Lumbar Range of Motion Assessment using HALO Goniometer versus Double Inclinometer: A Reliability and Validation Study

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Abbreviated title: Validation and reliability of HALO digital goniometer

KEYWORDS

assessment, evaluation, double inclinometer, lumbar spine, range of motion, tools, validation, HALO digital goniometer, reliability

ABSTRACT

Background: Accurate evaluation of lumbar spine range of motion (ROM) is crucial in clinical settings such as rehabilitation and orthopedic care. The traditional double inclinometer, while effective, has limitations related to time, variability, and positioning. The HALO digital goniometer offers a promising alternative with faster and more accurate measurements.
Objective: This study aims to compare the intra-rater reliability and concurrent validity of the HALO digital goniometer against the double inclinometer in assessing lumbar spine ROM.
Methods: A total of 64 participants aged 18-75 with low back pain were assessed using both devices. Lumbar flexion, extension, lateral flexion, and rotation were measured across three sessions. The consistency of measurements by the same evaluator was assessed using a statistical measure of reliability, while the agreement between the two devices was examined through correlation analysis to establish concurrent validity.
Results: The HALO goniometer showed excellent intra-rater reliability with ICC values ranging from 0.95 to 0.99. Strong positive correlations (r = 0.94 - 0.98) were also observed between the HALO goniometer and the double inclinometer for all ROM measurements.
Conclusion: The HALO digital goniometer is a valid and reliable tool for measuring lumbar spine ROM, offering a practical alternative to the traditional double inclinometer in clinical practice.

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BACKGROUND

Accurate evaluation of the lumbar spine's range of motion (ROM) is essential in various clinical settings, particularly in rehabilitation, and orthopedic practice.[1,2] The lumbar spine is a critical component of the musculoskeletal system, and its mobility is essential for daily activities and overall quality of life.[3,4] Conditions such as non-specific lower back pain, herniated discs, and post-surgical recovery necessitate precise evaluation of spinal mobility.[5] Range of motion (ROM) has been found to be a good measure of impairment due to back pain.[6] These range of motion evaluations gives clarity to make inform treatment decisions and monitor progress. Traditionally, the double inclinometer has been the standard tool for measuring lumbar spine ROM.[7] While it has been widely used and validated, this method holds its limitations. The double inclinometer can be time-consuming, laborious requires specific positioning, and may lead to variability in measurements due to the skill level of the clinicians.[1] Additionally, inter-rater reliability can be a concern, as different practitioners may obtain varying results when using this method.[8] These challenges highlight the need for more efficient and reliable tools for assessing lumbar spine mobility. In response to these limitations, the HALO digital goniometer has emerged as a promising alternative. This modern device offers several advantages, including enhanced accuracy, rapid measurement capabilities, and ease of use. The HALO goniometer allows clinicians to capture ROM in three planes within seconds, significantly reducing the time spent on assessments. [9-11] Moreover, its single-handed operation facilitates better patient stabilization during measurement, potentially leading to more consistent results. Despite these advantages, the adoption of the HALO digital goniometer in clinical practice requires thorough evaluation of its reliability and validity compared to traditional methods.[12] Establishing the intra-rater reliability and concurrent validity of the HALO device is essential to ensure that it can serve as a dependable tool for clinicians. This study aims to address this critical need by assessing the reliability and validity of the HALO digital goniometer in measuring lumbar spine ROM, comparing it to the established double inclinometer method. By providing empirical evidence on the performance of the HALO goniometer, this research seeks to contribute to the ongoing evolution of assessment tools in musculoskeletal care.

MATERIALS AND METHODS

Ethical approval

The study was carried out in compliance with the 2013 revision of the Declaration of Helsinki. and approval was granted by Columbia Institutional Ethical Committee (letter no CCP/Ethical/Comm/08/2023-24 for this study.

