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Kataoka, Kiminari ; Hoshino, Yuichi ; Nagamune, Kouki ; Nukuto, Koji ; Yamamoto, Tetsuya ; Yamashita, Takahiro ; Kanzaki, Noriyuki ; Kakutani...

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- 2 electromagnetic measurement system
- 3 Kiminari Kataoka^a, Yuichi Hoshino^a, Noriyuki Kanzaki^a, Koji Nukuto^a,
- 4 Tetsuya Yamamoto^a, Takahiro Yamashita^a, Takehiko Matsushita^a, Ryosuke
- 5 Kuroda^a
- ^a Department of Orthopaedic Surgery, Kobe University Graduate School of Medicine,
- 7 Kobe, Hyogo, Japan

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- 9 Corresponding Author:
- 10 Yuichi Hoshino M.D., Ph.D.
- 11 Department of Orthopaedic Surgery, Kobe University Graduate School of Medicine
- 12 7-5-1 Kusunoki-cho, Chuo-ku, Kobe, 650-0017, Japan.
- 13 Tel: +81-78-382-5985 / Fax: 81-78-351-6944
- 14 E-mail: you.1.hoshino@gmail.com

The quantitative evaluation of anterior drawer test using an

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The anterior drawer test (ADT) is the gold standard examination for the diagnosis of anterior talofibular ligament insufficiency, although there is no quantitative evaluation of ADT that is generally usable and reliable. An electromagnetic sensor (EMS) has been used to quantitatively evaluate joint kinematics, and has a high potential to be applied to the ankle joint. The aim of this study was to validate the EMS measurement of the ADT in comparison to the fluoroscopic evaluation and to evaluate the reproducibility of the EMS measurement. Six feet were included, and an examiner performed the ADT 5 times for each foot while the anterior translation of the ankle joint was quantitative evaluated using EMS and fluoroscope simultaneously. The anterior translation of the ankle joint during the ADT in EMS and in fluoroscope was 8.1 ± 5.7 mm and 3.6 ± 2.4 mm. A strong correlation was observed between the measurements using EMS and fluoroscope (p < 0.01, the correlation coefficient = 0.91). Another 20 feet were included, and three examiners performed the ADT five times for each foot with the EMS measurement. The intra and inter-examiner reliability was 0.99 and 0.89. The EMS could quantify the anterior translation during the ADT which corresponds to fluoroscopic evaluation. Keywords: ankle sprain; lateral ankle instability; electromagnetic sensor; biomechanics; quantitative evaluation

Introduction

39	Ankle sprains are common injuries in the sporting population, accounting for about 20%
40	of all musculoskeletal injuries (Slater, 2018; Vuurberg et al., 2018). The majority of
41	these injuries are inversion trauma, resulting in lateral ankle ligament injuries whose
42	primary structure is the anterior talofibular ligament (ATFL) (Hur et al., 2020; Teixeira
43	& Guillo, 2018). Nonoperative therapy, including functional treatment, is usually
44	prescribed, but 20 - 40 % of ankle sprains develop chronic lateral ankle instability
45	(CLAI) (Gerber et al., 1998; Pijnenburg et al., 2000, 2003).
46	The clinical diagnosis of ATFL insufficiency is made based on the medical
47	history and the anterior drawer test (ADT), a maneuver that provides a 4-point scale of
48	the anterior laxity of the ankle while pulling the rearfoot anteriorly (Ferran & Maffulli,
49	2006; Vuurberg et al., 2018). The ADT is also applied to determine the severity of
50	lateral ankle ligament injuries; there is no laxity on the ADT in a grade I, mild laxity
51	in a grade II, and moderate to severe laxity in a grade III (Ferran & Maffulli, 2006).
52	Because the ADT is just a 4-point scale which is estimated by the surgeons' manual
53	feeling, it is difficult to compare the results from different examiners and to detect a
54	small difference. Some studies reported that ADT may not be sufficient to diagnose
55	ATFL injuries and its low reproducibility (Fujii et al., 2000; Lahde et al., 1988).
56	Although recent modifications of the ADT maneuver improved the accuracy for the
57	determination of lateral ankle instability (Li et al., 2020; Phisitkul et al., 2009), ADT is
58	still lacking in objectivity and ability to provide quantitative values.
59	Stress radiography is an established method to quantitatively evaluate the
60	anterior laxity of the ankle with a high reliability (Hubbard et al., 2004; Lohrer et al.,
61	2008). However, sprained ankle patients often resist stress due to pain or discomfort
62	(Cho et al., 2016; Rijke, 1995). Moreover, radiation exposure is a great concern about

