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Two ankle joint laxity testers: reliability and validity

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Abstract Two test devices were manufactured to objectively measure ankle joint laxity: the dynamic anterior ankle tester (DAAT) and the quasi-static anterior ankle tester (QAAT). The primary aim was to analyse the reliability of both testers; The secondary aim was to assess validity in correlation with TELOS stress test and manual anterior drawer test. Twenty-four normal subjects and 14 patients 1 year after acute lateral ankle ligament injury were included. Both ankles were tested with the DAAT and QAAT by two different observers; one experienced orthopaedic surgeon performed the manual test; the TELOS stress X-rays were evaluated by one observer. Intra observer reliability for the DAAT varied between 0.81 and 0.94; for the QAAT between 0.71 and 0.94. Inter observer reliability for the DAAT varied between 0.84 and 0.94; for the QAAT between 0.76 and 0.82. Concurrent validity showed fair correlation between DAAT and QAAT for the first couple observers (0.71); however, a poor correlation was observed for the second couple (0.42). No significant correlations were found between neither DAAT and the TELOS and the manual test, nor QAAT and the TELOS and the manual test. In conclusion, reliability of both testers is high. Validity of the testers needs further investigation.

Keywords Ankle · Ligament injury · Ankle testers · Inversion injury · Reliability

Introduction

In The Netherlands, each year 80,000 patients present at the First Aid departments with an acute ankle injury [4]. After 6.5 years about 32,000 of these patients (40%) still have residual complaints (pain, fear of giving-way, actual instability and/or swelling) that interfere with daily living and/or sports activities [21]. Hence, an acute ankle injury is an important problem for general health. Adequate diagnosis and treatment are important to prevent chronic ankle joint instability. The extent of a ligament injury is determined by evaluating ankle joint laxity. The manual anterior drawer test is generally used to estimate ankle joint laxity [14, 20]. However, this manual test can be criticized because of its subjective nature and the inability to produce reproducible and quantitative results [7]. Although the ankle joint is more complex, equal inconveniences were observed in the measurement of anterior knee laxity after disruption of the anterior cruciate ligament. The need for a quantitative knee tester has lead to the development of an arthrometer, the KT1000, that measures absolute anterior tibial displacement relative to the femur with a given load [7]. As part of an extensive study to develop objective diagnostic and treatment procedures for lateral ankle ligament injuries, a dynamic anterior ankle ligament tester (DAAT) was developed that showed promising preliminary results [11]. Simultaneously, a quasi-static anterior ankle tester (QAAT) was developed [12] that used a similar approach as the above-mentioned KT1000. In the present study, the primary objective was to analyse the reliability of the two testers. The secondary objective was to assess the validity of the two testers in correlation with the TELOS stress test and the manual anterior drawer test.

Test devices

Dynamic anterior ankle tester (DAAT)

The DAAT was described earlier [11] Ankle joint laxity is measured as the anterior displacement of the talus relative to the tibia. The displacement results from a hammer (weight 1.0 kg) hitting the heel stand with a speed of 1.7 m/s (Fig. 1). Prior to the test, the hammer is placed in horizontal position and can be released by a snap connection. Releasing the hammer gives a force-impulse on the calcaneus and the slide follows the anterior drawer movement in the ankle joint. The resulting anterior translation and rotation in the horizontal plane (inward or outward) in the joint are measured. The mechanism of the DAAT is based on the principle that the force-impulse gives a load on the calcaneus within the reflex-time of the muscles. The force and the resulting anterior drawer movement takes less than 35 ms. Because of this short moment, muscle contraction can not influence the test results [8]. Hence test results depend on stiffness and pretension of the lateral ankle ligament complex.

The test with the dynamic ankle test device consisted of five measurements. The highest and the lowest score were discarded and the mean of the three remaining scores counted as the result of the test.