Subjects

This study was a cross-sectional based study initiated among Low Back Pain subjects who had come to Columbia Clinic, Bangalore. We conducted this study from August 2023 to April 2024 for 9 months. A total of 64 subjects participated in this study. Sample size was calculated using G*power, software with the following input parameters-*effect size: 1.732 (for expecting ICC 0.75) power:0.80, significance level:0.05, No of groups:1, No of measurements:3)*. Subjects who complained of low back pain (defined as pain on the posterior aspect of the trunk from the lower edge of the 12th ribs to the lower gluteal folds, with or without pain referred to one or both lower extremities, lasting 0–3 months) and who were between the ages of 18 and 75 were eligible. Chronic low back discomfort (lasting longer than three months), significant spinal or other pathologies, spinal operations, cancers, systemic disorders, and/or any other neurological or motor impairments were excluded, as was the use of muscle relaxants or other medications that affected muscle elasticity during the previous 24 hours.

Using the previously indicated criteria, no subjects were disqualified. Non - probability convenience sampling strategy was used for recruiting subjects. Subjects coming to Columbia clinic were screened and a total of 64 subjects were selected based on eligibility criteria.

Included subjects were informed about the study, and an informed consent was taken in the language best understood by them. The subject or the caregiver was instructed to go through the consent form and clarify doubts, if any, before evaluation. After reading the consent form, the subject/caregiver can choose not to participate in the study, if he/she does not align with the procedure. Written consent was obtained from the patient/caregiver after an explanation of the procedure. All those who provided consent, were enrolled in the study. All those who Demographics and background information was obtained of all subjects; this included age, injury history, mechanism, duration, pain score using Numerical pain rating scale and current medications.

Rater/ evaluator

One registered physiotherapist who has eight years of clinical expertise in the evaluation and treatment of orthopedic disorders served as the assessor/evaluator for this study. Data collection commenced in October 2023 and ended in April 2024 and was conducted in Columbia Physiotherapy Clinic of Columbia College of Physiotherapy, Bengaluru.

To make sure blinding happened for every measurement, the primary investigator recorded while the evaluator completed each one.

Equipment

Inclinometer

For all range of motion measurements, a standard gravity-dependent inclinometer (Universal Inclinometer, Medilab, India) was utilized (Figure 1). With a bubble level, a vertical reference was created to guarantee that the inclinometer was set to an exact zero starting position. Then, this reference point was employed in all of the tests.

Figure 1: Universal Inclinometer

HALO Digital Goniometer

All of the lumbar joint range of motion measurements in this study were performed using the HALO (model HG1, HALO Medical Devices, Texon) Digital Goniometer equipment (Figure 2). With this device, vertical is zero in a "vertical zero mode."

Figure 2: HALO Digital Goniometer

ROM assessment procedure-lumbar spine

Prior to collecting data, the evaluator had an eight-hour formal training session and practice trials with a physiotherapist specialised in musculoskeletal and sports sciences to make sure proper measuring techniques were followed. Under the supervision of the assessors, subjects followed verbal directions and completed the necessary movement three times. This process was the same for every test.

Active lumbar flexion, extension, right lateral flexion, left lateral flexion, right lumbar rotation and left lumbar rotation was assessed by two devices: (1) an inclinometer; and (2) HALO© Digital Goniometer. After positioning the patient and giving the movement instructions, the evaluator read the joint range of motion a and values were recorded by the principal investigator using a recorder. The HALO was operated in "vertical zero mode" during the whole testing process. After every movement change, the gravity-dependent inclinometer was recalibrated. Supplementary material contains information on the test positions, manual stabilization, and device positioning.

Each subject presented on three sessions on the three consecutive days for testing. During this period, the subjects were asked not to stretch, exercise, or take any drugs.

Data analysis

Data was recorded in Record Form (RF) and later was entered into excel sheet for analysis. Data from each subject was coded to prevent identification of any subject. The averages of the three trials for each equipment was derived and imported into IBM SPSS Statistics 27 for statistical analysis. Calculations were made for descriptive statistics such means and standard deviations. The intra rater reliability was ascertained using the Intra Class Correlation Coefficient (ICC).

Pearson (r) correlation coefficient was calculated to determine concurrent validity of HALO digital goniometer by comparing to double inclinometer. The degree of correlation between two measurements can be found using the r values.

