Original Article on Objective Monitoring and Wearable Technologies including Sensor-Based Accelerometers and Mobile Health Applications for the Spine Patient

Validation of a novel range of motion assessment tool for the cervical spine: the HALO© digital goniometer

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Background: Cervical spine range of motion (ROM) assessment has long been carried out via use of the universal goniometer (UG) as an objective tool in the evaluation of patient rehabilitation pre- and post-operatively. The advent of novel ROM assessment technology, such as HALO digital goniometer (DG), presents an avenue for research and potential application within clinical and surgical settings. The objective of this study was to examine the reliability and validity of the HALO DG in the assessment of the active ROM of the cervical spine.

Methods: One hundred healthy subjects were recruited for the study and were split into two groups to be assessed by either physiotherapists or medical students. The methodology for cervical spine ROM assessment was carried out per the American Association of Orthopaedic Surgeons (AAOS) guidelines. The reliability analysis was completed using IBM SPSS Statistics 25, calculating the intraclass correlation coefficients (ICC) to determine both the intra- and inter-rater reliability of the device.

Results: Inter-rater reliability within the physiotherapist cohort with the DG (ICCr =0.477, 0.718, 0.551) was higher compared to the UG (ICCr =0.380, 0.510, 0.255) for active cervical flexion, lateral flexion, and rotation, respectively. The UG (ICCr =0.819) showed better reliability versus the DG (ICCr =0.780) when assessing cervical extension. Similarly, in the medical student cohort, the DG outperformed the UG in all movement except cervical lateral flexion. When assessing for intra-rater reliability, the DG (ICCm =0.507, 0.773, 0.728, 0.691) performed better than the UG (ICCm =0.487, 0.529, 0.532, 0.585) in cervical flexion, extension, lateral flexion, and rotation, respectively.

Conclusions: The present validation study identified the DG as a reliable substitute for the UG.

Keywords: Range of motion (ROM); cervical spine; universal goniometer (UG); digital goniometer (DG)

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Introduction

Range of motion (ROM) assessment forms a critical component of the objective evaluation of patients in pre- and post-spinal surgeries (e.g., cervical and lumbar fusion and disc replacement surgeries), with a high degree of correlation with quality of life outcomes (1). Quantitative outcome assessments in neurosurgical and orthopaedic settings, with the notable exception of assessments such as the 6-minute walk test (6MWT), are lacking (2-4). Radiography is the accepted gold standard for cervical

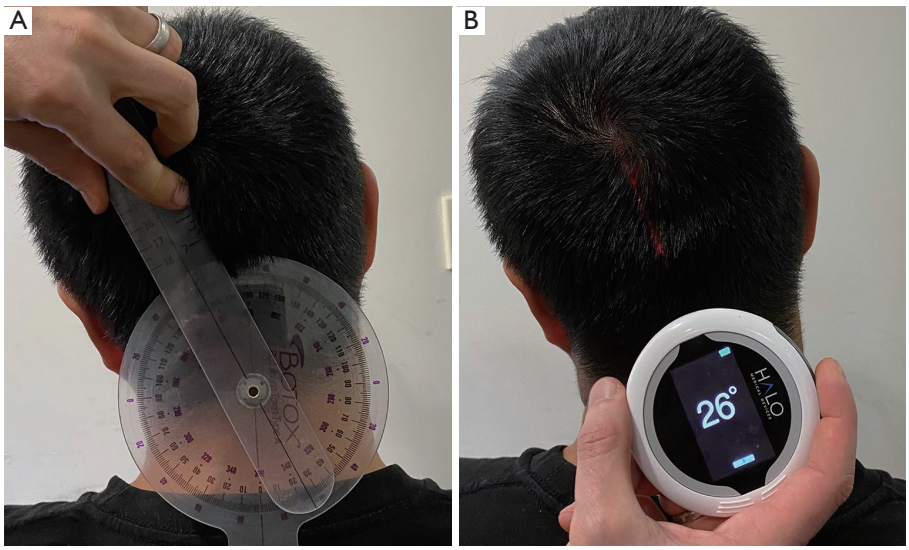

Figure 1 Example of the cervical lateral flexion measurement. (A) Measure cervical lateral flexion with the UG. (B) Measure cervical lateral flexion with the HALO DG. UG, universal goniometer; DG, digital goniometer.

