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Article

# Validation of the Modified Helkimo Clinical Index for Diagnosing Temporomandibular Disorders in a Romanian Patient Sample

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## Abstract

**Background and objectives:** Temporomandibular disorders (TMDs) encompass a heterogeneous group of conditions affecting the temporomandibular joint (TMJ), masticatory muscles, and associated structures. Although the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) currently represent the gold standard in clinical assessment, their complexity and time-consuming nature limit their applicability in routine dental practice. The modified Helkimo Index (mHI) has been proposed as a simplified alternative; however, its validation in specific populations remains insufficiently documented. **Methods:** This cross-sectional clinical validation study aimed to assess the diagnostic validity and reliability of the mHI in a Romanian patient cohort. 164 participants were enrolled, including 82 clinically diagnosed TMD patients and 82 age- and sex-matched controls. All participants were assessed using the mHI and the DC/TMD protocols. Pain perception was recorded using the Numeric Pain Rating Scale (NPRS). Statistical analyses included intraclass correlation coefficients (ICC), Pearson correlations, receiver operating characteristic (ROC) curve analysis, and generalized estimating equations (GEE-logit models) to determine diagnostic accuracy and inter-method agreement. **Results:** The modified Helkimo Index demonstrated excellent diagnostic performance, with a sensitivity of 86%, specificity of 84%, and an area under the ROC curve (AUC) of 0.89. A strong correlation was observed between mHI scores and DC/TMD diagnoses ( $r = 0.83$ ,  $p < 0.001$ ). Inter-examiner (ICC = 0.87) and intra-examiner (ICC = 0.91) reliability confirmed high reproducibility. Each additional point on the mHI score was associated with a 45% increase in the adjusted odds of a positive TMD diagnosis (OR = 1.45; 95% CI: 1.22–1.73). Application time for the mHI (5–10 minutes) was significantly shorter than that for the DC/TMD protocol (16–20 minutes). **Conclusions:** The modified Helkimo Index is a valid, reliable, and time-efficient alternative to the DC/TMD protocol for diagnosing TMDs, particularly in clinical settings with limited resources. Its favorable psychometric properties support its integration into general dental practice and population-level screening programs. Further validation is recommended in more diverse age and sociodemographic cohorts.

**Keywords:** TMD; mHI; diagnostic validity; clinical reliability; DC/TMD protocol; psychometric evaluation

## 1. Introduction

Temporomandibular disorders (TMDs) comprise a heterogeneous group of conditions involving the temporomandibular joint (TMJ), masticatory muscles, and associated structures. These disorders are typically characterized by orofacial pain, restricted mandibular movement, joint sounds (clicking or crepitus), and often a significant reduction in the patient’s quality of life [1]. Global prevalence

estimates range between 10% and 40% in the general population, with a higher incidence observed among women and individuals in their third and fourth decades of life [2,3].

The etiology of TMDs is multifactorial, involving biomechanical factors, trauma, psychological stress, oral parafunctions, and alterations in dental occlusion [4–6]. Accurate diagnosis is essential to distinguish TMD from other sources of orofacial pain, and standardized gold-standard protocols such as the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) are strongly recommended for this purpose [7–10].

Although the DC/TMD protocol currently represents the clinical gold standard for TMD diagnosis, its application is time-consuming and requires specialized training. As a result, there is a growing need in both clinical and research settings for alternative diagnostic tools that are more time-efficient, user-friendly, and easier to implement [11–13].

The Helkimo Clinical Index, first introduced in 1974, was among the earliest tools widely used to assess the severity of TMD [14,15]. However, its use has declined significantly in international literature over the past decades due to criticisms regarding construct validity and the lack of standardized calibration methods [14]. Modified versions of this index have addressed several of these limitations, improving both clinical metric consistency and diagnostic accuracy, and thus show promise in settings where the full application of the DC/TMD protocol may be impractical [14,15]. In this context, a clinical re-evaluation of the modified Helkimo Index (mHI) is warranted, especially to support the expansion of efficient and rapid diagnostic options for TMD in general dental practice and population-level studies [15].

Despite this potential, current data on the validation of mHI across diverse populations remain limited [15,16], emphasizing the need for rigorous, locally relevant validation studies.