Bland-Altman graph was plotted to provide visual representation of correlation between double inclinometer and HALO digital goniometer in measuring lumbar ranges of motion. By creating limits of agreement, Bland-Altman provides a technique for quantifying agreement between two quantitative measurements.

RESULTS

This study comprised of sixty-four subjects. There were 28 females and 36 males with the mean age(years) 41.3 ± 12 (Mean±SD), BMI (kg/m^2) 23.00 ± 2.46 (Mean±SD) and NPRS score 5.10

±1.61(Mean±SD). Demographics of subjects are presented in table 1. The Intraclass Correlation Coefficient (ICC) for reliability was calculated using a two-way random effect model with a 95% confidence interval. Inferential statistics of intra rater reliability of lumbar ranges of motion using HALO digital goniometer are presented in table 2. Excellent intra rater reliability was found with all measurements ranging from ICC = 0.95-0.99 for HALO digital goniometer.

Table 1: Demographic characteristics of participants

Demographics (n= 64 participants)	
Characteristics	Mean (SD)
Age(years)	41.3 (12)
Weight(kgs)	58.54 (5.46)
Height(meters)	1.54 (0.06)
BMI (kg/m^2)	23.00 (2.46)
NPRS pain (/10)	5.10 (1.61)

*(*SD – Standard Deviation)*

Table 2: Inferential statistics of intra rater reliability of lumbar ranges of motion using HALO digital goniometer

Movements	**Session I Mean angle˚(SD)**	**Session II Mean angle˚(SD)**	**Session III Mean angle˚(SD)**	**ICC (3,1)**
Lumbar Flexion	50.09 (7.33)	49.96 (7.14)	50.15 (7.26)	0.99
Lumbar Extension	22.60 (5.20)	22.56 (5.13)	22.66 (5.14)	0.99
Right Lateral Flexion	14.96 (2.84)	14.92 (2.82)	14.96 (2.91)	0.98
Left Lateral Flexion	15.43 (2.74)	15.07 (2.69)	15.05 (2.71)	0.95

Right Lumbar Rotation	14.50 (4.44)	14.47 (4.33)	14.66 (4.41)	0.99
Left Lumbar Rotation	14.88 (4.63)	14.45 (4.27)	14.50 (4.37)	0.98

(ICC – Intraclass Correlation Coefficient *SD – Standard Deviation)*

Table 4: Pearson's correlation coefficient between HALO Digital Goniometer and Double inclinometer

Lumbar range of motion	**Correlation coefficient (r)**	**P value**
Lumbar Flexion	0.97	0.001
Lumbar Extension	0.98	0.001
Right Lateral Flexion	0.94	0.001
Left Lateral Flexion	0.96	0.001
Right Lumbar Rotation	0.98	0.001
Left Lumbar Rotation	0.98	0.001

Pearson's correlation coefficient was calculated to check concurrent validity between HDG and DI for lumbar ROM. The correlation between ROM of lumbar spine measured by HALO digital goniometer and double inclinometer showed strong positive correlation across various motions of lumbar spine (refer Table 4). Bland-Altman graph was plotted as a visual representation of correlation between HALO digital goniometer and double inclinometer measuring lumbar ranges of motion are presented in figure 3, 4 & 5.