ROM measurement; however, it comes with the caveat of radiation exposure, increased time-to-assessment, and is most useful in flexion/extension, whilst not so much in the evaluation of cervical rotation. Additional tools commonly used to assess cervical ROM include visual estimation (5,6), tape measurement (7,8), inclinometers (9) and the universal goniometer (UG) (7).

The advent of novel ROM assessment technology, such as digital goniometer (DG), presents an avenue for research and potential application within clinical and surgical settings, given its ease of use, speed, and potential for increased accuracy of measurement. Indeed, if a digital tool proved more accurate, faster, and more user-friendly, it would represent a more viable tool than the oft-used UG in clinical settings, where high-volume batteries of assessment can lead to reduced precision and user fatigue. However, no previous study has been found to test the reliability of the DG in cervical ROM measurement. The aim of the present study was therefore to evaluate the DG in terms of validity, intra- and inter-rater reliability of the cervical spine. We present the following article in accordance with the MDAR reporting checklist (available at https://jss.amegroups.com/article/view/10.21037/jss-21-92/rc).

Methods

Ethics approval, inclusion and exclusion criteria

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). After approval by the Local Health District Ethics Committee and upon attaining verbal and/or written informed consent, 100 healthy subjects from the local university (The University of New South Wales) were recruited for the study. Sample size was chosen based on relevant validation studies (10). Sample calculations based on the results of a previous study evaluating 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-β) =0.8 (10). To be eligible for inclusion, subjects must have been over the age of 18 and have no current cervical spine injuries at the time of assessment. Subjects were excluded if they had any injury that had been managed surgically—irrespective of the time since management—if they had movement-restricting pain, or if they were unable to provide informed consent for the assessment.

Acquisition systems—the UG and the DG

The UG is an instrument that measures joint ROM around a central axis of rotation in one-degree increments (see *Figure 1A)*. A stationary arm provides a reference point for another motion arm that follows the joint or limb being assessed. The HALO© DG (model HG1, HALO Medical Devices, Sydney, Australia) is a digital ROM assessment tool that employs a laser-guided inclinometer system in place of the traditional arms of the UG (see *Figure 1B*).

Raters and subjects

All subjects were coded such that no identification of individual persons could be made.

A total of 100 subjects were assessed in two separate groups of 50, by two different groups of assessors. Fifty subjects (41 males, 9 females, mean age: 20.3±1.4 years) were assessed by physiotherapists (Rater 1/2) with 10 and 3 years of clinical experience, respectively. Rater 1 had 15 hours of experience using the DG, while Rater 2 had a single 1-hour training session prior to the commencement of this study. The remaining fifty (26 males, 24 females, mean age: 20±1.1 years) assessed by two 4TH year medical students (Rater 3/4). Both Rater 3 and 4 had 10 hours of experience with the UG and DG prior to the commencement of this study, The second group were assessed at a later follow-up session by Rater 3, at a mean follow-up time of 31.3 days. Each subject was randomly allocated into one of four groups, which determined the order of the device and rater they would get assessed by. Each rater was responsible for placement of the UG or DG, providing verbal instructions to commence each motion and obtaining a final reading from the device.

