

Validation of a Novel Digital Goniometer as a Range of Motion Assessment Tool for The Lower Extremity

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Abstract

Background: Range of Motion (ROM) assessments of the lower extremity are an important measurement tool for assessing an individual's joint health and affects their ability to complete activities of daily living. Lower extremity ROM has been identified as a useful predictor for lower limb injuries in both the general population and sporting professionals. The advent of novel ROM assessment technology, such as the HALO[®] (model HG1, HALO[®] Medical Devices, Australia) Digital Goniometer (HDG), presents an avenue for research and potential application within clinical and surgical settings.

The aim of the present study was to validate the HDG in terms of its validity, intra- and inter-rater reliability, for ROM assessment of the lower limb.

Methods: The Universal Goniometer (UG) and the HDG were used as the acquisition system. The methodology for lower limb ROM assessment was carried out per the American Association of Orthopedic Surgeons (AAOS) guidelines. One hundred healthy subjects were recruited for the study and were split into two groups to be assessed by either physiotherapists or medical students.

Results: There were high levels of agreement between the two devices with most motions having a mean difference < 2°. Intra-rater reliability was modest for all ranges of motion using the UG and for the HDG, with values between 0.368 and 0.663. In the physiotherapist cohort, inter-rater reliability was highest for hip flexion for both the UG and the HDG, with modest reliability at ICC values of 0.709 and 0.711, respectively. Reliability was poorest for ankle dorsiflexion for both devices, with ICCs of 0.409 and 0.436. In the medical student cohort, inter-rater reliability for all ROM was modest or good for the UG, ranging from 0.410 to 0.865 except for ankle dorsiflexion, which was poor with an ICC of 0.330. Inter-rater reliability was either modest or good for the HDG, with values between 0.468 and 0.889.

Conclusions: The present validation study identified the HALO Digital Goniometer as a valid and reliable substitute for the universal goniometer, with moderate to high inter-rater agreement and consistency, along with moderate intra-rater reliability.

Introduction

Range of Motion (ROM) assessments of the lower extremity provide a means to evaluate an individual's joint health which relates to their ability to complete activities of daily living [1,2]. Lower extremity ROM has also been identified as a useful predictor for lower limb injuries in both the general population and sporting professionals [3]. Additionally, lower extremity ROM has been shown to be a major factor that influences patient satisfaction

following lower extremity surgery [4]. Hence, accurate and reliable ROM assessment is required to allow surgeons to identify individuals at an increased risk of lower extremity injuries as well as chart the progress of patients post-operatively. This assessment has traditionally been conducted with the use of the universal goniometer, which has shown to have highly variable accuracy and reliability [5-10]. The HALO[®] (model HG1, HALO[®] Medical Devices, Australia) Digital Goniometer provides clinicians with

the ability to quickly and objectively assess an individual's lower extremity ROM. The present study aimed to assess the validity, intra- and inter-rater of the HALO® Digital Goniometer (HDG) for range of motion assessment of the lower extremity.

Materials and Methods

Ethics Approval, Inclusion and Exclusion Criteria

This study was approved by the Local Health District Ethics Committee. One hundred healthy subjects were recruited and were included in the study after obtaining written informed consent. To be eligible for the study, participants must have been over the age of 18, and have had no pain in the right lower extremity. Subjects were also excluded if they had any recent trauma (in the 6 months prior to assessment) or had any previous surgical management of injuries in the right lower extremity.

Acquisition systems – The Universal Goniometer and HALO Digital Goniometer

The Universal Goniometer is an instrument that measures joint range of motion around a central axis of rotation in one degree increments (Figure 1 bottom). A stationary arm provides a reference point for another motion arm that follows the joint or limb of being assessed. The HDG is a range of motion assessment tool which employs a laser-guided inclinometer system in place of the traditional stationary and motion arms of the universal goniometer (Figure 1 top).