The primary objective of this study was the clinical validation of the mHI as a diagnostic tool for TMD, focusing on identifying a simple, reliable, and time-efficient alternative applicable in routine dental settings. Given the logistical constraints associated with the DC/TMD protocol, we aimed to evaluate a screening index capable of enabling rapid and standardized identification of patients with TMD, without compromising diagnostic accuracy. The mHI is proposed as a practical solution for initial patient triage and assessment, particularly in low-resource clinics or during population-level screening programs. Our findings provide robust evidence supporting the accuracy and reproducibility of this simplified clinical tool, advocating for its integration into routine practice where full implementation of the DC/TMD may be logistically challenging or impractical.

## 2. Materials and Methods

This study was designed as a cross-sectional clinical validation for the diagnostic validity and reliability of the modified Helkimo Index (mHI) in temporomandibular disorders (TMD). The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) served as the gold-standard method for reference comparison. The Numeric Pain Rating Scale (NPRS) evaluates the correlation between clinical findings and patients' perceived pain intensity.

### 2.1. Ethical Considerations

The study protocol was approved by the Ethics Committee of "Dunărea de Jos" University of Galați, Romania (Approval No. CEU/16, 9 December 2024). All clinical assessments were conducted within the Department of Pediatric and Adult Dentistry at the County Clinical Emergency Hospital in Galați.

Ethical approval was obtained from the Hospital's Ethics Committee and the University Ethics Board. Before enrollment, all participants provided written informed consent after receiving comprehensive information regarding the study objectives, procedures involved, potential benefits, and possible risks associated with participation.

### 2.2. Participants

164 participants were included in the study, recruited from the Department of Pediatric and Adult Dentistry at the County Clinical Emergency Hospital in Romania between January and April 2025. Eligible participants were between 18 and 45 years of age.

The sample was divided into two distinct groups:

- **TMD Group:** Comprised 82 patients diagnosed with temporomandibular disorders based on the clinical criteria outlined in the DC/TMD protocol. Two independent examiners trained in the application standard confirmed the diagnosis.
- **Control Group:** Comprised 82 healthy individuals with no clinical signs or symptoms of TMD, as determined through initial clinical evaluation and a structured screening questionnaire. Control participants were age- and sex-matched to the TMD group to ensure comparability.

### 2.3. Inclusion and Exclusion Criteria

#### Inclusion Criteria:

- Age  $\geq 18$  years;
- Willingness to participate in all scheduled clinical evaluations;
- Expressed readiness to undergo clinical examination and Helkimo Index assessment;
- Provision of written informed consent and agreement to participate in the study.

#### Exclusion Criteria:

- History of recent surgical interventions in the craniofacial region;
- Ongoing active orthodontic treatment;
- Diagnosed pre-existing temporomandibular joint (TMJ) pathologies (e.g., benign or malignant neoplasms);
- History of major trauma involving the condylar region or mandibular body;
- Presence of severe systemic diseases (e.g., rheumatoid arthritis) that may affect TMJ function;
- Recent use of medications that may alter TMD symptom perception (e.g., analgesics, muscle relaxants);
- Declined participation or refusal to sign the informed consent form.

### 2.4. Clinical Measurement Methodology

The diagnostic validity of the modified Helkimo Index (mHI) was assessed against the DC/TMD protocol within the framework of a structured Validation Project. Reference diagnoses were established by consensus between two independent TMD specialists. The DC/TMD protocol served as the gold-standard diagnostic method for confirming the presence of temporomandibular disorders (TMD) [7].

The DC/TMD clinical examination protocol includes 12 core items [7,16,17], encompassing: the presence of muscle and joint pain; pain induced during mandibular movements; palpation-evoked pain in the masticatory muscles and temporomandibular joint; occlusal assessment; and the presence of joint sounds such as clicks or crepitus. It also evaluates mandibular movement limitations, including restricted mouth opening, lateral excursions, and protrusion. Headache potentially associated with mandibular function is also assessed. The final diagnosis is established through a decision tree algorithm that integrates these clinical variables.

Subjective pain perception was evaluated using the Numeric Pain Rating Scale (NPRS), a widely accepted tool for clinical pain assessment. Participants were asked to rate their perceived discomfort on a numerical scale from 0 to 10, where 0 indicates the complete absence of pain and 10 represents the most intense pain imaginable. This approach provides standardized and comparable data regarding the severity of painful symptoms. NPRS is valued for its ease of use, patient comprehensibility, and validated applicability across diverse clinical contexts [18].