ROM assessment protocol—cervical spine

All ranges of motion were carried out in accordance with the American Association of Orthopaedic Surgeons (AAOS) guidelines (11). A brief protocol is presented here. The subject was required to sit in a neutral position—spine straight, eyes forward—prior to the commencement of each ROM. From this neutral position, the subject was asked to move their chin towards their sternum (cervical flexion), look up towards the ceiling (cervical extension), bring their right ear to their right shoulder (cervical lateral flexion) and turn 90° to their right, or as far as possible (rotation). For cervical flexion/extension, the goniometers were placed over the mastoid process of the subject, with the stationary arm perpendicular to the motion arm, which was aligned with the base of the nose. For lateral flexion, the base of the goniometer was placed over C7, and both arms were aligned with the occipital prominence. For rotation, the base of the goniometer was placed over the occipital prominence and the arms were aligned with the midline of the nose. From these positions, the active movements were performed, and the motion arm of the goniometers tracked the landmark of interest (i.e., the nose and occiput). Each movement was performed, and the range was measured three times using each tool, following one practice movement to ensure the subject understood the procedure. The mean of the three measures were calculated and compared between each set of two raters to determine the inter-rater reliability.

Statistical analysis

All data analysis and statistical evaluation of ROM was carried out using IBM SPSS Statistics 25 (IBM Corporation, Armonk, NY, USA). Intra-rater reliability was evaluated using a two-way mixed-effects absolute agreement intraclass correlation coefficient model for single measures ($ICC_{3,1}$). Inter-rater reliability was determined using a two-way random effects absolute agreement ICC model for single measures ($ICC_{2,1}$) (12). Standard error of the mean (SEM) and Bland-Altman plots were employed to provide visualization of the results (13).

For both intra-rater and inter-rater reliability, ICCs greater than 0.90 were considered as "excellent" reliability, ICCs between 0.75 and 0.90 were considered as "good" reliability, ICCs between 0.40 and 0.75 as "modest" reliability and those less than 0.40 as "poor" reliability (12). The standard error of measurement (SEm) was calculated for both intra-rater and inter-rater reliability using the following formula:

$$\text{SEm}=\text{SD}\times\sqrt{1-\text{ICC}} \quad [1]$$

Using Eq. [1], the minimum detectable change at the 90% confidence interval (MDC_{90}) was calculated using the following formula:

$$\text{MDC}_{90}=1.65\times\text{SEm}\times\sqrt{2} \quad [2]$$

This value is of clinical significance as it describes the minimum amount of change that needs to occur to ensure that the change is not attributable to measurement error (14). 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 analysed through Bland-Altman plots to visualise 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.

Table 1 Mean and SD value of cervical ROM

Motion	Rater 1		Rater 2		Rater 3		Rater 4	
	UG (mean ± SD)	DG (mean ± SD)	UG (mean ± SD)	DG (mean ± SD)	UG (mean ± SD)	DG (mean ± SD)	UG (mean ± SD)	DG mean ± SD)
Cervical flexion	42.2±11.4	54.3±9.5	38.3±8.9	52.4±10.5	49.5±10.4	46.8±8.1	40.4±9.8	44.8±9.2
Cervical extension	60.4±17.3	66.1±15.0	59.6±15.0	65.6±14.3	55.8±12.7	56.5±11.3	54.6±11.6	57.5±11.6
Cervical lateral flexion	35.2±6.4	34.6±7.7	31.3±7.0	32.2±10.1	26.5±8.2	26.4±7.5	27.8±6.5	27.4±6.8
Cervical rotation	81.0±11.3	82.9±10.5	61.0±13.3	72.6±13.3	63.0±11.6	65.3±10.4	66.4±10.1	67.1±8.5

SD, standard deviation; ROM, range of motion; UG, universal goniometer; DG, digital goniometer.

Table 2 Inter-rater reliability/consistency (physiotherapists)

Motion	UG		DG		UG		DG	
	$ICC_{2,1}$	95% CI	$ICC_{2,1}$	95% CI	SEM (°)	MDC_{90} (°)	SEM (°)	MDC_{90} (°)
Cervical flexion	0.380	0.126 to 0.590	0.477	0.235 to 0.664	8.8	20.6	7.4	17.2
Cervical extension	0.819	0.702 to 0.893	0.780	0.642 to 0.869	4.2	9.7	4.6	10.7
Cervical lateral flexion	0.510	0.181 to 0.717	0.718	0.536 to 0.833	4.3	9.9	3.4	8.0
Cervical rotation	0.255	–0.094 to 0.589	0.551	–0.057 to 0.812	9.7	22.7	5.7	13.2

Results presented are average measures. UG, universal goniometer; DG, digital goniometer; ICC, intraclass correlation coefficients; CI, confidence interval; SEM, standard error of the mean; MDC, minimal detectable change.