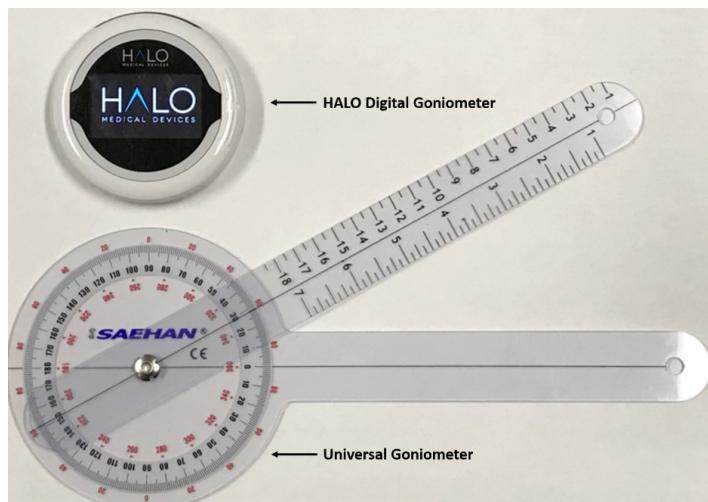


Figure 1: The HALO Digital Goniometer (top) and Universal Goniometer (bottom).

Raters

Out of the 100 recruited subjects, 50 were assessed by PB and LN, who were both registered physiotherapists with 10 years and 3 years of clinical experience, respectively. Prior to the commencement of this study, PB had 15 hours of experience using the HDG, while LN had a 1-hour training session to familiarize herself with the HDG. The other 50 subjects were assessed by SM and AWS, who were both 4th year medical students. Prior to the

commencement of this study, both SM and AWS had 10 hours of experience with the UG and the HDG to orientate themselves with the two devices. Each rater was responsible for placement of the UG or HDG, providing verbal instructions to commence each motion and obtaining a final reading from the device. The raters would then verbally announce the measurement to an independent observer who would record each of the measurements.

Range of Motion Assessment Protocol - Lower Extremity

All ROM were carried out in accordance with the American Association of Orthopedic Surgeons (AAOS) guidelines, which have been detailed and validated extensively [11]. Anatomical landmarks were not marked for any measurement to allow for reproducibility of the protocol in a clinical setting. A brief protocol is presented here. Subjects were asked to carry out Hip Flexion (HF) and Abduction (HA), Knee Flexion (KF) and Ankle Dorsiflexion (AD) and Plantarflexion (AP). The subject was required to lie in a supine position with a single pillow supporting their head. For measurements of ankle dorsiflexion and plantarflexion, a second pillow was placed under the subject's calf muscles to raise the ankle joint off the floor. From this position, the subjects were asked to bring their knee to their chest (hip flexion), take their right leg as far out to the right as possible (hip abduction), bring their heel to their glutes (knee flexion), point their toes to the sky (ankle dorsiflexion) and point their toes to the ground (ankle plantarflexion). When measuring hip flexion, the goniometers were placed on the greater trochanter of the femur with the stationary arm aligned with the mid-axillary line, and the moving arm tracking the motion of the lateral epicondyle of the femur. For hip abduction, the axis of the goniometer was placed on the ASIS of the right lower extremity with the stationary arm being aligned with the left ASIS and the moving arm lining up with the patella. For knee flexion, the goniometer axis was placed on the lateral epicondyle of the femur, with the stationary arm being aligned with the greater trochanter and the moving arm with lateral malleolus. For ankle dorsiflexion and plantarflexion, the goniometer axis was aligned with the lateral base of the heel, with the stationary arm aligned with the base of the 5th metatarsal prior to the commencement of the movement and the moving arm aligned with the same landmark at the conclusion of the movement. After the subject was allowed a single practice movement to ensure their understanding of the procedure, each ROM was repeated three times with each goniometer. During this procedure, if there was any movement that produced angles that were considered highly implausible, the movement was repeated, and that initial data was excluded.

Data analysis

Data from each subject was coded to prevent identification of any individual. The goniometer data was collected and stored on a Google Sheets application which was password-protected. The averages of the three trials for each goniometer was derived and imported into IBM SPSS Statistics 25 for statistical analysis.

Statistical analysis

Sample size calculation was based on the results of a

previous study. A study validating a novel goniometric device to assess passive hip ROM showed that a minimum sample size of $n = 50$ is required to detect an effect size of 0.1 with a type 1 error rate (α) = 0.05% and power ($1 - \beta$) = 0.8 [12]. A recently published study evaluating the validity and reliability of the HALO[®] when measuring active shoulder ROM, quoted that a sample size of $n = 42$ is required to establish statistical significance [13].