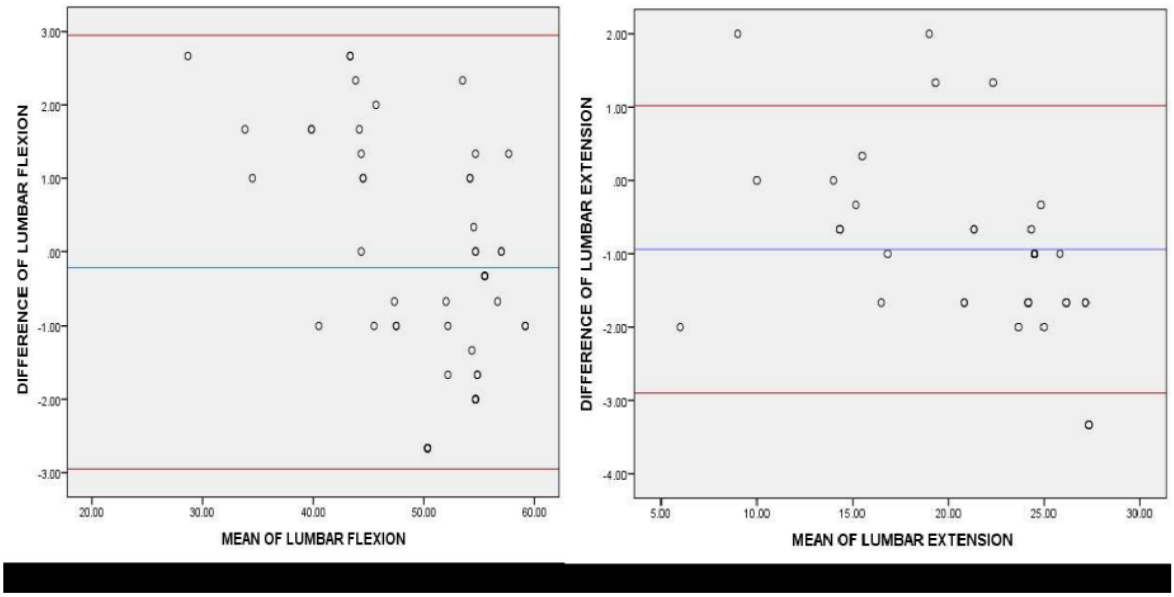

Figure 3: **Bland-Altman plots,** Central blue line indicates the mean difference. Red lines indicate limits of agreement (Mean difference ± 1.96 SD).
(Left Plot): The Bland-Altman plot for lumbar flexion.
(Right Plot): The Bland-Altman plot for lumbar extension.

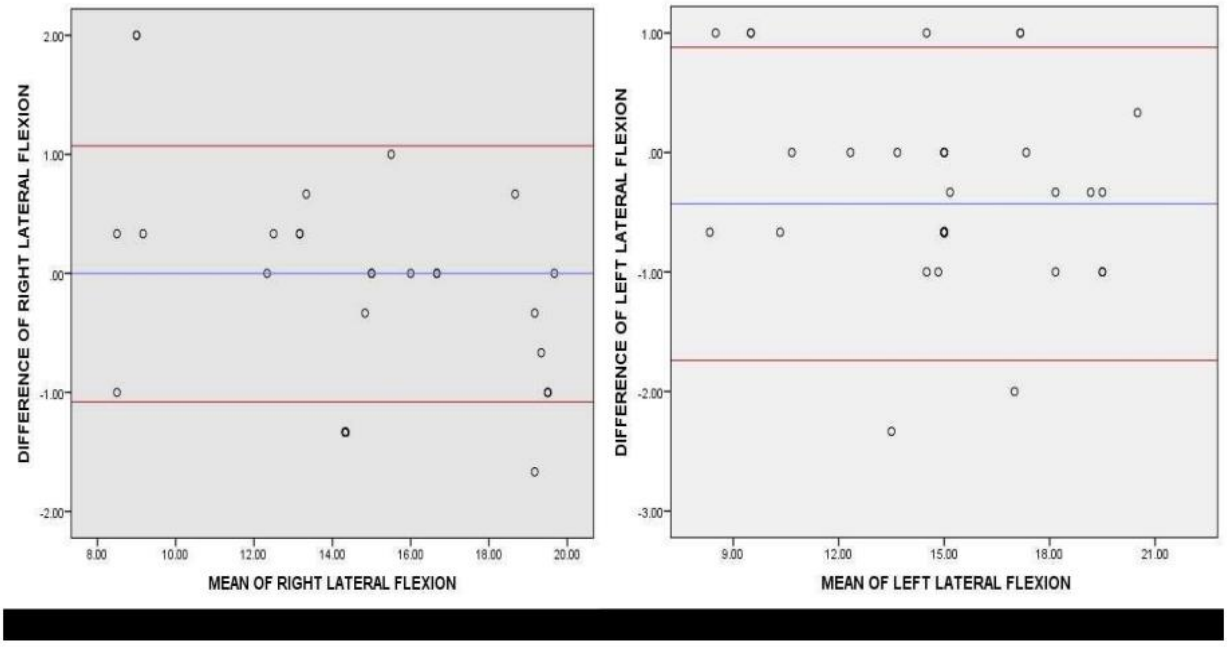

Figure 4: **Bland-Altman plots,** Mean difference is shown by the central blue line; limits of agreement are shown by red lines (Mean difference ± 1.96 SD).
(Left Plot): The Bland-Altman plot for right lumbar lateral flexion.
(Right Plot): The Bland-Altman plot for left lumbar lateral flexion.