63 the stress radiography to limit its general application. On the other hand, another 64 potential measurement methods for ankle anterior laxity is an ultrasound and instrumented measurement devices which are non-invasive and useful in the clinical 65 66 setting (Campbell et al., 1994; Docherty & Rybak-Webb, 2009; Gehring et al., 2019; Lee et al., 2014; Radwan et al., 2016). In recent years, stress ultrasound has been 67 68 developed to examine ankle anterior laxity (Cho et al., 2016; Croy et al., 2012; Lee et 69 al., 2014). However, the ultrasound has a limitation of the capturing range and is unable 70 to evaluate the ankle joint kinematics comprehensively. As for instrumented measurement devices, a number of devices have been developed, however there are 72 reports that they are not suitable for detecting ankle instability in clinical setting; their 73 usefulness remains questionable (de Vries et al., 2010; Kerkhoffs et al., 2005; Wenning 74 et al., 2019).

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75 A three-dimensional motion tracking system using electromagnetic sensors 76 (EMS) has a great accuracy to capture the relative movement between the objects and 77 has been applied for several joint motion assessments with the benefit of non-78 invasiveness to the human body (Ahldén et al., 2012; Araki et al., 2011; Delorme et al., 79 2005; Du & Yanai, 2020; Gatt et al., 2020; Hoshino et al., 2007; Manocha et al., 2019). 80 Delorme et al. first utilized EMS to evaluate three rotations of the ankle motion, i.e. 81 dorsi-/planter flexion, inversion/eversion, and internal/external rotation (Delorme et al., 82 2005), although an EMS has a potential to evaluate full 6 degree-of-freedom evaluation 83 of the joint motion including three rotations and three translations. Recent technical 84 improvement of the EMS application for joint movement evaluation can be 85 implemented to quantitatively evaluate the ADT of the ankle.

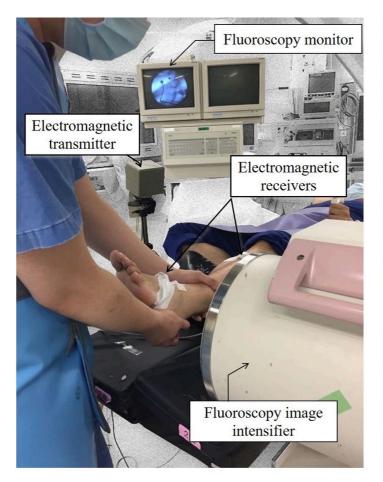
The aim of this study was to validate the measurement of the ADT of the ankle using EMS in comparison to the radiographic evaluation and to evaluate the precision

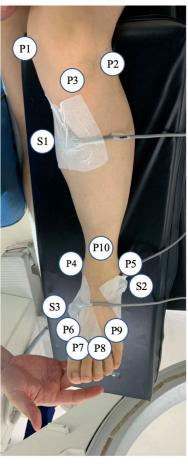
and reproducibility of ADT of the ankle using EMS. Our hypothesis was that there
would be a good correlation between the anterior translation of the ankle joint measured
using EMS and radiography and an acceptable reproducibility of the EMS measurement
for the ADT would be obtained.