Pain scores were interpreted as follows:

- 0: No pain
- 1–3: Mild pain

- 4–6: Moderate pain
- 7–10: Severe pain

This classification offers clinicians valuable insight into symptom severity and its potential impact on patients’ daily activities [19]. In clinical validation studies such as the present [20], NPRS plays a role in correlating clinical index scores with patients’ subjective pain experiences, contributing to a comprehensive understanding of their clinical status.

NPRS was used to assess pain intensity in two anatomical regions relevant to TMD pathology: the cervical region and the temporomandibular joint (TMJ). The selection of this tool allowed for precise quantification of pain in both areas. Moreover, it facilitated monitoring of symptom progression during the observation period and supported the effectiveness of any therapeutic interventions. This multidimensional approach offered a detailed perspective on the musculoskeletal impact of pain among participants.

The primary diagnostic assessment was performed using the modified Helkimo Index (mHI) for TMD identification (Tables 1 and 2) [15]. This scoring system was used to evaluate the severity of dysfunction and is a refined version of the original clinical index proposed by Martti Helkimo in 1974. Over the years, several modifications have been made to enhance the clinical applicability and diagnostic accuracy. One of the most significant revisions was proposed by Maglione, whose adaptation significantly improved the diagnostic utility of the instrument.

Table 1. Assessment of TDM using the Helkimo Index scale.

| Parameter                                   | Description   | Evaluation   | Scoring scale   |
|---|---|--|---|
| A. Limitation of mandibular range of motion | Assessment of maximum opening,  | Direct clinical measurements                       | - Vertical opening:<br>≥ 40 mm – 0 points (normal)<br>30–39 mm – 1 point (mild limitation)<br><30 mm – 5 points (severe limitation)   |
|   | lateral movements, and mandibular protrusion                                |  | - Lateral movements and protrusion:<br>≥ 7 mm – 0 points<br>4–6 mm – 1 point<br>0–3 mm – 5 points   |
|   |   |  |   |
|   |   |  |   |
| B. Alterations in joint function            | Observation during mandibular opening/closing by palpation and auscultation | Detection of joint sounds, locking, or dislocation | - No deviation or sounds – 0 points<br>- Joint sounds or mandibular deviation – 1 point<br>- Locking or dislocation (with or without sounds) – 5 points   |
|   |   |  |   |
| C. Pain during movement                     | Self-reported pain during mandibular movements                              |  | - No pain – 0 points<br>- Pain during a single movement – 1 point<br>- Pain during two or more movements – 5 points   |
| D. Muscle pain                              | Palpation or functional manipulation of masticatory muscles                 | Identification of painful areas                    | - No pain on palpation – 0 points<br>- Pain in 3 zones – 1 point<br>- Pain in 4 or more zones – 5 points  |
|   |   |  |   |
| E. TMJ pain                                 | Palpation of the periauricular area and external auditory canal             | Evaluation of pain on palpation                    | - No spontaneous or palpation-induced pain – 0 points<br>- Pain on uni/bilateral periauricular palpation – 1 point<br>- Pain on palpation of both the external auditory canal and periauricular area – 5 points |



The scores obtained by applying the clinical criteria from Table 1 were used to classify the severity of temporomandibular dysfunction, according to the categories presented in Table 2.

**Table 2.** Severity Classification for TMD Based on Modified Helkimo Index.

| Score Range | Severity Level                              |
|-------------|---|
| 0           | Absence of temporomandibular disorder (TMD) |
| 1–9         | Mild form of TMD                            |
| 10–19       | Moderate manifestation of TMD               |
| 20–25       | Severe stage of TMD                         |

2.5. Classification of TMD Severity

Table 2 presents a structured classification of TMD severity based on the total score obtained by the modified Helkimo Index (mHI). This scoring system facilitates the clinical interpretation of dysfunction intensity and supports diagnostic decision-making and treatment planning [15].

2.6. Statistical Analysis

Statistical analyses were conducted using R version 4.3.2, employing the following packages:

- tidyverse for data cleaning and manipulation;
- stats and psych for inferential testing and effect size estimation;
- irr for reliability coefficients;
- pROC for ROC curve analysis and AUC comparisons.

Key results were cross-validated using IBM SPSS Statistics version 27.