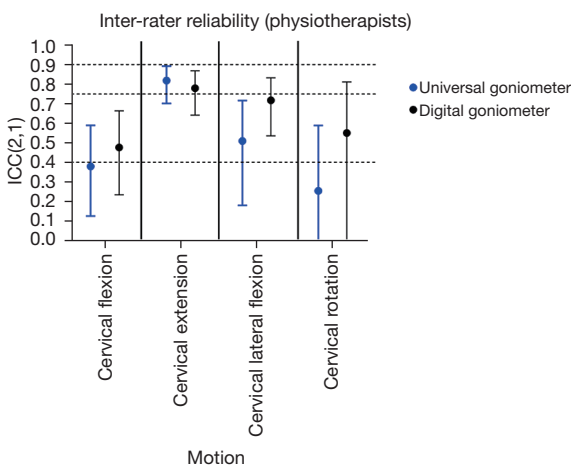

Figure 2 Inter-rater reliability between the physiotherapists. Error bar indicates the confidence interval. Dash line indicates the ICC =0.9, 0.75 and 0.4. ICC, intraclass correlation coefficients.

Results

Inter- and intra-rater reliability

The mean and standard deviation (SD) value of the cervical ROM was summarized in the *Table 1*. For the reliability analyses, in the physiotherapist cohort, inter-rater reliability was highest for cervical extension for both the UG and DG, with good reliability at ICC values of 0.819 and 0.780, respectively (*Table 2* and *Figure 2*). Reliability for cervical flexion and cervical rotation was poor with the UG, with ICCs of 0.380 and 0.255 respectively, but modest for the DG, with ICCs of 0.477 and 0.551. In the medical student cohort, the reliability of all planes of motion were modest for the UG (*Table 3* and *Figure 3*). The reliability of all planes of motion were modest to good for the DG, with values between 0.477 and 0.831. Intra-rater reliability was modest for all ranges of motion when using UG and between modest to good with DG (*Table 4* and *Figure 4*). In the physiotherapy cohort, cervical extension for the UG and cervical lateral flexion for the DG were the most accurate planes, with MDC_{90} values of 9.7 and 8.0 degrees (*Table 2*). For the medical student cohort, the most accurate planes were cervical lateral flexion for the UG and cervical flexion for the DG with MDC_{90} values of 10.48 and 10.10 degrees, respectively (*Table 3*).

When assessing concurrent validity, the mean difference was the smallest for cervical lateral flexion throughout all the raters (*Table 5* and *Figure 5*). This was further analysed

Table 3 Inter-rater reliability/consistency (medical students)

Motion	UG		DG		UG		DG	
	$ICC_{2,1}$	95% CI	$ICC_{2,1}$	95% CI	SEM (°)	MDC_{90} (°)	SEM (°)	MDC_{90} (°)
Cervical flexion	0.579	0–0.822	0.707	0.487–0.833	6.35	14.81	4.33	10.10
Cervical extension	0.789	0.628–0.880	0.831	0.703–0.904	5.97	13.93	4.52	10.55
Cervical lateral flexion	0.685	0.448–0.820	0.655	0.393–0.804	4.49	10.48	4.70	10.96
Cervical rotation	0.561	0.239–0.748	0.720	0.510–0.841	7.95	18.55	5.29	12.35

Results presented are average measures. UG, universal goniometer; DG, digital goniometer; ICC, intraclass correlation coefficients; CI, confidence interval; SEM, standard error of the mean; MDC, minimal detectable change.