Methods

Six feet of four healthy volunteers (three males/one female, 31.3 ± 10.1 y. o.) were included to compare the measurement of the ADT of the ankle using EMS and the radiographic evaluation. Three participants did not present any physical limitations or musculoskeletal injuries that could affect testing, one participant had a history of an ankle sprain. A single well-experienced foot and ankle surgeon performed the ADT five times for each foot while quantitative evaluations were conducted using EMS and fluoroscopy simultaneously (Figure 1). A total of 30 tests were evaluated and compared between the values obtained from EMS and radiographic evaluations.

Ethical approval was obtained from our institutional review board prior to this study (ID No. B190150). Informed consent was obtained from all individual participants.





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Figure 1. The experimental setting and the positions of the sensors and the bone-based landmarks for the lower leg and the foot. (a) The anterior drawer test was performed by an examiner while recording the ankle movement using an electromagnetic tracking system and a fluoroscopy simultaneously. (b) Three sensors were fixed to the tibia (S1), the lateral side of the calcaneus (S2), and the medial side of the first metatarsal bone (S3). The five anatomical landmarks on the lower leg were the intersection of the medial collateral ligament and the knee joint line (P1), the distal end of the fibula head (P2), the center of the tibial tubercle (P3), the peak of the medial malleolus (P4), and the peak of the lateral malleolus (P5). The five anatomical landmarks on the foot were the center of the first metatarsal bone head (P6), the medial and lateral edges of the second metatarsal bone (P7, 8), the center of the fifth metatarsal bone head (P9), and the attachment of the Achilles tendon (P10).

Equipment

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An electromagnetic sensor system (LIBERTY, Polhemus, Colchester, VT, USA) was utilized, and four sensors were employed in this experiment. Three sensors were fixed to the tibia, the lateral side of the calcaneus, and the medial side of the first metatarsal bone. The fourth sensor was applied to register the three-dimensional (3D) positions of the bone-based landmarks for the lower leg and the foot in relation to the other fixed three sensors. The five anatomical landmarks on the lower leg were the intersection of the medial collateral ligament and the knee joint line (P1), the distal end of the fibula head (P2), the center of the tibial tubercle (P3), the peak of the medial malleolus (P4), and the peak of the lateral malleolus (P5). The five anatomical landmarks on the foot were the center of the first metatarsal bone head (P6), the medial and lateral edges of the second metatarsal bone (P7, 8), the center of the fifth metatarsal bone head (P9), and the attachment of the Achilles tendon (P10) (Figure 1). The lower leg and the foot were virtually recognized based on the registered 3D position data of the landmarks as rigid objects in reflection to the sensors that were attached to the skin. The coordinate system of the ankle joint according to Wu et al was then established to provide the 6 degree-offreedom kinematics (Wu et al., 2002). The center of P4 and P5 was used as the origin of the lower leg and the foot. The medial and lateral (M-L) axis of the ankle joint was the line connecting P4 and P5, and rotation around this axis was defined as dorsiflexion/plantarflexion and translation along this axis was defined as medial/lateral. The anterior and posterior (A-P) axis of the ankle joint was the line perpendicular to the torsional plane of the lower leg (the plane connecting P4, P5 and the point located midway between Pland P2), and rotation around this axis was defined as inversion/eversion and translation along this axis was defined as anterior/posterior. The proximal and distal (P-D) axis of the ankle joint was the common line perpendicular to the M-L axis and A-P axis, and rotation around this axis was defined as internal

rotation/external rotation and translation along this axis was defined as proximal/distal. The manufacturer reported this EMS had a root-mean-square accuracy of 0.76 mm for position and 0.15° for orientation when it was used within 106 cm of a transmitter-to-receiver separation, and validation study has shown a root-mean-square accuracy as low as 0.20 mm to be consistent with these claims (Nafis et al., 2006). Ankle kinematics data were acquired with 240 Hz during the ADT. The 6 degree-of-freedom of the ankle joint was obtained as shown in figure 2. The difference between the maximum and minimum value of the anterior translation during an ADT was calculated and compared to the fluoroscopic evaluation.