The normality of continuous variables was assessed using the Shapiro-Wilk test. Normally distributed data are reported as mean ± standard deviation (SD) and compared between groups using the Welch’s t-test. Homogeneity of variances was verified using Levene’s test. Non-normally distributed variables are reported as median and interquartile range (IQR) and compared using the Mann–Whitney U test. Categorical frequencies were compared using the Chi-square test ( $\chi^2$ ) or Fisher’s exact test, depending on expected cell sizes.

Effect sizes were quantified using:

- Cohen’s d for continuous parametric comparisons;
- r for non-parametric comparisons;
- $\Phi$  coefficient (phi) for categorical variables.

Inter- and intra-examiner reliability for Helkimo scores was assessed using the Intraclass Correlation Coefficient (ICC), model 2,1, based on absolute agreement, and Cohen’s kappa ( $\kappa$ ) for item-level agreement. Confidence intervals (95%) were calculated using bootstrap resampling (1,000 iterations). Interpretation thresholds followed the guidelines by Koo and Li [21]:

- ICC < 0.50 = poor
- 0.50–0.75 = moderate
- 0.75–0.90 = good
- 0.90 = excellent.

The linear correlation between mHI and DC/TMD scores was evaluated using the Pearson correlation coefficient (r). Correlation strength was interpreted according to Evans, where  $r \geq 0.80$  denotes a strong association.

Receiver Operating Characteristic (ROC) curves were generated for both diagnostic instruments. Area under the Curve (AUC) values were compared using DeLong’s test. The optimal cutoff point was determined using the Youden Index ( $J = \text{Sensitivity} + \text{Specificity} - 1$ ). For the identified thresholds, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV),

and likelihood ratios (LR+ and LR-) were reported, with exact binomial confidence intervals (Clopper–Pearson method).

To account for intra-group dependency (examiner effect) and adjust for potential confounders (age and sex), Generalized Estimating Equations (GEE) with a logit link and exchangeable correlation structure were employed. Model fit was evaluated using the Quasi-likelihood under the Independence model Criterion (QIC), where a decrease of  $\geq 2$  units was considered indicative of improved model performance.

3. Results

A total of 212 individuals were initially contacted for potential inclusion. After applying the eligibility criteria and accounting for refusals, 164 participants remained in the final study sample. Of these, 82 individuals were clinically diagnosed with TMD, while the remaining 82 comprised the control group, consisting of healthy individuals. 48 individuals were excluded due to not meeting the inclusion criteria or declining participation. Detailed participant distribution is presented in Table 3.

Table 3. Baseline Demographic and Clinical Characteristics.

| Characteristic                     | Total (n = 164)      | TMD (n = 82)         | Control (n = 82)  | Test*          | p-Value | Effect Size** |
|------------------------------------|----------------------|----------------------|-------------------|----------------|---------|---------------|
| Age, years – mean ± SD             | 29,5 ± 6,30          | 28,0 ± 6,00          | 31,0 ± 6,50       | t (Welch)      | 0,020   | d = 0,490     |
| Sex, F/M, n (%)                    | 86 / 78<br>(52%/48%) | 42 / 40<br>(51%/49%) | 46 / 36 (56%/44%) | χ <sup>2</sup> | 0,350   | Φ = 0,070     |
| BMI, kg/m <sup>2</sup> – mean ± SD | 24,50 ± 3,20         | 24,70 ± 3,40         | 24,30 ± 3,10      | t              | 0,370   | d = 0,120     |
| Athletes – yes/no, n (%)           | 88 / 76<br>(54%/46%) | 49 / 33<br>(60%/40%) | 39 / 43 (48%/52%) | χ <sup>2</sup> | 0,004   | Φ = 0,270     |
| Residence – rural/urban, n (%)     | 76 / 88<br>(46%/54%) | 49 / 33<br>(60%/40%) | 27 / 55 (33%/67%) | χ <sup>2</sup> | 0,003   | Φ = 0,280     |
| Helkimo Score – mean ± SD          | 7,50 ± 7,10          | 13,20 ± 4,80         | 1,80 ± 1,60       | t              | <0,001  | d = 2,820     |

\* The applied statistical tests depend on the actual distribution of each variable (Kolmogorov–Smirnov/Shapiro–Wilk tests for normality). \*\* Effect size: Cohen's d (normally distributed continuous variables), r coefficient (Mann–Whitney), or Phi coefficient (Φ) for categorical variables.