All data analysis was performed using IBM SPSS Statistics 25 for Windows (IBM Corporation, Armonk, NY, USA). The concurrent validity of the HALO[®] was established using a paired samples t-test to determine if the differences in the means obtained by the two different devices assessing a single motion were statistically significant. This was further analyzed through Bland-Altman plots to visualize whether the two devices produced comparable results. The 95% Limits of Agreements (LOA) were calculated from these plots to determine the level of agreement between the two devices. Intra-rater reliability was evaluated using a two-way mixed effects absolute agreement Intra class Correlation Coefficient model for single measures ($ICC_{3,1}$) [14,15]. Inter-rater reliability was determined using a two-way random effects absolute agreement Intraclass Correlation Coefficient model for single measures ($ICC_{2,1}$) [14,15]. For both intra-rater and inter-rater reliability, ICC values greater than 0.90 were considered as excellent reliability, ICCs between 0.75 and 0.90 were considered as good reliability, those between 0.40 and 0.75 as modest reliability and those less than 0.40 as poor reliability. [15] The standard error of measurement (SEM) was calculated for both intra-rater and inter-rater reliability using the following formula:

$SEM = SD \times \sqrt{1 - ICC}$. Using this, the minimum detectable change at the 90% confidence interval (MDC_{90}) was calculated using the following formula: $MDC_{90} = 1.65 \times SEM \times \sqrt{2}$.

Results

A total of 50 right lower limbs (50 subjects: 41 males, 9 females with a mean age of 20.3 ± 1.4 years) were assessed by physiotherapists PB and LN. Another 50 right lower limbs (50 subjects: 26 males, 24 females, with a mean age of 20 ± 1.1 years) were assessed by medical students, SM and AWS, with these reassessed by AWS at a mean follow-up time of 31.3 days. A total of 9 measurements of hip abduction were required to be reassessed based on our protocol as the HDG recorded angles of $<10^\circ$, when it was obvious to the rater that the angle was significantly greater.

Concurrent Validity

Table 1 shows the mean differences between values obtained by the UG and HDG for each motion by each rater. This shows that the agreement between the devices is very high with most motions

have a mean difference of $<2^\circ$. Figure 2-5 also show examples of the Bland-Altman plots that were constructed for each motion and rater to determine the 95% LOA, through which it was concluded that there is a high level of agreement between the two devices.

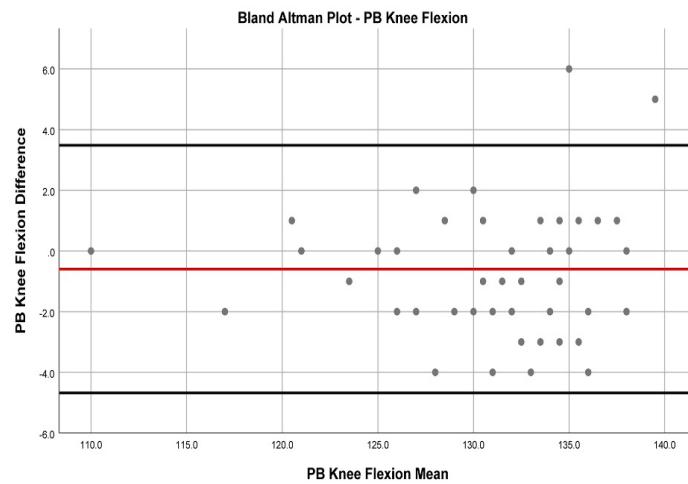


Figure 2: PB Bland Altman Plot, Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements.

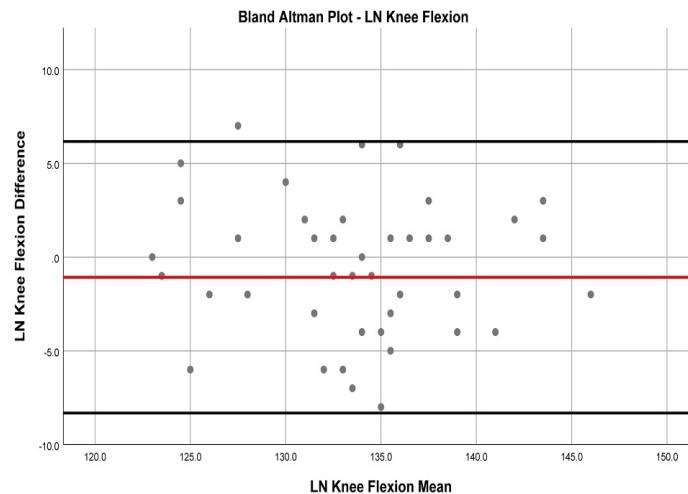


Figure 3: LN Bland Altman Plot. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements.