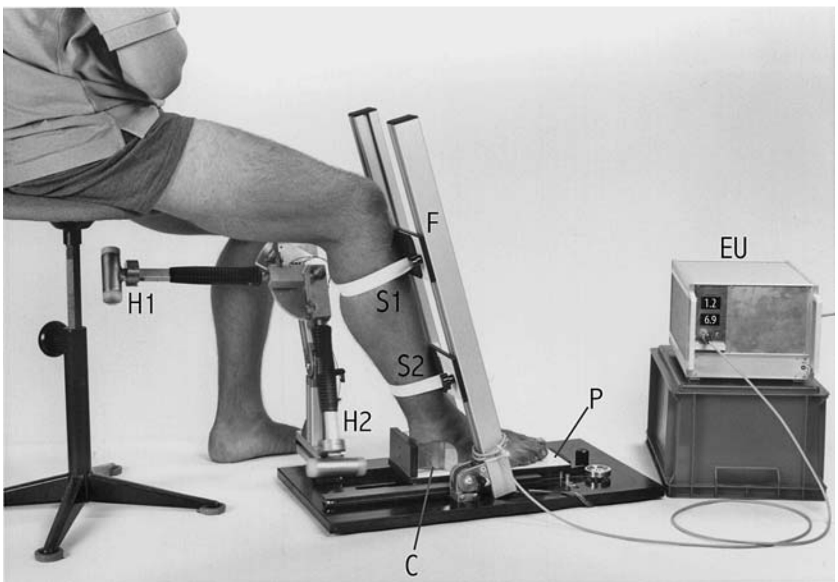

Fig. 1 The dynamic anterior ankle tester (DAAT)[7], as previously described. The tibia is securely attached to the frame (*F*) using straps (*S1* and *S2*). The foot is placed on the footplate (*P*). Low-friction ball bearings connect the footplate to the base plate. The heel is fixed in a Perspex clip (*C*). The hammer (*H1*) is released and hits (*H2*) the heel stand of the footplate (note: the photograph shows the same hammer in two positions). The footplate moves in anterior-posterior and mediolateral direction. Two potentiometers connected between the footplate and the base plate measure the anterior and mediolateral translation of the foot-plate. The electronic unit (*EU*) registers the maximum translation of the foot-plate in both directions as a measure of anterior ankle laxity. (Reproduced with permission from J Biomech 35: 1666)

Quasi static anterior ankle tester (QAAT) [12]

The tibia is firmly attached to a shank holder using straps and the foot is securely held to the footplate using an additional strap (Fig. 2). A linkage mechanism through a subframe allows manual force application on the shank and heel, resulting in an anterior drawer movement in the ankle joint. The footplate is attached to the moving subframe by means of a force transducer. The linkage mechanism allows manual force application up to a maximum of 200 N. The test is performed with the lower leg hanging downwards freely. As a result of the load on the heel of the patient, the horizontal footplate moves. The tester uses two displacement transducers to measure anterior translation of the heel relative to the tibia. One transducer measures the displacement of the footplate and subframe relative to the