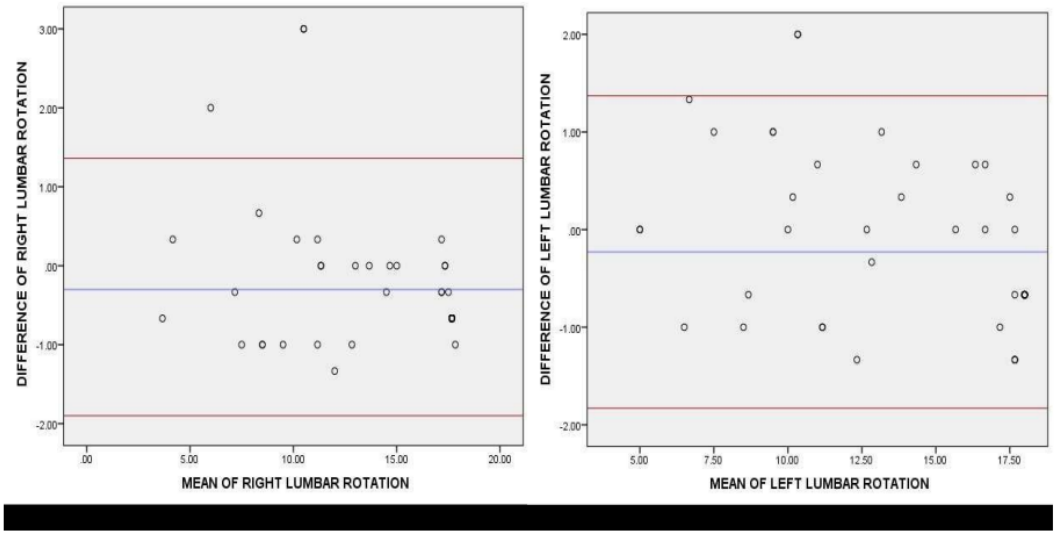

Figure 5: **Bland-Altman plots,** Mean difference is shown by the central blue line; limits of agreement are shown by red lines (Mean difference ± 1.96 SD).
(Left Plot): The Bland-Altman plot for right lumbar rotation.
(Right Plot): The Bland-Altman plot for left lumbar rotation.

DISCUSSION

This study's findings revealed strong intra-rater reliability of the HDG, with Intraclass Correlation Coefficients (ICCs) ranging from 0.95 to 0.99 across various motions, showing a high level of consistency in measures obtained by the same evaluator throughout multiple sessions. The high ICC values found in the study are comparable to previous studies that validated the HDG for shoulder and knee joint ROM assessments with ICCs reaching 0.90.[9,11,12]

The study also demonstrated strong concurrent validity of the HALO Digital Goniometer (HDG) when compared to the gold standard double inclinometer (DI), with Pearson correlation coefficients (r values) ranging from 0.94 to 0.98 across lumbar flexion, extension, lateral flexion, and rotation movements. These findings are consistent with similar studies that have compared new digital ROM assessment tools against established methods, further strengthening the case for the HDG as a reliable alternative to traditional tools. A study by Wilson-Smith et al validated the HDG for assessing cervical spine ROM, reporting similar Pearson correlation coefficients between the HDG and traditional methods, with values reaching as high as 0.98, particularly for cervical flexion and extension.[10] The consistency between this study and the current research on lumbar spine ROM suggests that the HDG performs consistently across multiple regions of the body, reinforcing its reliability as a universal measurement tool.