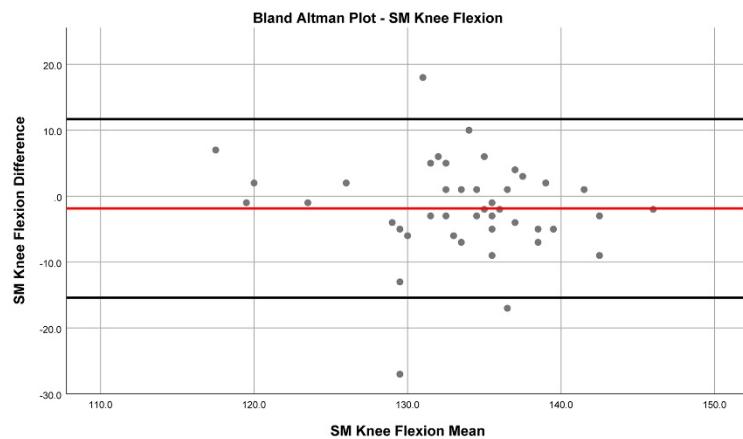


Figure 4: SM Bland Altman Plot. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements.

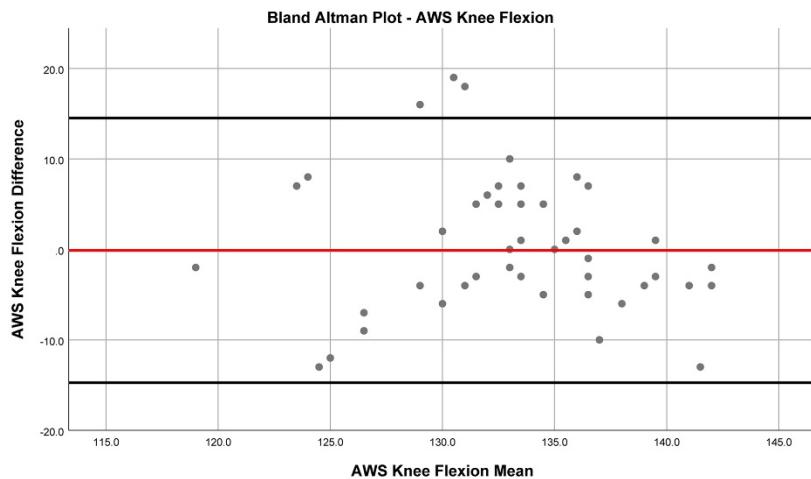


Figure 5: AWS Bland Altman Plot. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements.

Motion	Mean Difference			
	PB	LN	SM	AWS
Hip Flexion	0.040	-0.680	-2.184*	-1.673
Hip Abduction	1.271	-3.708*	-1.720*	-0.560
Knee Flexion	-0.600*	-1.080*	-1.854	-0.104
Ankle Dorsiflexion	-0.400*	-3.420*	-0.840*	0.060
Ankle Plantarflexion	-0.440	5.960*	1.120	1.000

*indicates statistical significance ($p < 0.05$)

Table 1: Mean Differences between devices.

Intra-Rater Reliability

Intra-rater reliability was consistently higher with the use of the HDG for all ROMs, with the exception of hip flexion. All ICC values fell between 0.368 and 0.663 (Table 2).

Motion	UG		HALO [®]	
	ICC _{2,1}	95% CI	ICC _{2,1}	95% CI
Hip Flexion	0.663	0.345-0.828	0.465	-0.047-0.728
Hip Abduction	0.518	0.032-0.758	0.585	0.171-0.791
Knee Flexion	0.514	0.024-0.756	0.569	0.170-0.779
Ankle Dorsiflexion	0.000	-0.126-0.451	0.368	-0.276-0.684
Ankle Plantarflexion	0.459	-0.088-0.729	0.629	0.281-0.810

Table 2: Intra-Rater ICC.