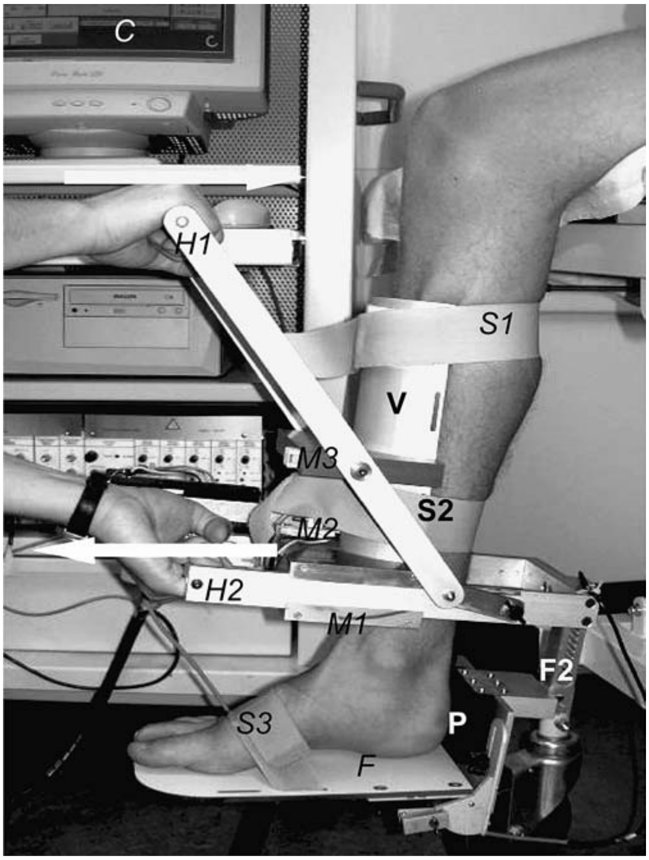

Fig. 2 The quasi-static anterior ankle tester (QAAT)[8] . The tibia is firmly attached to a vertical construction (*V*) using straps (*S1* and *S2*) and the foot is securely held to the footplate (*F*) using a strap (*S3*). A double handle system (*H1* and *H2*) allows manual force application on the tibia and a resulting anterior drawer movement in the ankle joint. The applied load is registered by a force transducer (*F2*) that connects the vertical construction to the footplate. The switch plate (*P*) registers contact between hind foot and vertical construction. Three displacement meters measure anterior translation of the heel relative to the tibia (*M1*) respectively motion of the tibia in the vertical construction (*M2* and *M3*). While testing, data can be read online on a computer screen (*C*) by the observer. (Reproduced with permission from Clin Biomech 20:220)

shank holder and the other transducer measures the displacement of the anterior aspect of the tibia relative to the shank holder. Applied force and the displacements of the footplate and the tibia are registered online during the test by a data-acquisition system. Data are shown on a computer screen, providing direct feedback for the observer. The intrinsic accuracy of the test device with respect to the measured values is 0.1 mm and 1.0 N respectively. The measurements consist of a set of five loading cycles. Three loading cycles were used for evaluation. Data were processed with use of Microsoft Excel. The calculations resulted in a value for the anterior displacement at a force of 150 N.

Stress radiographs

Lateral view radiographs of both ankle joints were made with and without a force being applied. The stress radiographs were made with the TELOS GAII/E stress apparatus (ARD Medizin Produkte GmbH, Germany). While constraining the posterior aspect of the heel, a force of 150 N is applied to the anterior aspect of the distal shank. Anterior displacement is measured on the printed radiographs using a custom-made template. Displacement of the talar dome relative to the cranial-caudal axis of the tibia is used for this measurement according to Lindstrand [15]. All radiographs were twice analysed by the corresponding author (GK), the Kappa value of these two measurements was 0.89.

Manual anterior drawer test

The patient sits on a bench with the legs hanging downwards. The knee joint is flexed and the foot held in 15° plantar flexion. First the healthy ankle is examined. Examination is performed according to Van Dijk [20]. The examiner assigned one of four predetermined numbers to each examined ankle joint, based on the estimated anterior displacement of the talus relative to the tibia: 0 = 0–2 mm; 1 = 3–5 mm; 2 = 6–10 mm; 3 = 11–15 mm.

Patients and method

Patients

First, 24 subjects (13 male and 11 female; mean age 34 years, range 25–51) without complaints of ankle joint laxity were included. Second, 14 subjects (six male and eight female; mean age 30 years, range 22–50) with functional complaints of ankle joint instability were included. All these subjects had complaints of recurrent giving way, minimally 1 year following an acute lateral ankle ligament injury. On investigation, patients had signs of mechanical laxity i.e. a positive manual anterior drawer test (left-right difference > 3 mm). This group of patients was added to broaden the range of measurement values, thereby improving the quality of the analyses for performance precision (reliability) and accuracy (validity). The medical ethical committee of the Academic Medical Centre approved the study.