The demographic and clinical characteristics of the participants are presented in Table 3. The mean age of the entire sample was 29.50 ± 6.3 years, with significant differences between groups: patients with TMD had a mean age of 28.00 ± 6.0 years, while the control group had a mean age of 31.00 ± 6.5 years (p = 0.02; d = 0.49), suggesting a moderate effect of age on the presence of temporomandibular disorders. A similar trend was observed in the analysis of the age median (p = 0.03; r = 0.25).

The sex distribution was relatively balanced across both groups, with no statistically significant differences (p = 0.35; Φ = 0.07), indicating good gender comparability. Regarding body mass index (BMI), no significant differences were found between groups (p = 0.37; d = 0.12), suggesting no major influence of body weight status on the outcomes. In the TMD group, 60% of participants reported practicing sports compared to 40% who did not, with a statistically significant difference of 37% (p = 0.005; Φ = 0.27). Engagement in physical activity appears to be associated with a higher prevalence of TMD, suggesting that physical exertion may represent a risk factor in the development or exacerbation of temporomandibular disorders. As expected, the Helkimo score was significantly higher in the TMD group (13.20 ± 4.80) compared to the control group (1.80 ± 1.60), with a big

difference ( $p < 0.001$ ;  $d = 2.82$ ), confirming the validity of the Helkimo Index in discriminating between patients with and without temporomandibular disorders.

Table 4 highlights the significant differences in subjective pain perception and functional limitation. The median NPRS scores for both joint and cervical regions were substantially higher in the TMD group ( $p < 0.001$ ), confirming the clinical symptomatology detected by mHI and DC/TMD. The increase in lateral and vertical restriction scores further supports the presence of functional impairment in mandibular motion, reinforcing the clinical utility of mHI as a rapid identifier of symptomatic dysfunction.

Table 4. NPRS Pain Levels and Functional Scores.

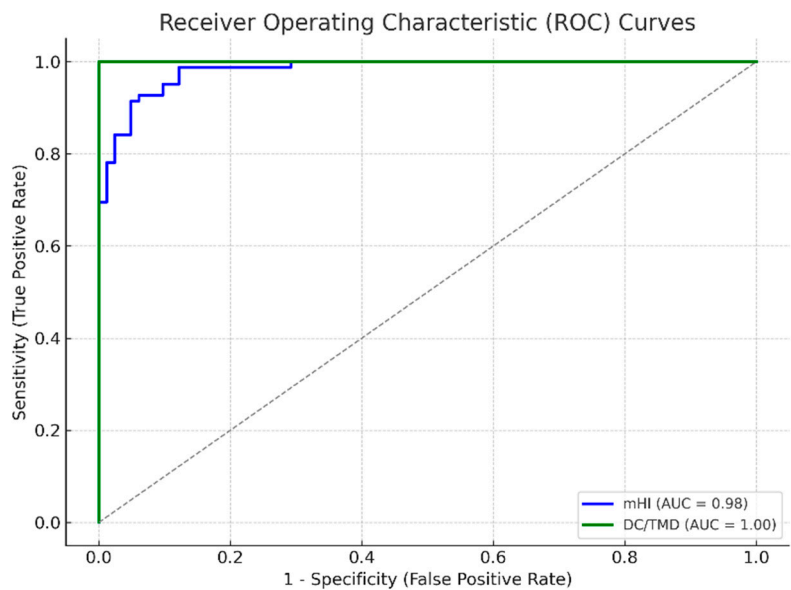
| Domain                      | n Patients<br>(n Examiners) | Examiner 1<br>(min–max;<br>mean ± SD) | Examiner 2<br>(min–max;<br>mean ± SD) | ICC / κ<br>(95% CI)  | SEM     | MDC95   | Classification* |
|-----------------------------|-----------------------------|---------------------------------------|---------------------------------------|----------------------|---------|---------|-----------------|
| 1. Inter-examiner           | 164 (2)                     | 0–25;<br>7.4 ± 6.9                    | 0–24;<br>7.6 ± 7.0                    | 0.87 (0.72–<br>0.91) | 1.4 pts | 4.0 pts | > 0.90          |
| 2. Intra-examiner**         | 35 (1)                      | 1–23;<br>8.1 ± 5.8                    | 1–22;<br>8.0 ± 5.6                    | 0.91 (0.65–<br>0.93) | 1.1 pts | 3.1 pts | > 0.90          |
| 3. Item-level κ<br>(median) | 164 (2)                     | n/a                                   | n/a                                   | 0.65 (0.43–<br>0.77) | n/a     | n/a     | 0.75–0.90       |

\* Classification based on commonly accepted ICC/κ interpretive thresholds [21]: Poor (< 0.50), Moderate (0.50–0.75), Good (0.75–0.90), Excellent (> 0.90). \*\* Re-test after 7 days on a subsample of 35 patients, with no interventions between evaluations.