Inter-Rater Reliability

Analysis of inter-rater reliability between the two physiotherapist PB and LN revealed modest reliability ($0.40 \leq \text{ICC} < 0.75$) for both the UG and HDG for all motions except hip abduction with the UG, which had poor inter-rater reliability. The results of this analysis are presented in Table 3. For all motions except for knee flexion, the HDG showed a marginally higher ICC than the UDG when assessments were completed by PB and LN. When assessments were completed by SM and AWS, the inter-rater reliability was consistently higher with the HDG across all motions with some motions (hip flexion, hip abduction, ankle plantarflexion) having ICCs in the good range ($0.75 \leq \text{ICC} < 0.90$). These results are shown in Table 4. The inter-rater reliability for all motions when assessed by the HDG was higher when comparing assessments made by two medical students with the same amount of experience with the device than two physiotherapists with a different amount of experience with the device. Table 5 and 6 present the SEM and MDC values for the inter-rater reliability analysis. For assessments completed by the physiotherapist, the MDC was higher with the HDG than UG for all motions except ankle plantarflexion, while for the medical students, the MDC was lower with the HDG for all motions.

Motion	UG		HALO [®]	
	ICC _{2,1}	95% CI	ICC _{2,1}	95% CI
Hip Flexion	0.709	0.519-0.829	0.711	0.542-0.824
Hip Abduction	0.225	-0.096-0.528	0.430	0.117-0.643
Knee Flexion	0.663	0.401-0.783	0.545	0.278-0.725
Ankle Dorsiflexion	0.409	0.066-0.646	0.436	0.188-0.633
Ankle Plantarflexion	0.430	0.182-0.639	0.503	0.244-0.690

Table 3: Inter-Rater ICC: Physiotherapists.

Motion	UG		HALO [®]	
	ICC _{2,1}	95% CI	ICC _{2,1}	95% CI
Hip Flexion	0.865	0.764-0.924	0.889	0.805-0.937
Hip Abduction	0.661	0.470-0.793	0.773	0.634-0.865
Knee Flexion	0.410	0.144-0.621	0.657	0.462-0.791
Ankle Dorsiflexion	0.330	0.068-0.552	0.468	0.220-0.659
Ankle Plantarflexion	0.701	0.528-0.818	0.794	0.665-0.878

Table 4: Inter Rater ICC: Medical Students.

Motion	UG		HALO [®]	
	SEM (°)	MDC ₉₀ (°)	SEM (°)	MDC ₉₀ (°)
Hip Flexion	3.2	7.4	3.6	8.4
Hip Abduction	5.6	13.0	5.9	13.8
Knee Flexion	2.8	6.5	3.4	8.0
Ankle Dorsiflexion	2.1	4.9	2.7	6.3
Ankle Plantarflexion	7.3	17.1	5.6	13.0

Table 5: Inter-Rater SEM and MDC: Physiotherapists.

Motion	UG		HALO [®]	
	SEM (°)	MDC ₉₀ (°)	SEM (°)	MDC ₉₀ (°)
Hip Flexion	3.4	7.9	2.8	6.5
Hip Abduction	4.7	11.0	3.0	7.0
Knee Flexion	5.2	12.1	3.3	7.7
Ankle Dorsiflexion	4.2	9.8	2.8	6.6
Ankle Plantarflexion	5.7	13.4	3.7	8.5

Table 6: Inter Rater SEM and MDC: Medical Students.

Discussion

Validity and reliability of the HALO Digital Goniometer

This study has shown that the HDG has a high degree of agreement with the UG. Prior research on the UG has shown that it is a valid device to assess joint ROM as the ranges obtained from assessment with the UG closely correlated with values calculated from radiographs which detail exact joint position [16-19]. As such, we can infer that measurements taken by the HDG accurately reflect joint position, however, it would be ideal for us to confirm this through further research comparing the HDG to radiographs. A previous study examined the accuracy of the HDG as a goniometer by attaching the device to a 6-axis robot. When comparing the values obtained by the HDG to those obtained by the robot, the HDG was always accurate to $\pm 1^\circ$ in all three ranges of motion [20].