Procedure

All subjects were tested according to the same protocol; two observers tested the group of 24 subjects without functional complaints and two other observers tested the group of 14 patients. All visited the outpatient clinic twice with a minimum of one week in between, in order to ensure the independency of the repeated measurements. During the first visit, the subjects were tested with both ankle testers by two observers. The QAAT preceded the DAAT. After the first test session, ankle stress-radiographs were taken with TELOS. After the radiographs, subjects were tested again by the same two observers with both devices. This was the second test session. During the second visit, subjects were tested by the first observer with both testers: the third test session. During this visit, the manual anterior drawer test was performed by the senior author (CVD).

Statistical analysis

Reliability analysis of the DAAT and the QAAT was performed using the first two test sessions of each observer. Intra-class Correlation Coefficients (ICC) with a 95% confidence interval were calculated to assess both intra and inter observer reliability [17]. Values >0.70 were considered as clinically acceptable, >0.80 as accurate. Paired t-tests were performed to determine systematic differences between the observers.

Concurrent validity was determined by using Spearman's Rank Correlation Coefficients.

Additionally, differences between injured and non-injured ankles in the 14 patients with one-sided functional ankle joint instability complaints were calculated. Paired T-tests or non-parametric variants were used to determine laxity differences between injured and non-injured ankles. P-values <0.05 were considered as statistically significant.

Results

ICCs for intra observer reliability varied between 0.81 and 0.94 for the DAAT; between 0.71 and 0.94 for the QAAT (Table 1). Inter observer reliability values for the DAAT varied between 0.84 for the first couple observers and 0.94 for the second; for the QAAT, between 0.76 and 0.82 (Table 2).

Concurrent validity, as analysed with Spearman's Rank Correlation, showed fair correlation between DAAT and QAAT for the first couple observers (F1: 0.63; F2: 0.71), however poor correlation for the second couple (S1: 0.42; S2: 0.42) (Fig. 3). No significant correlations were found between neither DAAT and the TELOS and the manual test, nor QAAT and the TELOS and the manual test.

Calculated differences between the injured and non-injured ankle in the 14 patients with one-sided functional ankle joint instability complaints showed no statistically significant differences in laxity values, as measured with the DAAT, QAAT or TELOS (Table 3). However, Wilcoxon Signed Ranks Test showed a statistically significant difference in laxity when measured by the manual anterior drawer test ($P=0.029$).

Table 1 Intra observer values presented as ICC's with 95% confidence intervals (CI) for both observer couples with DAAT and QAAT

Tester	Observer (N^a)	ICC^b (95% CI)
DAAT	F1 (48)	0.81 (0.68–0.89)
	F2 (48)	0.88 (0.80–0.93)
	S1 (28)	0.93 (0.86–0.97)
	S2 (28)	0.87 (0.74–0.94)
QAAT	F1 (38)	0.94 (0.88–0.97)
	F2 (41)	0.87 (0.77–0.93)
	S1 (28)	0.82 (0.65–0.91)
	S2 (27)	0.71 (0.46–0.88)

^{a} N presents the number of subjects without protocol violations, available for calculation of the intra observer values
^{b} $P<0.001$ for all tests

Discussion

As part of a greater study to develop objective diagnostic and post-therapy evaluation procedures, two ankle joint laxity testers were developed. The present study described an analysis of the reliability and validity of both testers.

