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ORIGINAL RESEARCH ARTICLE

Concurrent validity of a novel digital dynamometer for assessing performance on the Cranio-Cervical Flexion Test

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ABSTRACT

Introduction: The Cranio-Cervical Flexion Test (CCFT) is a validated clinical test used to evaluate deep cervical flexor muscle function. A pressure biofeedback unit (PBU) has traditionally been the reference device. Recently, a new portable digital device known as the Neuromuscular Cranio-cervical Device (NOD) has been developed as a potential alternative.
Methods: In this cross-sectional concurrent validation study, 88 participants were recruited from four outpatient physiotherapy practices, including individuals with current neck pain and individuals with a previous history of neck pain. All participants performed the CCFT using both devices. The PBU was inflated to a baseline pressure of 20 mmHg, with the participant then performing C-CF to increase the pressure in increments of 2 mmHg over five progressive stages, while the NOD was calibrated to corresponding force targets. Agreement and concurrent validity between the devices were assessed, and C-CF range of motion (ROM) was analyzed using linear mixed-effects models.
Results: Agreement between CCFT performance scores obtained with the NOD and the PBU was 94.3%, with a very strong positive correlation (Spearman's $\rho = 0.930$, $p < 0.001$). The NOD measured slightly greater C-CF ROM than the PBU (mean difference 0.68°), with significant differences at lower CCFT stages that converged at higher stages of the test.
Conclusion: These findings demonstrate strong concurrent validity between the NOD and the PBU, supporting the NOD as a valid digital alternative for assessment of the CCFT.
Keywords: Cranio-Cervical Flexion Test, Concurrent validity, Deep neck flexors

What is already known about this topic?

- *The CCFT is a validated clinical test for assessing deep cervical flexor function, typically performed using a PBU, with moderate evidence supporting its reliability.*

What does the study add?

- *This study shows that a digital dynamometer (NOD) provides a valid alternative to the PBU for CCFT assessment, maintaining task integrity while improving visual feedback and clinical usability.*

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Introduction

The Cranio-Cervical Flexion Test (CCFT) is a validated test to assess the deep cervical flexor (longus capitis and longus colli) muscle activity during the task of cranio-cervical flexion (C-CF) (1,2) and is endorsed as a recommended assessment test in evidence-based clinical practice guidelines (3).

There is extensive evidence documenting poor performance on this test in people with both acute and chronic neck pain, which is characterized by an inability to reach the higher levels of the test, reduced electromyographic activity of the deep cervical flexors and compensatory strategies, in particular, an increase of superficial cervical flexor electromyographic activity during test performance compared to healthy controls (4-9). Furthermore, an association was reported between the level of neck pain intensity and activation of the deep cervical flexor muscles on the CCFT in women with persistent neck pain (10).

Collectively, these findings led to the development of C-CF training interventions for people with neck pain, and there is now extensive evidence to support C-CF training for pain reduction, functional disability reduction, enhanced muscle endurance, and restored neuromuscular coordination in people with neck pain (11-19).

A pressure biofeedback unit (PBU; Stabilizer™, Chattanooga Group, Inc., Hixson, TN, USA) has traditionally been the reference tool for performing the CCFT. Performance on the test using the PBU demonstrated a positive convergent validity with electromyographic measures of deep cervical flexor activation (1). Moreover, moderate evidence of both inter-rater and intra-rater reliability has been reported, although evidence regarding responsiveness remains limited (20-22). More recently, a reliability study conducted on individuals with non-specific chronic neck pain also provided estimates of measurement error and change indices, reporting a standard error of measurement of 1.73 mmHg (intra-rater) and 1.66 mmHg (inter-rater), and a minimal detectable change ranging from 4.81 to 4.60 mmHg, respectively (23).

More recently, a portable digital handheld dynamometer known as the Neuromuscular Cranio-Cervical Device (NOD; OT Bioelettronica, Turin, Italy) was introduced to quantify force during C-CF (amongst other tasks). Initial pilot testing has explored the use of NOD in CCFT-derived protocols (24), while separate validation studies have demonstrated good-to-excellent reliability and concurrent validity for the assessment of neck strength using the NOD device when compared to gold-standard dynamometry systems (25). The NOD device has the advantage that it incorporates real-time digital biofeedback capabilities and potentially enhanced measurement precision. However, the concurrent validity between the NOD device and the PBU for the assessment of the CCFT remains unexplored, and this must be addressed before the NOD can be considered as a viable alternative in clinical practice and research settings for the assessment of the CCFT. Therefore, the aim of this study is to determine the concurrent validity of the NOD compared with the traditional PBU for assessing performance on the CCFT.