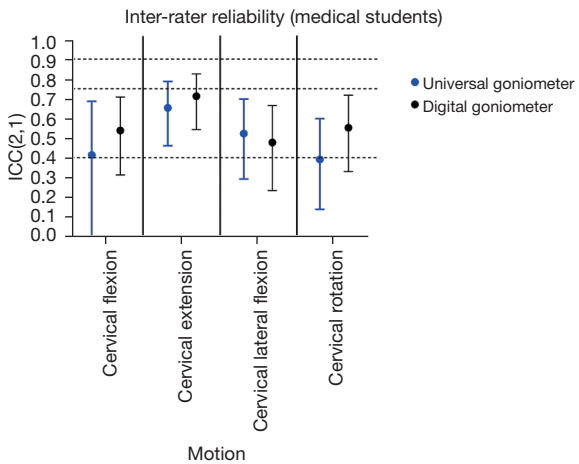

Figure 3 Inter-rater reliability between the medical students. Error bar indicates the confidence interval. Dash line indicates the ICC =0.9, 0.75 and 0.4. ICC, intraclass correlation coefficients.

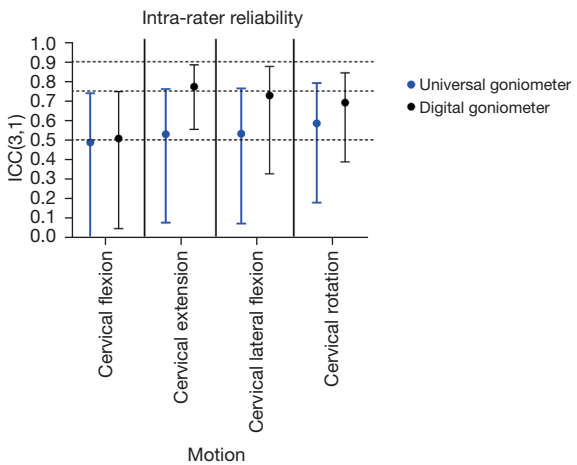

Figure 4 Intra-rater reliability. Error bar indicates the confidence interval. Dash line indicates the ICC =0.9, 0.75 and 0.4. ICC, intraclass correlation coefficients.

Table 4 Intra-rater reliability/consistency

Motion	UG		DG	
	$ICC_{3,1}$	95% CI	$ICC_{3,1}$	95% CI
Cervical flexion	0.487	–0.011 to 0.740	0.507	0.045 to 0.748
Cervical extension	0.529	0.075 to 0.761	0.773	0.554 to 0.885
Cervical lateral flexion	0.532	0.071 to 0.764	0.728	0.326 to 0.877
Cervical rotation	0.585	0.178 to 0.791	0.691	0.387 to 0.844

Results presented are average measures. UG, universal goniometer; DG, digital goniometer; ICC, intraclass correlation coefficients; CI, confidence interval.

using Bland-Altman plots and the 95% LOA (*Figures 6-9*), which again showed the most consistency between the two devices when assessing cervical lateral flexion. There was no statistically significant difference when comparing the values obtained by either device while assessing cervical lateral flexion for each rater. In contrast, however, there was a statistically significant difference for each rater when assessing cervical flexion.

Table 5 Mean differences between devices

Motion	Mean difference			
	Rater 1	Rater 2	Rater 3	Rater 4
Cervical flexion	−12.2*	−14.1*	2.7*	−4.3*
Cervical extension	−5.6*	−6.0*	−0.7	−2.9
Cervical lateral flexion	0.6	−0.9	0.1	0.4
Cervical rotation	−1.9	−11.6*	−2.3*	−0.7

*, indicates statistical significance (P<0.05).