Ankle ligament laxity measurements with the DAAT shows realistic outcome values with a mean, for all ankles, of 8.9 mm. These laxity values nearly equalled ankle laxity outcome measurements in studies with radiographic stress tests [1, 16]. However, with a mean laxity of 22 mm, laxity values measured with the QAAT were too high when compared to values described in literature [2, 13, 19]. This discrepancy raises the question as to what is it is, that actually being measured. A non-invasive measurement uses external reference points. With the QAAT, references are shank and heel; using these structures as external references means that the measurement comprises motion in both ankle and

Table 2 Inter observer values for both observer couples, presented as ICC's with 95% confidence intervals (CI). The values are the results of an analysis of two measurements sessions

Test	Observers (N^a)	ICC^b (95% CI)
DAAT	F1–F2 (48)	0.84 (0.60–0.92)
	S1–S2 (28)	0.94 (0.87–0.97)
QAAT	F1–F2 (40)	0.82 (0.59–0.91)
	S1–S2 (27)	0.76 (0.34–0.90)

^{a}N presents the number of subjects without protocol violations, available for calculation of the intra observer values
^{b}$P<0.001$ for all tests

Table 3 Mean left-right differences in anterior laxity values for 14 subjects with one-sided functional ankle joint laxity complaints. All subjects were tested by the same two different observers with both DAAT and QAAT

Tester	Observer	Ankle (*N*[a])	Mean laxity value (mm)[b] (95% CI)
DAAT	S1	Asymptomatic (14)	8.7 (7.7–9.7)
		Symptomatic (14)	9.0 (8.1–10)
	S2	Asymptomatic (14)	8.7 (7.8–9.7)
		Symptomatic (14)	9.2 (8.3–10)
QAAT	S1	Asymptomatic (14)	22 (20–24)
		Symptomatic (14)	23 (21–25)
	S2	Asymptomatic (14)	21 (19–23)
		Symptomatic (13)	21 (19–24)
TELOS	S1	Asymptomatic (14)	1.8 (0.7–2.9)
	S2	Symptomatic (13)	1.7 (0.4–2.9)

[a] *N* presents the number of subjects without protocol violations, available for calculation of the intra observer values
[b] No differences were found to be statistically significant

subtalar joint [8]. Thickness of the soft-tissue envelope covering the heel differs between individuals and consequently the amount to which the envelope is compressed during the test differs between individuals. There is also the possibility that the higher values result from a too great magnitude of applied force (in comparison the load applied with the DAAT is much lower) [12, 19]. Hence, probably several factors contribute to the extent of the laxity values as measured with the QAAT. An in-vitro study evaluating the 3D bone kinematics in ankle joint laxity testing with the QAAT will provide more information on the extent of the measured values.

In the present study, fair correlations were described between DAAT and QAAT for the first couple of observers. However, no correlations between neither DAAT and the TELOS and the manual test, nor QAAT and the TELOS and the manual test were found. Consequently, DAAT nor QAAT could be validated in the present study through a comparison with TELOS stress test or the manual anterior drawer test. The absence of a validation hampers interpretation of the ankle joint laxity values and laxity differences between symptomatic-asymtomatic joints. Although mean displacements values of symptomatic ankle joints appear to be higher