Methods

Study design

This cross-sectional concurrent validation study was designed and is reported according to guidelines for reporting reliability and agreement studies (GRRAS) (26). Ethical approval was obtained from the Comitato etico cantonale, Switzerland (BASEC No. 2023-00625; approval date: 08/05/2023). All participants provided written informed consent prior to participation.

Setting and Participants

Participants were recruited from four outpatient physiotherapy practices in the Canton of Ticino, Switzerland, between May 2023 and April 10, 2024. An a priori sample size calculation for correlation analyses indicated that at least 29 participants were required ($\alpha = 0.05$, power = 0.80, expected correlation $r = 0.50$) (27). Recruitment was planned to continue beyond this minimum number to improve the precision of the correlation estimate and to stop at the end of the predefined recruitment period or earlier if no further eligible individuals consented to participate within the participating practices. Potentially eligible individuals were identified by the practice owners at each site by screening appointment schedules and clinical records and were then invited to participate. Eligible participants were adults (≥18 years) with either current or a previous history of neck pain. Neck pain was defined as pain perceived within the region bounded superiorly by the superior nuchal line, inferiorly by an imaginary transverse line through the tip of the first thoracic spinous process, and laterally by sagittal planes peripheral to the lateral borders of the neck (28). Pain could be local and/or referred to the head or one or both upper limbs. Participants with current neck pain were experiencing pain at the time of testing. Participants with a history of neck pain had previously experienced neck pain but reported no symptoms of neck pain at the time of assessment. This study population was intentionally selected to include participants expected to present with a broad spectrum of deep cervical flexor motor control impairments. Participants with a history of neck pain but pain-free at the time of testing were expected to contribute to the higher end of the performance spectrum while still representing a clinically relevant population.

Exclusion criteria included diagnosed neurological or rheumatological disorders, and inability to understand or follow test instructions. All testing was conducted by a single physiotherapist trained in CCFT administration according to standardized protocols (2) to ensure procedural consistency across sites. Demographic and clinical data were collected to characterize the sample. For participants with current neck pain, pain intensity was assessed using the Numerical Pain Rating Scale (NPRS) and disability using the Italian version of the Neck Disability Index (NDI) (29). For participants with a history of neck pain but asymptomatic at the time of testing, the time since the last neck pain episode was recorded.

Equipment

The PBU (Stabilizer™, Chattanooga Group, Inc., Hixson, TN, USA) is designed to provide pressure feedback during muscle re-education and motor control assessment. It consists of an air-filled pressure cuff connected to an analogue manometer and an inflation bulb. During the CCFT, the PBU is inflated to a baseline of 20 mmHg and provides visual feedback via the analogue pressure gauge, which features colored marks on the dial to indicate progressive pressure targets (22-30 mmHg). This allows participants to visually track each

stage of the test while the clinician monitors head and neck movements and superficial neck flexor muscle activity.

The NOD device (OT Bioelettronica, Turin, Italy) is a handheld digital dynamometer with integrated biofeedback functionality. Real-time visual feedback via mobile application (CCFT, OT Bioelettronica, 2023, beta version) is displayed on a tablet and provides both numerical and graphical representations of the applied force. A silicone pad is fixed to the dynamometer, providing comfort and ensuring consistent force transmission. The NOD was calibrated to pressure levels of the PBU using the conversion factor 1 mmHg = 1.7 N, enabling force targets corresponding to PBU increments (22-30 mmHg = 37,4–51 N). During the CCFT, both the PBU and the NOD were positioned posterior to the upper cervical spine in order to detect the subtle flattening of the cervical lordosis which occurs with activation of the deep cervical flexors, and this is registered as a small increase in pressure (PBU) or force (NOD) and used to monitor the contractile performance of the cranio-cervical flexors during the nodding action.