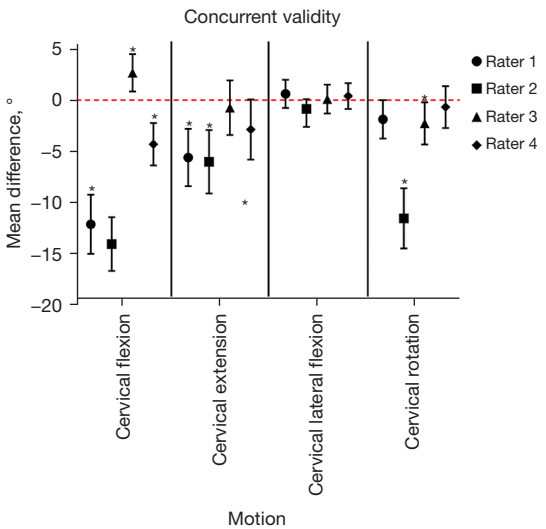

Figure 5 Mean difference of measurements obtained by each rater for each motion. Error bar indicates the confidence interval. *, indicates statistical significance (P<0.05) between two devices.

Discussion

The current study results showed the HALO© DG as a valid and reliable substitute for the UG in the setting of ROM assessment of the certain planes of movement of the cervical spine. With the laser-guidance technology, pocket-size, single-handed operation design and 3-plane measurement capability, this device will benefit the ROM assessment for the patient undergoing cervical spine surgery and rehabilitation.

Inter-rater reliability and validity of the DG

The DG appears to be a reliable and valid substitute for the UG in the setting of ROM assessment, with a minimum of modest correlations attained when evaluating inter-rater reliability. Intra-rater reliability findings in this study are also in line with the work of previous ROM studies (15). According to the guideline (16) ICC ≥0.7 for a measure is generally accepted as 'sufficient reliability', DG performed well on the cervical extension and lateral flexion measurement, however, less sensitive (but still fair-good) on flexion and rotation. In essence, the DG had difficulties detecting changes when placed on a horizontal axis (i.e., on the occiput) versus the mastoid positioning to its own. It was not entirely clear why this was an issue across all raters but is most likely reflective of device-related sensitivity issues which could be rectified with additional improvements in future iterations.

Previous studies assessing the DG's validity and reliability in the assessment of ROM have proven useful in illustrating the device's capabilities but have suffered from significant methodological flaws. The most recent study evaluating the DG for knee ROM found unrealistically high ICCs for all methods, with values of >0.98; this was only carried out in a cohort of three subjects (17). As detailed previously, a statistical analysis completed showed that a sample size of 50 patients is required for statistical significance and to elicit valid data.

Other cervical ROM measurement tools reported previously also achieved good reliability. Alaranta *et al.* (18) used an inclinometer and tape measure to exam cervical sagittal movements, lateral flexion, and rotation. They reported high inter-rater reliability ICCs from 0.69 to 0.86, and fair good intra-rater reliability ICCs on sagittal and lateral flexion from 0.61 to 0.68, and poor intra-rater reliability ICC on rotation with 0.37. Their results showed better reliability compared to the UG from the current study, however, DG appears to be a more reliable tool, especially in rotation measurement with 0.69 intra-rater reliability ICC. The only setback of DG was flexion measurement, but Alaranta *et al.* (18)

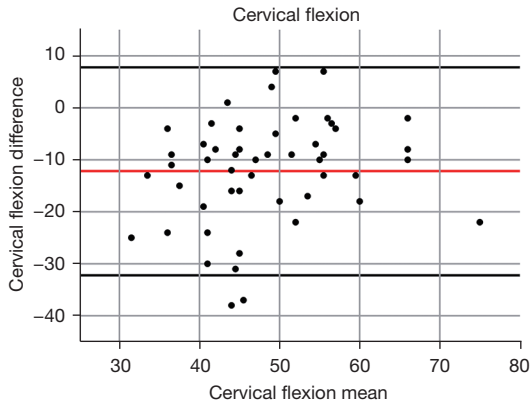

Figure 6 Bland-Altman plot detailing the comparison between the UG and DG when Rater 1 was assessing cervical flexion. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements. UG, universal goniometer; DG, digital goniometer.