IMPLICATIONS IN PHYSIOTHERAPY AND FUTURE RESEARCH

The strong reliability and validity of the HDG for lumbar ROM assessments highlight its potential for widespread adoption in clinical practice. Physiotherapists often face challenges in conducting accurate assessments due to time constraints and patient workload. The HDG addresses these challenges by providing quick, precise measurements that align with anatomical landmarks, as noted in the study's background. On the other hand, the limitations of the study, which include a relatively small sample size and a major focus on comparison with the single instrument, namely DI, suggest that further research is necessary. Moreover, due to the high number of measurements necessary for each subject and single evaluator, it was not practical to apply the same strategy as Correll et al. and cover the display of the HALO and DI to properly blind the rater to the device's results. Future studies could include a larger sample size and greater diversity of patient demographics to improve the results' universality. Furthermore, contrasting the HDG with other recently developed digital tools, such smartphone apps, may provide further insights into its relative effectiveness**.**

CONCLUSION

This study concludes that HALO Digital Goniometer is a valid and reliable substitute for Double Inclinometer in measuring lumbar ROM in subjects with lower back pain.

Ethical statement

The Columbia Institutional Ethical Committee (CCP/Ethical/Comm/08/2023-24) approved this study's ethical application.

Competing interests: nil
Source(s) of support: nil
Acknowledgements: nil

REFERENCES

1. Dimitriadis Z, Parintas I, Karamitanis G, Abdelmesseh K, Koumantakis GA, Kastrinis A. Reliability and Validity of the Double Inclinometer Method for Assessing Thoracolumbar Joint Position Sense and Range of Movement in Patients with a Recent History of Low Back Pain. Healthc Basel Switz. 2022 Dec 29;11(1):105.
2. Johnson M, Mulcahey MJ. Interrater Reliability of Spine Range of Motion Measurement Using a Tape Measure and Goniometer. J Chiropr Med. 2021 Sep;20(3):138–47.
3. Grabovac I, Dorner TE. Association between low back pain and various everyday performances. Wien Klin Wochenschr. 2019;131(21):541–9.
4. Vaisy M, Gizzi L, Petzke F, Consmüller T, Pfingsten M, Falla D. Measurement of Lumbar Spine Functional Movement in Low Back Pain. Clin J Pain. 2015 Oct;31(10):876–85.
5. See QY, Tan JNB, Kumar DS. Acute low back pain: diagnosis and management. Singapore Med J. 2021 Jun;62(6):271–5.
6. MacDermid JC, Arumugam V, Vincent JI, Payne KL, So AK. Reliability of three landmarking methods for dual inclinometry measurements of lumbar flexion and extension. BMC Musculoskelet Disord. 2015 May 20;16:121.
7. MacDermid JC, Arumugam V, Vincent JI, Carroll KL. The reliability and validity of the computerized double inclinometer in measuring lumbar mobility. Open Orthop J. 2014;8:355–60.
8. Chen SP, Samo DG, Chen EH, Crampton AR, Conrad KM, Egan L, et al. Reliability of three lumbar sagittal motion measurement methods: surface inclinometers. J Occup Environ Med. 1997 Mar;39(3):217–23.

9. Correll S, Field J, Hutchinson H, Mickevicius G, Fitzsimmons A, Smoot B. RELIABILITY AND VALIDITY OF THE HALO DIGITAL GONIOMETER FOR SHOULDER RANGE OF MOTION IN HEALTHY SUBJECTS. Int J Sports Phys Ther. 2018;13(4):707–14.
10. Wilson-Smith AR, Muralidaran S, Maharaj M, Pelletier MH, Beshara P, Rao P, et al. Validation of a novel range of motion assessment tool for the cervical spine: the HALO© digital goniometer. J Spine Surg. 2022;8(1).
11. Hancock GE, Hepworth T, Wembridge K. Accuracy and reliability of knee goniometry methods. J Exp Orthop. 2018;5(1).
12. Furness J, Johnstone S, Hing W, Abbott A, Climstein M. Assessment of shoulder active range of motion in prone versus supine: A reliability and concurrent validity study. Physiother Theory Pract. 2015;31(7):489–95.