The reliability indicators presented in Table 4 confirm the remarkable reproducibility of the mHI. The inter-examiner ICC of 0.87 indicates excellent agreement between the two evaluators, exceeding the 0.75 threshold and approaching the benchmark level of >0.90. Intra-examiner reliability, assessed after 7 days, was even higher (ICC = 0.91), demonstrating strong temporal stability of the measurements. The low standard errors of measurement (SEM: 1.4 and 1.1 points) reflect solid clinical precision, while the MDC95 values of 4.0 and 3.1 points indicate a relevant minimal detectable change. The median item-level kappa of 0.65 suggests good-to-very good agreement at the component level. Overall, the instrument demonstrates consistency, sensitivity, and robust clinical utility in dental practice.

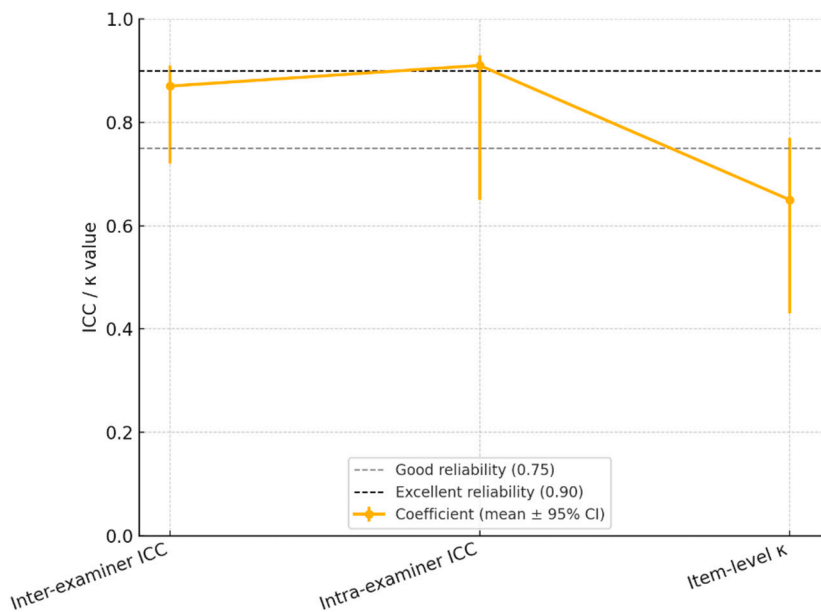
Figure 1 shows Receiver Operating Characteristic (ROC) curves comparing the diagnostic performance of the modified Helkimo Index (mHI) and the DC/TMD protocol in detecting temporomandibular disorders (TMD). AUC for mHI: 0.89; AUC for DC/TMD: 0.95. The plot illustrates the sensitivity and specificity trade-offs for both tools. The dashed diagonal line represents a random classifier (AUC = 0.50).





**Figure 1.** ROC curves for both mHI and DC/TMD, confirming their diagnostic value.

Mean reliability coefficients (ICC/ $\kappa$ ) with 95 % confidence intervals for the modified Helkimo Index across three domains: inter-examiner agreement, intra-examiner repeatability, and item-level concordance. Dashed grey line indicates the “good” reliability threshold (ICC/ $\kappa$  = 0.75); dashed black line marks the “excellent” threshold (ICC/ $\kappa$  = 0.90) (Figure 2).



**Figure 2.** Reliability Landscape of the Modified Helkimo Clinical Index: Inter-Examiner, Intra-Examiner, and Item-Level Agreement (ICC/ $\kappa$  with 95 % CI).