Kinematic Analysis of cranio-cervical flexion

Head kinematics during the CCFT were recorded using a digital video camera positioned laterally and aligned with the external acoustic meatus, ensuring acquisition of motion in the sagittal plane. Camera placement was kept constant across trials to minimize perspective errors.

Video sequences were processed offline using custom routines implemented in MATLAB (MathWorks, Natick, MA, USA). A set of virtual markers was manually initialized on visible facial anatomical landmarks (e.g., external auditory meatus, lateral canthus, nasal ala) as well as on identifiable natural skin features to facilitate robust tracking. The temporal evolution of these points was then automatically tracked using a point-tracking algorithm based on the Kanade–Lucas–Tomasi feature tracking framework, as implemented in the MATLAB vision PointTracker object (30,31)

Tracking reliability was ensured through bidirectional error thresholding, and only valid tracked points were retained for subsequent analysis. The 2D coordinates of the tracked markers were stored frame-by-frame for further kinematic processing.

The cranio-cervical flexion and extension angle was computed for each frame from the relative orientation of the segment defined by the tracked markers (Fig. 1). Specifically, the angle was calculated using standard trigonometric relationships based on the arctangent of coordinate differences between marker pairs.

To ensure geometric consistency and robustness of the tracked trajectories, point configurations across frames were optionally aligned using a rigid-body transformation estimated in a least-squares sense via a quaternion-based method (32), as implemented in established registration algorithms. This approach allows optimal estimation of rotation (and, if required, translation and scaling) between corresponding point sets.

All algorithms employed are widely validated in the fields of computer vision and motion analysis (30,33,34), and the same processing pipeline was consistently applied to all subjects and experimental conditions.

Procedures

With the participant in supine, the physiotherapist positioned their neck in a neutral position (2) and provided standardized instructions emphasizing that the test assessed movement control rather than strength, using gentle “nodding” actions without lifting the head. Before data collection, participants were allowed to perform a few practice trials with active assistance to familiarize themselves with the CCFT procedure using both devices.

For the assessment with the PBU, the uninflated pressure cuff was placed posterior to the upper neck and was inflated to a baseline pressure of 20 mmHg. Participants were then asked to perform the five progressive stages of the

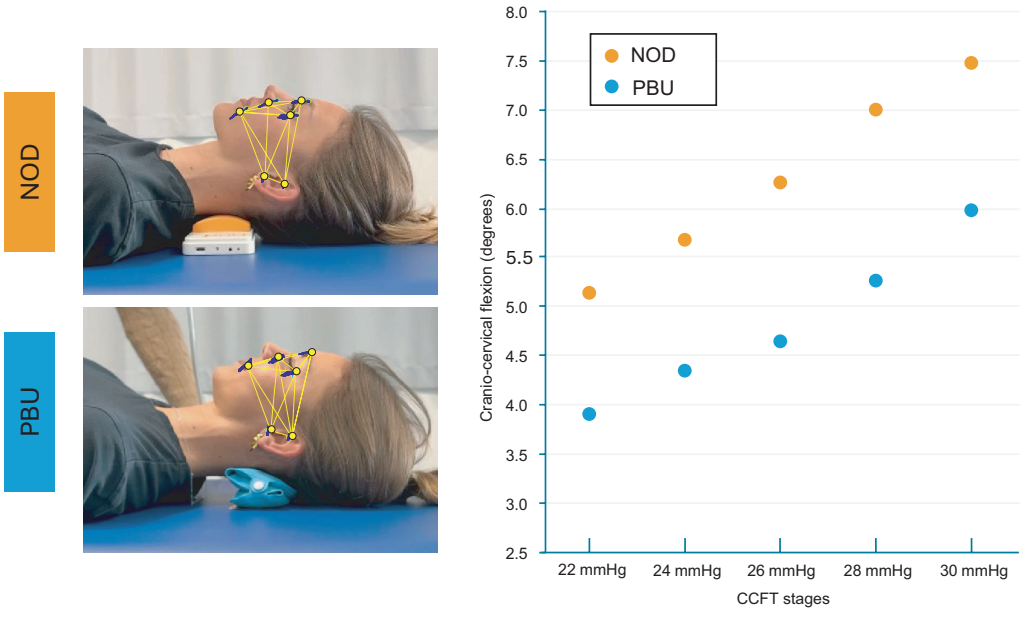

FIGURE 1 - Representative example of sagittal-plane cranio-cervical flexion during performance of the CCFT using the NOD (NOD; upper panel) and the PBU (PBU; lower panel). The figure illustrates the head movement pattern tracked using a rigid-body model for kinematic analysis.