Another 20 feet of ten healthy volunteers (nine males/one female, 34.1 ± 8.6 y. o.) were included to evaluate the ADT measurement reliability. Fifteen feet had a history of an ankle sprain. Three examiners performed anterior drawer test 5 times for each foot while quantitative evaluations were conducted using EMS. A total of 300 tests were evaluated, and Interclass Correlation Coefficient (ICC) for inter and intra-observer reliability were calculated.

A lateral view of the ankle joint was captured by a fluoroscopy during the ADT. In order to measure the anterior translation of the ankle joint in the fluoroscopic image, a baseline was set connecting the anterior and posterior tip of the tibial articular surface, and two perpendicular lines to the baseline were drawn at the posterior edge of the tibial cortex and the posterior edge of the talus. The distance between the perpendicular lines through the posterior edges of the tibia and talus was calculated as the anterior-posterior position of the ankle joint (Figure 2). The distance was corrected with respect to the size of a 1cm diameter metal ball which was attached in front of the ankle and captured in the same image. The difference between the maximum and the minimum anterior-posterior positions during the ADT was calculated as the anterior translation of the

ankle joint according to previous reports (Johannsen, 1978; Lohrer et al., 2008; Seligson

171 et al., 1980).

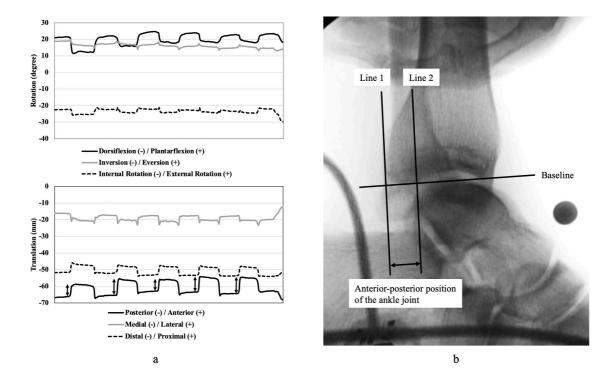


Figure 2. An example of the 6 degree-of-freedom measurement of the ankle joint during the anterior drawer test (ADT) and anterior-posterior position of the ankle joint in a fluoroscopic image. (a) The ADT was repeated 5 times. The difference between the maximum and minimum value of the anterior translation during an ADT (double arrow) was calculated. (b) Baseline; intersects anterior and posterior tip of the tibial articular surface. Line 1; perpendicular to the baseline which insets the posterior edge of the tibial cortex. Line 2; perpendicular to the baseline which insets the posterior edge of the talus. Anterior-posterior position of the ankle joint; the distance between Line 1 and Line 2 on the baseline.

Statistical analysis

All measurements were expressed as mean \pm standard deviation (SD). The Pearson's correlation coefficient was calculated to evaluate the correlation between the two anterior talar displacements measured using the EMS and fluoroscope. ICC was used to assess inter and intra-examiner reliability for the anterior translation of the ankle joint measured using EMS. In reference to a previous study, the categorization of ICC scores was determined *a priori*, whereby ICC < 0.50 indicates poor agreement, $0.50 \le$ ICC < 0.75 indicates moderate agreement, $0.75 \le$ ICC < 0.90 indicates good agreement, and ICC \ge 0.90 indicates excellent agreement (Koo & Li, 2016). The results were analyzed statistically using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria)(Kanda, 2013). Statistical significance was set at a p value of 0.05.

Results

Correlation between the anterior translation of the ankle joint measured using EMS and radiography

Anterior translation of the ankle joint during ADT by EMS was 8.1 ± 5.7 mm [range 2.6mm – 21.0mm], whereas that by radiographic evaluation was 3.6 ± 2.4 mm [range 1.4mm – 9.0mm]. There was a significant positive correlation between the anterior translation of the ankle joint measured using EMS and radiography (p<0.01). The correlation coefficient was 0.91 (Figure 3).