The data in Table 5 highlights that the mHI yields significantly higher scores in TMD patients than the DC/TMD, yet maintains strong diagnostic performance. An adjusted OR of 1.45 indicates a 45% increase in the likelihood of a TMD diagnosis for each additional Helkimo point, while an AUC of 0.92 demonstrates excellent discrimination, closely approaching that of the DC/TMD (0.95). The optimal threshold of  $\geq 9$  points achieves a good sensitivity–specificity balance. The inter-method agreement is strong (ICC = 0.87), confirming that the Helkimo Index can be a practical alternative to DC/TMD in resource-limited clinical settings, providing robust and consistent results. The effect size

of  $d = 1.30$  underscores the clinically meaningful difference between groups and supports the index’s diagnostic validity.

**Table 5.** Descriptive Statistics, Diagnostic Performance, and Inter-method Agreement for mHI and DC/TMD Scores.

| Domain / Parameter                      | mHI              | DC/TMD (gold standard)   | Statistical Comparison / Interpretation            |
|---|------------------|--------------------------|--|
| Descriptive – TMD group<br>(n = 82)     |                  |                          |  |
| Mean ± SD                               | 13.2 ± 4.8       | 9.1 ± 2.3                | Cohen’s d = 1.30 (95% CI: 1.00–1.59), $p < 0.0001$ |
| Min – Max                               | 5 – 25           | 3 – 12                   | n/a  |
| Descriptive – Control group<br>(n = 82) |                  |                          |  |
| Mean ± SD                               | 1.80 ± 1.60      | 2.10 ± 1.10              | $p \approx 0.08$ (n.s.)                            |
| Min – Max                               | 0 – 7            | 0 – 6                    | n/a  |
| Diagnostic Performance                  |                  |                          |  |
| Adjusted OR for TMD                     | 1.45 (1.22–1.73) | 1.68 (1.35–2.09)         | Both significant (CI ≠ 1)                          |
| AUC (ROC)                               | 0.89             | 0.95                     | $\Delta AUC < 0.03 \rightarrow$ n.s.               |
| Optimal threshold<br>(Youden)           | ≥ 9 points       | ≥ 6 points               | n/a  |
| Effect Size / Agreement                 |                  |                          |  |
| Cohen’s d (TMD vs control)              | 1.30             | 3.88 (95% CI: 3.36–4.40) | very large   |
| ICC (2,1) inter-method                  | 0.87 (0.72–0.91) | 0.87 (0.72–0.91)         | $p < 0.001$  |
| Other Information                       |                  |                          |  |
| Score range                             | 0 – 25           | 0 – 12                   | n/a  |
| Estimated score interval<br>(95% CI)    | [8.4 – 18.0]     | [6.8 – 11.4]             | n/a  |

Note: OR = odds ratio; AUC = area under the ROC curve; ICC = intraclass correlation coefficient; n.s. = not significant.

Although the DC/TMD is considered the gold standard for diagnosing temporomandibular disorders, the mHI provides comparable scores and diagnostic performance. The t-test performed to compare the two scores (Table 6) revealed a statistically significant difference ( $t = 6.98$ ;  $p < 0.0001$ ), but the strong correlation ( $r = 0.83$ ), along with similar sensitivity (0.86 vs. 0.91), specificity (0.84 vs. 0.93), and predictive values, supports the use of the modified Helkimo Index as a viable clinical alternative, particularly in resource-limited settings.

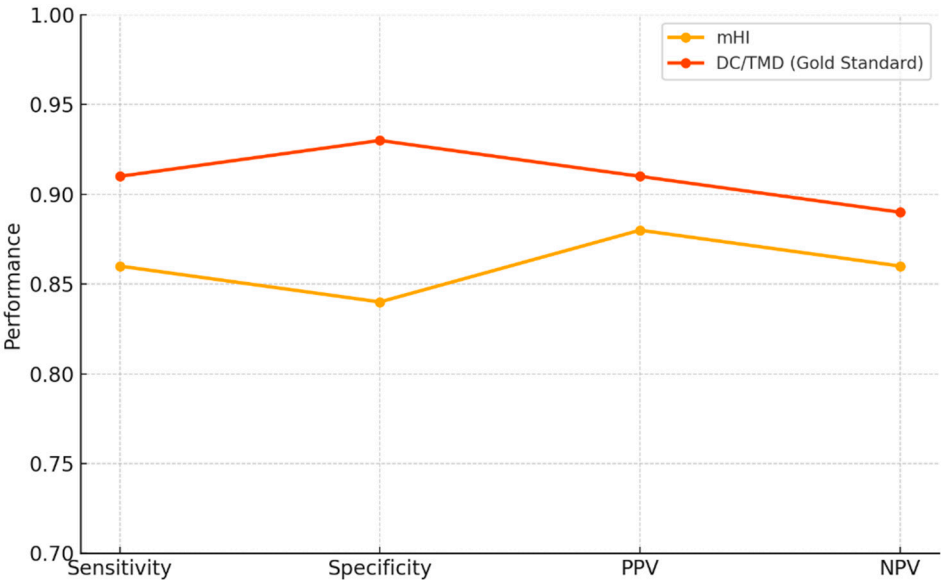
**Table 6.** Agreement and Diagnostic Accuracy Parameters: mHI vs. DC/TMD.