CCFT (22,24,26,28,30 mmHg) with short rests in between stages (approximately 30 seconds) and guided by visual feedback displayed on an analog pressure gauge (2).

For the assessment using the NOD, the device was placed under the upper neck region with a silicone pad attached to the upper surface of the NOD. The device was calibrated before each trial, with force targets corresponding to PBU pressure levels as described above (1 mmHg = 1.7 N). Participants were asked to perform the five progressive stages of the CCFT with real-time visual digital feedback and short periods of rest in between stages. The sequence of the testing was randomized, with a five-minute rest interval between assessments.

For both assessments, the highest stage of the test that was performed correctly was recorded as the CCFT activation score. Test performance was monitored by the physiotherapist through observation and palpation of the superficial neck flexors and by observing movement quality and range of motion (ROM), while simultaneously verifying that the device signal indicated a stable increase at the target level, consistent with the subtle cervical flattening expected during deep cervical flexor contraction. Compensatory strategies were recorded as test failures and included (1) head lifting, (2) neck retraction, (3) excessive activation of superficial flexors, (4) failure to increase ROM between stages, and (5) compensation with the thoracic region.

The primary outcome was the CCFT activation score obtained with the NOD and PBU devices. A secondary outcome was the ROM of C-CF during each stage of the CCFT.

Statistical Analysis

The level of agreement between CCFT scores obtained with the NOD and the PBU was first evaluated using percentage agreement. Subsequently, concurrent validity between the two devices was assessed using Spearman's rank correlation coefficient (ρ), which is appropriate for ordinal and non-normally distributed data (35).

To determine whether the two devices influenced the ROM measured during performance of the CCFT, ROM values were analyzed using a linear mixed-effects model (LMM) with device (NOD, PBU) and stage (20-30 mmHg) as fixed factors and a random intercept for participants to account for within-subject correlations (36). Post-hoc pairwise comparisons (device within stage) were performed with Bonferroni correction.

Statistical analyses were performed using Jamovi (version 2.5; University of Amsterdam, The Netherlands) with the GAMLj3 module. Statistical significance was set at $p < 0.05$ for all analyses.

Results

A total of 88 participants were included in the study, comprising 62 individuals with a history of neck pain (Age: 50.2 ± 24.3 years; Height: 167.5 ± 8.2 cm; Weight: 68.1 ± 13.3 kg; BMI: 24.3 ± 4.7.) and 26 individuals with current neck pain (Age: 55.2 ± 17.2 years; Height: 169.2 ± 7.3 cm; Weight: 73.3 ± 14.4 kg; BMI: 25.6 ± 4.8). Participants with a history of neck pain reported that their last neck pain episode occurred, on average, 56.08 ± 33.72 weeks prior to the assessment. Participants with current neck pain reported a mean pain intensity of 4.3 ± 2.3 out of 10 on the NPRS and a mean disability score of 8.5 ± 4 out of 50 on the NDI.

The overall agreement between CCFT scores obtained with the NOD and the PBU was 94.3% (83 out of 88 CCFT scores). Spearman's rank correlation also revealed a very strong positive association between scores obtained with both devices ($\rho = 0.930$, $p < 0.001$) (Fig. 2).

The linear mixed-effects model showed significant main effects of stage ($F(4,607) = 87.28$, $p < 0.001$) and device