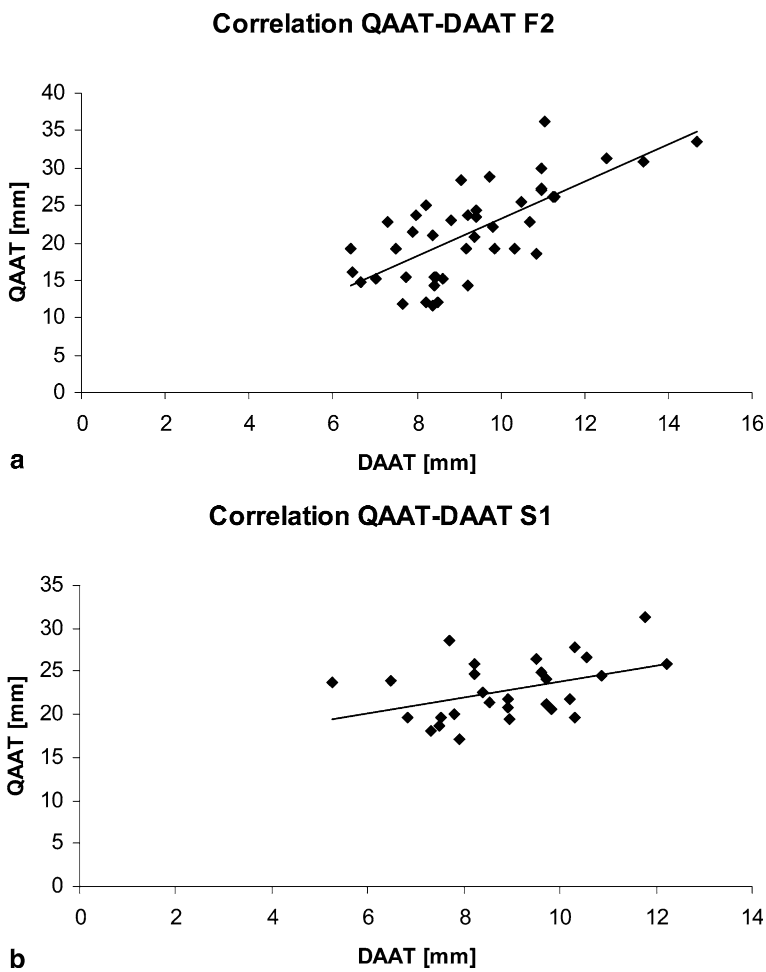

Fig. 3 a, b Correlation (as analysed with Spearman's Rank Correlation) between quasi static anterior ankle tester (QAAT) and dynamic anterior ankle tester (DAAT) illustrated in scatter diagrams. Absolute displacement values of 48 ankles and 28 ankles are presented as measured with QAAT and DAAT by one observer of the first and second couple respectively than of asymptomatic ankles, none of these measured symptomatic-asymptomatic differences were statistically significant as opposed to the measurements with the manual anterior drawer test. The TELOS test also failed to measure statistically significant laxity differences between ankles in the present study. Other studies found a correlation between functional instability complaints and increased laxity using TELOS stress radiographs [9, 10]. The reason for this difference could be that the DAAT and the QAAT were not yet sensitive enough. However, the complaints of functional ankle joint instability in the population of the present study could also be provoked by factors other than solely lateral ankle ligament laxity. Several factors are known to contribute to joint (in)stability: congruence of the articulating surfaces, load on the joint, mechanical properties of capsules and muscles, reflex activity in the muscles around the joint and the effect of proprioceptive information from the joint and joint surrounding tissues on reflex muscle activity [6, 18, 22].

It is an obvious fact, that even with a reliable instrumented test, interpretation of absolute ankle joint laxity values forms a difficult entity. As is stated in previous studies [2, 13, 19], laxity values differ greatly between individuals and between left and right ankles, seemingly not influenced by the presence or absence of functional ankle joint instability i.e. complaints of giving way. The absolute value of laxity can be questioned as a diagnostic tool. Consequently, an objective ankle joint laxity tester could be more important as a tool for individual or group wise comparisons of laxity values at different moments in time, rather than a tool for determination of individual or mean population laxity values. An objective tester could, for example, be used to monitor ankle joint laxity before and after surgical ankle ligament reconstruction. In such a setting, the laxity value can be used as an outcome measure that facilitates comparisons between different studies and/or treatments.

Future research should primarily focus on options to assess the validity of both testers. One option to evaluate the validity of laxity measurements with DAAT and QAAT could be simultaneous registrations, using Roentgen stereometric analysis [3]. An alternative could be to incorporate the testers in the diagnostic process of acute lateral ankle ligament ruptures and to compare their outcome with arthrography and/or delayed physical examination, both considered gold standards in diagnosis of an acute lateral ankle ligament injury [14, 20].

Conclusions

As a result of this study, it is observed that the reliability of both testers is good, but no definite conclusion can be drawn with regard to the validity of both testers.

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