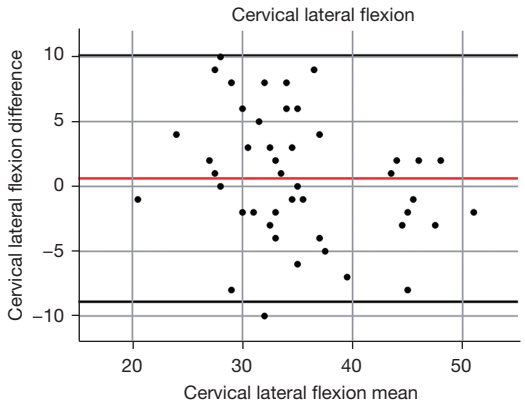

Figure 8 Bland-Altman plot detailing the comparison between the UG and DG when Rater 1 was assessing cervical lateral flexion. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements. UG, universal goniometer; DG, digital goniometer.

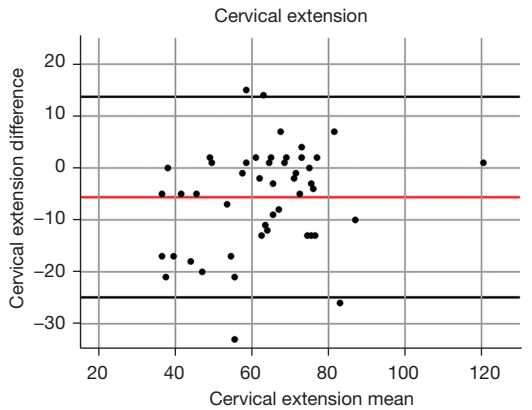

Figure 7 Bland-Altman plot detailing the comparison between the UG and DG when Rater 1 was assessing cervical extension. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements. UG, universal goniometer; DG, digital goniometer.

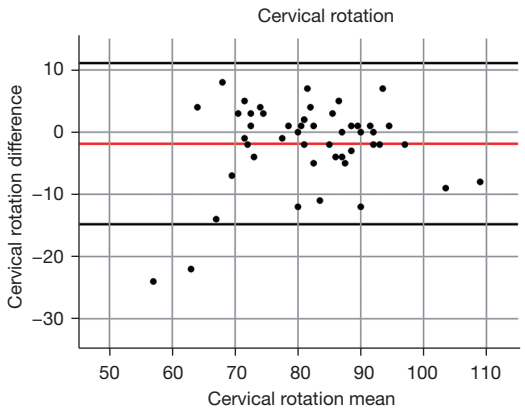

Figure 9 Bland-Altman plot detailing the comparison between the UG and DG when Rater 1 was assessing cervical rotation. Red line (middle one) indicates the mean difference. Black lines (extremities) indicate upper and lower agreements. UG, universal goniometer; DG, digital goniometer.

did not separate flexion and extension measurement in their study, thus it cannot directly compare the flexion and extension reliability between two studies. Antonaci *et al.* (19) used a 3D motion capture system to measure the human cervical motion and got ICCs from 0.68 to 0.86 in all motions except left lateral flexion with 0.47. Six markers and two infrared cameras were employed in this study. It is a statistically reliable method, also able to fully descript the head/neck mobility, however, the complex setup may not be suitable for daily clinical use compared to the DG. The CROM device tested by Audette *et al.* (20) also resulted good to excellent reliability. The follow-up time in their study was 2 days. The relatively extended follow-up time used in the present study was one month. A one-month follow-up time was chosen to avoid memory recall of the raters and minimise outside influences such as injury that may produce confounding results. Meanwhile, the CROM device was only designed for measure cervical ROM, whereas DG can also be used in other clinical applications such as ROM assessment of lower extremities (21).

Contemporary issues in the assessment of spine surgery outcomes: an overview

Generally, surgical candidates are evaluated per their response to conservative therapy, individual symptoms, functionality, and the cost-effectiveness of the operation. The efficacy of such operations is primarily assessed through a series of outcome measures; however, there is no consensus regarding the best tools to utilize in this population at present. Outcome measures often aid the clinical decision-making process, from determination of ongoing therapeutic modalities, to assessing the degree of impact of a patient's disease (22). Several tools evaluating the nature and severity of back pain have been validated for use in the setting of spinal stenosis. However, there is limited data available on the efficacy of existing tools when compared in a head-to-head analysis, and they often require certain degrees of expert familiarity, particularly when several tools are niche and used only within select institutions. Indeed, a review by Vavken *et al.* (23) affirmed that further research is required in order to advance the field's understanding of spinal outcome assessment and personalized spine care, as it is far from holistic at present.