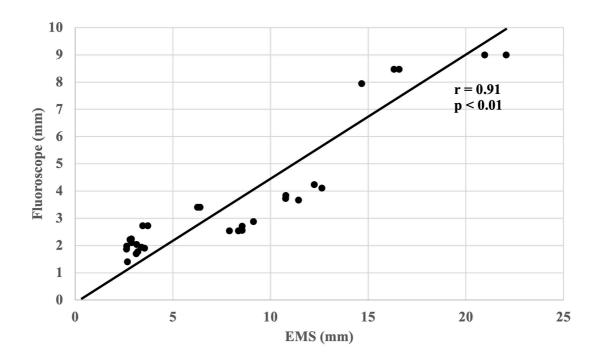


Figure 3. Correlation between the anterior translation of the ankle joint measured using EMS and fluoroscope.

211	Inter and intra-examiner reliability for the anterior translation of the ankle
212	joint measured using EMS
213	The anterior translation of the three examiners averaged 5.0 ± 2.2 mm, 5.7 ± 2.7 mm,
214	and 5.2 ± 2.7 mm, respectively. The ICC of inter-examiner reliability was 0.89, and the
215	ICC of intra-examiner reliability was 0.99; good inter-examiner agreement and
216	excellent intra-examiner agreement were achieved. Furthermore, the mean anterior
217	translation for the foot with and without a history of sprain was 6.4 ± 2.2 mm and $2.7 \pm$
218	1.8 mm, indicating a significant difference (p ≤ 0.001).
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Discussion and Implications

The main finding of this study was that there was a strong positive correlation between the anterior translation of the ankle joint measured using EMS and radiographic evaluation. Another key finding was that a high inter and intra-examiner reliability was obtained in the EMS measurement of the anterior translation of the ankle during the ADT. Therefore, a quantitative evaluation of the ADT of the ankle could be achievable in a non-invasive manner and, thus, widely used in the clinical setting.

The ADT is the most common and conventional procedure to test ankle instability after ankle sprains (Vuurberg et al., 2018). However, in a cadaveric study, the impact of the ATFL on the anterior displacement of the talus was only 2 to 4 mm (Fujii et al., 2000), which is difficult to detect by manual testing consistently. Lahde et al. reported that 28% of ATFL tears were not detected by ADT (Lahde et al., 1988). Thus, a quantitative assessment of ADT is desirable to detect such a small change due to ATFL insufficiency. The root-mean-square accuracy of the electromagnetic sensor system was reported from 0.20 to 0.76 mm (Nafis et al., 2006), which seems to be sufficient to detect 2mm difference. In the current study, the mean anterior translation for the ankle with and without a history of sprain was 6.4 ± 2.2 mm and 2.7 ± 1.8 mm respectively, the difference was similar to that of the previous cadaveric study (Fujii et al., 2000). The EMS measurements were able to detect a significant difference between the anterior translation with and without a history of sprain. Taken together, the results suggested that the EMS could be a useful tool to diagnose ATFL insufficiency.

Recently, ADT has been modified to ALDT (Phisitkul et al., 2009; Vaseenon et al., 2012) or reverse ALDT (Li et al., 2020). ALDT is performed with one hand stabilizing the leg just above the ankle joint and the other hand providing a combination of the anteriorly directed force, measurement of talar translation, and control of ankle

plantarflexion (Phisitkul et al., 2009). One cadaveric study reported that ALDT was more accurate than ADT to diagnose lateral ligament injuries (Phisitkul et al., 2009). Reverse ALDT was performed to palpate the posterior displacement of the tibia. Li et al. reported higher sensitivity and specificity in the reverse ALDT than conventional ADT (Li et al., 2020). Although these newly introduced tests were not utilized in the current study, they could improve the measurement accuracy and sensitivity to detect the abnormal anterior laxity of the ankle.

Stress radiography is well-known as a gold standard method of measuring the anterior ankle laxity. Lohrer et al. assessed several stress radiographic tests for the ankle joint and demonstrated acceptable reliability in the ADT (Lohrer et al., 2008). Hubbard et al. reported its clinical utility to assess functional ankle instability (Hubbard et al., 2004). However, a wide clinical application of the radiographic assessment is largely limited due to radiation exposure. Moreover, it is well known that pain and discomfort caused by the instrumented stress to the ankle during the test depreciate the radiographic assessment, and anesthetics or regional nerve block was suggested (Rijke, 1995). The EMS measurement could be a good alternative to the radiographic evaluation without radiation concerns and painful loading instrumentations.