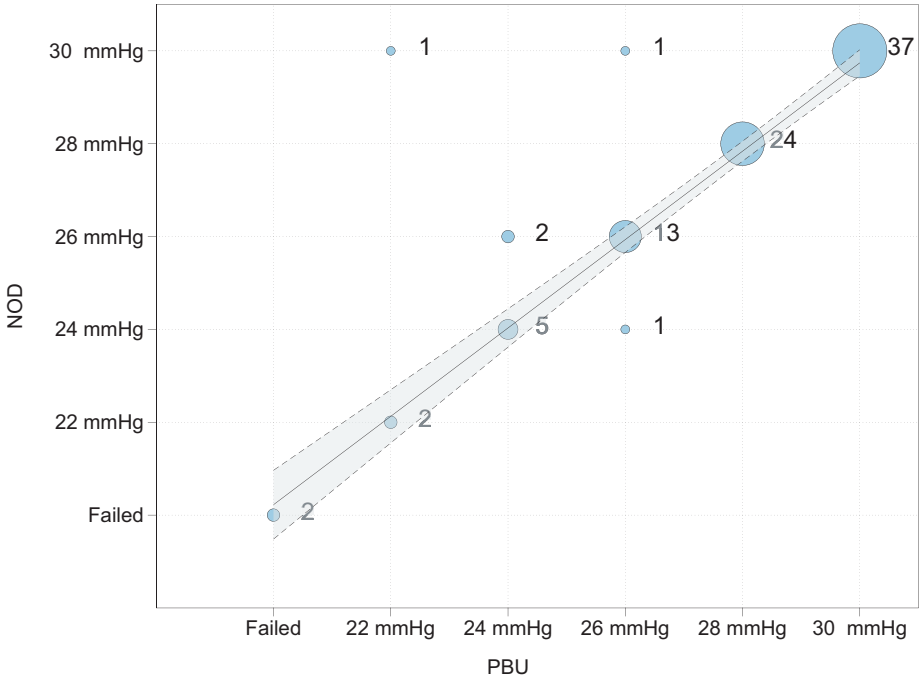

FIGURE 2 - Scatterplot illustrating the relationship between CCFT scores obtained with the NOD and the PBU. Each bubble represents one or more participants (bubble size proportional to frequency). The solid line represents the linear regression fit (NOD = 0.112 + 0.952·PBU), with the shaded band indicating its 95% confidence interval. Abbreviations: CCFT; Cranio-Cervical Flexion Test, NOD; neuromuscular cranio-cervical device, PBU; pressure biofeedback unit.

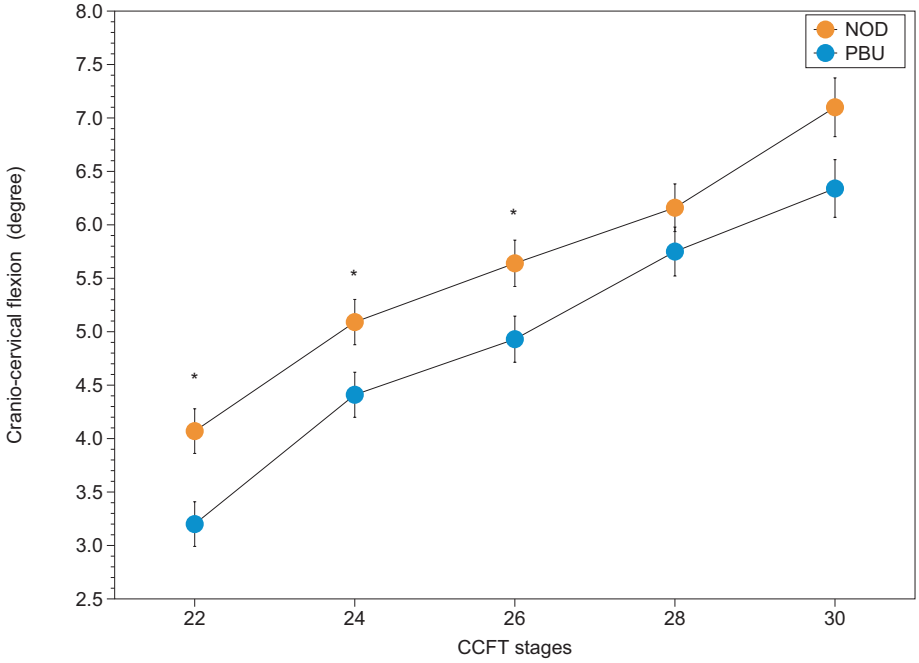

FIGURE 3 - Cranio-cervical flexion (mean ± SE) across CCFT stages for the NOD and the PBU. Use of the NOD resulted in greater ROM at 22, 24, and 26 mmHg ($p < .05$), while measurements converged at higher stages. Asterisks indicate significant between-device differences. Abbreviations: C-CF; cranio-cervical flexion, CCFT; Cranio-Cervical Flexion Test, NOD; neuromuscular cranio-cervical device, PBU; pressure biofeedback unit.

