 3

ケ）百メートルくらい歩く………………………………□ 1 □ 2 □ 3

コ）自分で風呂に入ったり、着がえたりする……………………□ 1 □ 2 □ 3

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問４　過去1カ月間に、仕事やふだんの活動（家事など）をするにあたって、身体的な理由で次のような問題がありましたか。（ア～エまでのそれぞれの質問について、一番よくあてはまるものに〇印をつけて下さい）

<table>
<thead>
<tr>
<th>いつも</th>
<th>ほとんど</th>
<th>ときどき</th>
<th>まれに</th>
<th>ぜんぜんない</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

ア）仕事やふだんの活動をする
時間がへらした .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5

イ）仕事やふだんの活動が
思ったほど、できなかった ........................................ □ 1 □ 2 □ 3 □ 4 □ 5

ウ）仕事やふだんの活動の内容によっては、できないものが
あった ................................................................. □ 1 □ 2 □ 3 □ 4 □ 5

乙）仕事やふだんの活動をする
ことがむずかしかった
（例えばいつもより努力を必要としたなど） ........................ □ 1 □ 2 □ 3 □ 4 □ 5

問５　過去1カ月間に、仕事やふだんの活動（家事など）をするにあたって、心理的な理由で（例えば、気がおちこれたり不安を感じたりしたために）、次のような問題がありましたか。（ア～ウまでのそれぞれの質問について、一番よくあてはまるものに〇印をつけて下さい）

<table>
<thead>
<tr>
<th>いつも</th>
<th>ほとんど</th>
<th>ときどき</th>
<th>まれに</th>
<th>ぜんぜんない</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

ア）仕事やふだんの活動をする時間をへらした ........................ □ 1 □ 2 □ 3 □ 4 □ 5

イ）仕事やふだんの活動が
思ったほど、できなかった ........................................ □ 1 □ 2 □ 3 □ 4 □ 5

ウ）仕事やふだんの活動が
いつもほど、集中して
できなかった .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5

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問6　過去1か月間に、家族、友人、近所の人、その他の仲間にとぶだんのつきあいが、身体的あるいは心理的な理由で、どのくらい妨げられましたか。
（一番よくあてはまるものに□印をつけて下さい）

<table>
<thead>
<tr>
<th>ぜんぜん、務められなかった</th>
<th>わずかに、務められた</th>
<th>少し、務められた</th>
<th>かなり、務められた</th>
<th>非常に、務められた</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

問7　過去1か月間に、体の痛みをどのくらい感じましたか。
（一番よくあてはまるものに□印をつけて下さい）

<table>
<thead>
<tr>
<th>ぜんぜん、痛みなかった</th>
<th>かすかな痛み</th>
<th>軽い痛み</th>
<th>中くらいの痛み</th>
<th>強い痛み</th>
<th>非常に激しい痛み</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
<td>□ 6</td>
</tr>
</tbody>
</table>

問8　過去1か月間に、いつもの仕事（家事も含みます）が痛みのために、どのくらい妨げられましたか。
（一番よくあてはまるものに□印をつけて下さい）

<table>
<thead>
<tr>
<th>ぜんぜん、務められなかった</th>
<th>わずかに、務められた</th>
<th>少し、務められた</th>
<th>かなり、務められた</th>
<th>非常に、務められた</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

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(SF-36v2 Standard, Japanese)
問9 次にあげるのは、過去1ヵ月間に、あなたがどのように感じたかについての質問です。
（ア〜ケまでのそれぞれの質問について、一番よくあってはまるものに☑印をつけて下さい）

<table>
<thead>
<tr>
<th>いつも</th>
<th>ほとんど</th>
<th>ときどき</th>
<th>まれに</th>
<th>ぜんぜんしない</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

ア）元気いっぱいでいたか................................... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

イ）かなり神経質でしたか................................... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

ウ）どうにもならないくらい、
气氛がおちこんでいましたか...... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

エ）おちついていて、
おだやかな気分でしたか........... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

オ）活力(エネルギー)に
あふれていましたか............... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

カ）おちこんで、ゆううつな
気分でしたか............................ □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

キ）疲れはてていませんでしたか........... □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

ク）楽しい気分でしたか................. □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

ケ）疲れを感じましたか................. □ 1 ........... □ 2 ........... □ 3 ........... □ 4 ........... □ 5

問10 過去1ヵ月間に、友人や親せきを訪ねるなど、人とのつきあいが、身体的ある
いは心理的な理由で、時間的にどのくらい妨げられましたか。
（一番よくあってはまるものに☑印をつけて下さい）

| いつも | ほとんど | ときどき | まれに | ぜんぜん
      | いつも |        |        |        | しない |
|--------|----------|--------|--------|--------|--------|
| ▼      | ▼        | ▼      | ▼      | ▼      | ▼      |

□ 1 □ 2 □ 3 □ 4 □ 5

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(SF-36v2 Standard, Japanese)
問11 次にあげた各項目はどのくらいあなたにあてはまりますか。（ア〜エまでのそれぞれの質問について、一番よくあてはまるものに☑印をつけて下さい）

<table>
<thead>
<tr>
<th>まったく</th>
<th>ほぼ</th>
<th>何とも</th>
<th>ほとんど</th>
<th>ぜんぜん</th>
</tr>
</thead>
<tbody>
<tr>
<td>その他</td>
<td>あてはまる</td>
<td>言えない</td>
<td>あてはまらない</td>
<td>あてはまらない</td>
</tr>
</tbody>
</table>

ア）私は他の人に比べて病気になりやすいと思う ..........................□ 1 □ 2 □ 3 □ 4 □ 5

イ）私は、人並みに健康である ..........................□ 1 □ 2 □ 3 □ 4 □ 5

ウ）私の健康は、悪くなるような気がする ..........................□ 1 □ 2 □ 3 □ 4 □ 5

エ）私の健康状態は非常に良い ..........................□ 1 □ 2 □ 3 □ 4 □ 5

これまでこのアンケートはおわりです。
ご協力ありがとうございました。