Measurement using ultrasound has been attracting attention for quantitative assessment of ankle instability. Cho et al. described the deformity of the ATFL under the external stress to demonstrate better sensitivity of ATFL insufficiency (Cho et al., 2016). Also, ATFL length was suggested to be related to the severity of ADT (Lee et al., 2014). The direct assessment of the ATFL structure might be better achieved by the ultrasound, but the accuracy of the ultrasound measurement highly depends on the technical proficiency especially when a stress test is applied. Also, the entire joint movement cannot be assessed by the limited range of the ultrasound assessment. On the

other hand, the EMS measurement of the anterior translation during the ADT showed a very high intra and inter-examiner reliability, suggesting that it would be a consistent evaluation of the ankle anterior laxity independent of the examiner's proficiency.

An EMS has been applied to the knee joint especially for evaluating knee joint laxity testing, such as pivot-shift test and Lachman test (Ahldén et al., 2012; Araki et al., 2011; Hoshino et al., 2007; Nagai et al., 2015; Tanaka et al., 2018). Unlimited clinical application of the EMS measurement has enabled to perform several clinical studies to improve clinical diagnosis and treatments of the knee joint (Araki et al., 2011; Hiroshima et al., 2020; Hoshino et al., 2019, 2020; Miyaji et al., 2019). Furthermore, the EMS measurement has a great advantage of 6DOF measurement unlike 2D evaluation of fluoroscopy. In addition to anterior translation, other rotations and translations can be evaluated and might be useful to assess severity of the ankle lateral ligament injury and/or concomitant injuries affecting ankle kinematics. The application of the EMS to the ankle could have a great potential to enhance the clinical diagnosis and treatment of the ankle similarly to the knee joint.

The accuracy of EMS is known to be affected by the metal or other source which causes a distortion of the magnetic field. Fluoroscopy was located closely to the measurement electromagnetic field, therefore measurement errors due to a magnetic field distortion had been anticipated. Therefore, prior to each testing session, no magnetic field distortion in the testing environment was verified by confirming a consistent evaluation of a defined distance and angle between sensors which were fixed in the scaled platform. Furthermore, it was reaffirmed that a consistent waveform was obtained after the measurement. Thus, the quantitative evaluation using EMS was free from magnetic field distortion in the experimental setting.

There are some limitations in this research. At first, the sample size was small. A

larger number of subjects might exemplify the diverse conditions of the ankle joint, but this study did not focus on the diagnosis of the ankle joint but on the measurement accuracy. Therefore, each single testing movement of the ankle can be dealt with as a separate subject in this study. A total of 30 tests were assumed to be sufficient to test the correlation between the two measurements. Secondly, soft tissue movement between a sensor and bones affects the measurement accuracy of the EMS. The locations of the sensor placement were selected to minimize the soft tissue interference, and the skin motion around the ankle is relatively small compared to the other joints especially when the ADT is performed in a gentle manner. However, the effect of skin motion should be properly tested by a cadaver experiment. Lastly, the EMS requires additional procedures to set up the coordinate system of ankle joint movement before testing and to analyze the acquired data after testing, and the whole evaluation process is not necessarily short compared to the other measurement systems and might affect the clinical usability of the EMS.

The clinical relevance of this study is that the EMS measurement of the ADT can be used as a quantitative evaluation of anterior ankle laxity in place of the radiographic assessment in the clinical setting. Future applications for clinical study and practice are highly expected.

Conclusions

A newly introduced electromagnetic measurement of the anterior ankle laxity during ADT could provide a comparable evaluation to the radiographic assessment and the high precision and reproducibility. The electromagnetic measurement can be an acceptable alternative to the radiographic assessment of the ADT in the clinical setting.

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