The major limitation of existing functional outcome measures is that they are subjective in nature, relying heavily on data derived from patient-reported surveys, questionnaires, visual analogue scales and the like (22,24-27). These processes place great emphasis on the subjectivity of the reporter, which may prove to be a hindrance in long-term prediction of functional outcome and when informing patients of the impact of surgical interventions. Hence, standardization remains a significant challenge for clinicians and researchers (28). To the author's knowledge, this is the largest study of its kind assessing a novel, quantitative tool to address this lack of standardization. It is hoped that with an increased focus on ROM assessment as a correlate measure for long-term functionality following surgical procedures, surgical outcomes can be better conveyed to patients and surgeon confidence in the efficacy of said procedures can be affirmed.

Existing objective outcome measures

At present, most objective assessment tools are physical task batteries, including the 6-minute walk test (6MWT), the self-paced walking test (SPWT) and the Timed Up and Go test (TUG)—gait analyses and activity monitors (4). Shorter and longer variants of these tests have also been utilized based on patient demographics and pre-operative individual ability. The SPWT has been shown to have high re-test reliability in the spinal stenosis population. Often, these tools attempt to distinguish between a patient's capacity to perform a given task, versus their actual performance of the task itself relative to a normal individual. Unfortunately, the impact of spinal stenosis on each individual can be highly variable and hence can influence patient capacity and performance across a wide, multi-dimensional range (29). Mobbs *et al.* (2) affirmed this using accelerometery data derived from wearable activity tracking devices. In their pilot study of 30 patients examined over a three-month perioperative period, the team found no statistically significant correlation between the improvement in steps or distance travelled per day with improvements in Visual Analog Scale back or leg pain, Oswestry Disability Index, or Physical Component Summary scores at follow-up.

ROM assessment, similar to that utilized in the present study, has also emerged, with highly specific outcomes being assessed. For instance, Goto *et al.* (30), utilizing gait analysis software and electromyographic recordings, found that knee angle, knee torque and activity of the vastus lateralis increase significantly following decompressive surgery for lumbar spine stenosis, whereas activity of the paravertebral muscles decreases. This was also linked to an improvement in walking speed and posture, suggesting functional recovery. Evidently, this is of substantial use in terms of tailoring future treatment modalities. Again, however, lone physical assessment fails to quantify the effect of the disease process on a patient's other psychometric facets, which can have clinically significant outcomes, which necessitates that ROM assessment should accompany well-validated, patient-conducted outcome measures (31).

Implications, limitations, and future directions

With the successful validation of the DG, application of the device in the assessment of a pathological cohort is the next logical step. The authors intend to recruit a patient population in a pre-operative setting (i.e., prior to spinal fusion), assess them and then conduct a follow-up at regular post-operative intervals. This study was constrained by several limitations. The physiotherapy cohort consisted of predominantly male subjects, where ideally, a more equal distribution between the sexes would be met to reflect clinical practice more accurately. The authors hypothesized that subject fatigue may begin to impair ROM measurements and hence after completing one battery of assessments, the subsequent tool would not be reading the subject's full ROM capacity, but rather is reporting an

"exhausted" value.

One limitation of the DG is its price. At approximately $400 AUD, the DG would have to bring significant benefits to clinical environment to be more favoured than its inexpensive analogue counterpart.

Conclusions

The present validation study identified the HALO© DG as a valid and reliable substitute for the UG in the setting of ROM assessment of the cervical spine in certain anatomic planes, with moderate to high inter-rater agreement, consistency, and validity, along with moderate intra-rater reliability.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Local Health District Ethics Committee [Low/Negligible Risk (LNR). HREC 17/210] and informed consent was taken from all individual participants.

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