(F(1,600) = 41.46, p < 0.001), whereas the interaction between device and stage was not significant (F(4,600) = 0.55, p = 0.698). Across stages, ROM increased from 3.65° at 22 mmHg to 6.66° at 30 mmHg (estimated marginal means). The NOD produced higher ROM values than the PBU (5.61° vs 4.93°), corresponding to an average difference of 0.68°, indicating that the NOD tended to measure slightly greater C-CF across the full CCFT (Fig. 3). Pairwise comparisons indicated that NOD measured higher ROM than PBU at 22 mmHg (Δ = 0.872°, p < 0.001) and, to a lesser extent, at 24 mmHg (Δ = 0.678°, p = 0.047) and 26 mmHg (Δ = 0.707°, p = 0.048), while no significant differences were observed at 28-30 mmHg (all p ≥ 0.65).

Discussion

The present study demonstrates excellent concurrent validity between the digital NOD device and the traditional PBU in the assessment of the CCFT in a mixed population, including individuals with current neck pain or a history of neck pain. The strong linear association observed between the scores obtained with the two devices (ρ = 0.930, p < 0.001) (37), together with the high level of agreement (93.5%), supports the use of NOD as a valid alternative to the reference device (i.e., PBU) currently employed in clinical practice and research. Notably, the level of agreement observed between the NOD and PBU should be interpreted in light of the existing literature on the measurement properties of the CCFT performed with PBU. Multiple systematic reviews have reported that the reliability of the CCFT is generally acceptable but supported by only moderate-quality evidence and characterized by substantial methodological heterogeneity (20-22). In this context, the agreement observed between the two devices suggests that the variability associated with the use of NOD is unlikely to exceed the intrinsic variability already reported for PBU-based CCFT assessment.

The small proportion of discordant cases observed between the two devices (6.5%) warrants specific consideration. These discrepancies may reflect differences in test execution by some participants, with motor strategies that were not fully comparable between the two testing conditions. Alternatively, they may be related to differences in device sensitivity in detecting the successful completion of progressive CCFT levels, or to variability in the application of clinical evaluation criteria (e.g., identification of compensatory strategies). It is therefore plausible that the observed discordances do not represent true measurement errors, but rather the result of an interaction between participant motor behavior, device characteristics, and clinical judgment.

An additional relevant finding concerns the differences in C-CF ROM observed between the two testing conditions. The linear mixed-effects analysis showed that the NOD measured slightly greater C-CF ROM than the PBU during performance of CCFT, with an average difference of approximately 0.68°. This difference was primarily evident at the lower test stages (22–26 mmHg), whereas no significant differences were observed at higher stages (28-30 mmHg). Importantly, the absence of a significant device × stage interaction indicates that NOD and PBU describe a comparable pattern of ROM progression across the CCFT levels, supporting equivalence between the two devices.

The small systematic differences observed are likely related to the different mechanical characteristics of the device–head interface. Specifically, the greater rigidity of the NOD interface compared to the deformable PBU cuff may alter the mechanical conditions of the task, promoting a predominantly isometric contraction of the deep cervical flexors and resulting in a slightly greater excursion of C-CF.

In contrast, when performing the CCFT with the PBU, the movement occurs against a deformable support that allows ventral displacement of the cervical segments in contact with the cuff, facilitating a slight reduction in the cervical lordosis during task execution.

It should be noted that the kinematic analysis used in the present study captured only global C-CF motion and did not allow assessment of individual cervical segment motion; therefore, it is not possible to determine how these differences were distributed along the cervical spine or to fully elucidate their contribution to the observed ROM differences.

The validation profile of the NOD should be interpreted within the broader context of the known clinimetric characteristics of the CCFT. Systematic reviews have shown that, when performed with a PBU, the CCFT is characterized by moderate reliability and non-negligible measurement error, highlighting intrinsic limitations of the test and of its clinical interpretation rather than of a specific device (20). Although a direct biomechanical equivalence between pressure (mmHg) and force (Newton) cannot be assumed, even after laboratory calibration, both instruments are used to determine the highest CCFT level correctly performed. In this context, the strong correlation observed indicates that the NOD and PBU provide a comparable representation of the progression of the task underlying the CCFT, rather than of a purely biomechanical quantity.