By analyzing the agreement between the UG and HDG for each of the various raters in this study, it was clear that with increased experience and familiarity with the use of the two devices, it is possible to reduce the mean difference between the two devices $< 2^\circ$. This is an exceptionally high level of agreement between the devices given that the UG is marked in 1° increments and the HALO[®] provides an angle measurement to a precision of 1° . Further, our study found that the HDG was comparable to the UG in terms of its intra-rater reliability and in most ROMs exceeded its capability.

With regards to the inter-rater reliability of the two devices, the HDG largely produced a higher reliability than the UG. This was most pronounced when considering the assessments conducted by the two medical students, suggesting that the HDG might be the most clinically useful tool for ROM assessments for individuals with little to no prior experience of goniometry. Absolute measures of reliability were also determined as if there is little variation among subjects, as could be the case in the measurement of joint ROM in healthy individuals, the ICC value may suggest poor reliability, though there may be little difference between the measurements [21]. This was particularly important for the assessment of ankle dorsiflexion where the normal range is between 0° and 16.5° and most healthy individuals have a ROM between 10° and 16.5° [22].

To our knowledge, there is only a single published study regarding the HDG and its validity and reliability when assessing ROM of the lower extremity. However, this study only examined the knee joint of three healthy subjects. The results showed an ICC value of 0.999 for inter-rater reliability and an ICC value of 0.994 for intra-rater reliability both of which were obtained through a two-way random effects model, but it is unclear whether the single or average measures model was chosen [23]. It is equally valid to use $ICC_{3,1}$ or $ICC_{2,1}$ to assess inter-rater reliability, however, $ICC_{2,1}$ allows the generalization of our results to a larger sample of raters with similar characteristics, including years of clinical experience, whereas, $ICC_{3,1}$ does not. Hence the mixed effects

model ($ICC_{3,1}$) is traditionally used for intra-rater reliability. Using an average measures model, however, is not appropriate for studies of goniometry. In a clinical setting when assessing joint ROM, we will only use the measurements from a single rater as the basis of assessment and not the average of two separate raters, and hence the single rater type model of ICC should be used for analysis [15]. As such, it is difficult to accept the results of this study due to the unclear nature of the analysis conducted [15].

Limitations

Previous validation studies for novel technologies used to assess joint ROM have experienced various limitations. Repeated trials of the same motion are inherently variable as subject fatigue and overcompensation can alter these measurements [12,24]. Previous research has shown that with repeated measurements, the ROM of joints tends to increase due to improved elasticity of the surrounding tissue [21]. These limitations were addressed to some extent by asking the participants to perform a single trial motion which was not measured before assessments were commenced. Also, several values obtained by the HALO[®] appeared implausible to the two raters as assessments were being completed and as such these measurements were repeated with the invalid data being excluded from data analysis. This error was likely due to inadequate calibration of the device, or motion of the device out of the horizontal plane of motion, an issue also noted in prior studies on the HALO[®] [13]. However, this could introduce the potential of a selection bias to the data obtained. As this study was conducted on a convenience sample of healthy participants, the results may not be successfully generalized to a clinical setting where patients present with restricted joint ROM. However, the protocol that was used for testing should be easily transferable to a clinical setting with a pathological cohort and such a study has been proposed.

Due to the large volume of measurements that were required to be taken of each participant (204 ROM measurements), it was not feasible to use the same method as Correll et al. and cover the display of the HALO[®] and UG so that the rater would be truly blinded to their readings with the device [13]. The other reason why blinding in this fashion would not be advisable is that the HALO[®] required 2-3 seconds to settle on a specific reading, and thus by blinding the rater we would not be able to ensure that the reading had settled, and an accurate reading was obtained. However, the large volume of measurements itself ensured that the rater was blinded as it would highly unlikely for the rater to remember the values obtained with one device when assessing the same motion 7-15 minutes later with the second device.

Conclusion

The present validation study identified the HALO Digital Goniometer as a valid and reliable substitute for the universal goniometer in the setting of lower limb range of motion assessment, with moderate to high inter-rater agreement and consistency, along with moderate intra-rater reliability.

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