From a visual feedback perspective, the NOD offers a relevant advantage over the analogue PBU manometer. The latter provides limited visual feedback, which is often difficult to interpret for both patients and clinicians and offers limited information regarding force modulation during task execution. In contrast, the large tablet display, which can be used with the NOD, allows clear, immediate, and continuous visualization of the target and performance, facilitating more effective feedback and potentially enhancing motor control during test execution.

Recent studies have proposed different digital and sensor-based solutions aimed at improving the assessment of deep cervical flexor function in the context of the CCFT. Among these, the Spinetrack device has been specifically developed as a potential alternative to the traditional PBU, proposing a chin-in and chin-out task of the upper cervical spine to estimate the force-generating capacity of the deep cervical flexor muscles (38). This approach has demonstrated good test–retest reliability; however, its construct validity with respect to the CCFT and its underlying motor control demands remains to be fully established.

In contrast, other recent studies have focused on the integration of inertial measurement units (IMUs) positioned on the head to complement, rather than replace, the CCFT (39-41). These approaches primarily aim to enhance assessment and training of the deep cervical flexor muscles by providing objective measures of C-CF ROM and real-time kinematic feedback during the task. Importantly, such IMU-based solutions do not propose a substitution of the PBU, but rather an augmentation of the CCFT through additional movement-related information.

Taken together, these developments highlight a growing interest in digital solutions designed to address the practical and clinimetric limitations of analogue instruments (42). While some technologies aim to redefine the task itself (38), others seek to enrich the CCFT by integrating complementary kinematic information (41). In this context, the NOD device represents a further step in this technological evolution by directly targeting the pressure-based paradigm of the CCFT, with the aim of overcoming limitations related to analogue measurement, manual data recording, and limited feedback, while preserving the original task structure and clinical interpretation. As such, the present study contributes to the broader validation needs of novel digital assessment tools emerging in the market to support clinical decision-making and research in the rehabilitation of people with neck pain.

There are some limitations of the present study which should be acknowledged. To ensure maximal standardization of CCFT execution and to avoid variability related to the use of multiple examiners, all assessments were performed by a single operator. Consequently, it was not possible to blind the operator to the test outcome, although this information was not explicitly communicated to participants. Therefore, an unconscious and unintentional influence of outcome awareness on the application of clinical evaluation criteria cannot be excluded.

A further limitation concerns the distribution of CCFT scores, as most participants achieved scores within the normal range, while only a limited number exhibited clear impairment of motor control with low CCFT scores. This skewed distribution limits the generalizability of the findings to populations with more pronounced motor control deficits. Future studies should include more heterogeneous samples, encompassing individuals with greater pain severity and clearly defined motor impairments.

Finally, it should be acknowledged that the CCFT in this study was administered according to how it is assessed in clinical practice, with performance judged from movement quality and device-monitored achievement of each stage rather than from laboratory measures of muscle activity or segmental motion. Consequently, it was not possible to determine whether the NOD and PBU elicited subtle differences in the shape of the cervical lordosis or selective deep cervical flexor activation. Therefore, future research integrating EMG, imaging, or segmental kinematic measurements will be necessary to verify whether comparable neuromuscular activation strategies during the CCFT are seen when using the NOD and the PBU.

Conclusion

This study confirms the concurrent validity of the NOD in the assessment of CCFT performance when compared with the traditional PBU in a mixed population, including individuals with current or previous neck pain. The implementation of NOD may facilitate clinical assessment by improving usability, feedback, and data traceability while maintaining continuity with established CCFT protocols. Further studies are warranted in populations with greater pain severity, as well as investigations addressing inter-rater reliability, to further establish the robustness of the NOD-based CCFT assessment.

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Disclosures

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Author contributions: MB, DF, EC, CC contributed to the conception and design of the study. AB, TN, EF, SP were responsible for patient recruitment and enrollment. DL performed the experiments and contributed to data collection. MB, CC, MG performed the data analysis. MB, DL, MG, CC drafted the manuscript. All authors contributed to the interpretation of the data, critically revised the manuscript for important intellectual content, and approved the final version of the manuscript.

Data availability statement: The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request, subject to ethical and privacy restrictions.

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