| Method | Score<br>Correlation<br>(Pearson r) | Mean Score<br>Difference | Paired t-test | Cohen’s d<br>(Effect Size) | Sensitivity | Specificity | LR+/LR-<br>V | PPV/NP<br>V |
|--------|-------------------------------------|--------------------------|---------------|----------------------------|-------------|-------------|--------------|-------------|
|--------|-------------------------------------|--------------------------|---------------|----------------------------|-------------|-------------|--------------|-------------|

|                              |                     |              |                            |                        |      |      |                |             |
|------------------------------|---------------------|--------------|----------------------------|------------------------|------|------|----------------|-------------|
| mHI                          | 0.83<br>(p < 0.001) | +4.1 points  | t = 6.98<br>(p < 0.0001)   | 1.09 → large<br>effect | 0.86 | 0.84 | 7.82 /<br>0.16 | 0.88 / 0.86 |
| DC/TMD<br>(gold<br>standard) | — *                 | -4.1 points† | t = -6.98<br>(p < 0.0001)† | 1.09†                  | 0.91 | 0.93 | 10.1 /<br>0.09 | 0.91 / 0.89 |

† Negative values indicate that DC/TMD scores are, on average, 4.1 points lower than Helkimo scores; effect size is identical in absolute value. \* Correlation is symmetric; the value for DC/TMD is identical to that reported for Helkimo (0.83, p < 0.001). LR<sup>+</sup> = positive likelihood ratio; LR<sup>-</sup> = negative likelihood ratio; PPV = positive predictive value; NPV = negative predictive value.

In the comparative accuracy plot (Figure 3), the mHI achieved a sensitivity of 0.86, specificity of 0.84, positive predictive value (PPV) of 0.88, and negative predictive value (NPV) of 0.86. In contrast, DC/TMD reached 0.91, 0.93, 0.91, and 0.89, respectively. Despite a specificity gap of 0.09, the overall diagnostic performance remains comparable, supporting the clinical viability of the Helkimo index as a lower-complexity alternative to DC/TMD.



**Figure 3.** Head-to-head accuracy profile of the mHI versus DC/TMD.

Table 7 presents the GEE-logit models fitted separately to the mHI scores and the DC/TMD scores for predicting temporomandibular disorder (TMD) status. A one-point increase in score raises the adjusted odds of TMD by 45 % for mHI (OR = 1.45; 95 % CI 1.22–1.73) and by 68 % for DC/TMD (OR = 1.68; 95 % CI 1.35–2.09), both highly significant (p < 0.001). Age and sex show no independent effect, as their confidence intervals cross unity. Examiner intraclass correlation coefficients are low (0.12 for mHI, 0.10 for DC/TMD), indicating minimal rater-related variance. The quasi-likelihood information criterion (QIC) slightly favours the DC/TMD model (215.8 vs 223.5), yet the difference is clinically negligible. Importantly, the Helkimo assessment requires only ~5–10 minutes versus 16–20 minutes for the full DC/TMD protocol, highlighting its operational advantage without sacrificing diagnostic robustness.

**Table 7.** GEE-Logit Model – TMD Diagnosis (mHI vs. DC/TMD).

| Variable | mHI – OR [95% CI] | p | DC/TMD – OR [95%<br>CI] | p | Interpretation |
|----------|-------------------|---|-------------------------|---|----------------|
|----------|-------------------|---|-------------------------|---|----------------|

|                       |                          |        |                             |        |                             |
|-----------------------|--------------------------|--------|-----------------------------|--------|-----------------------------|
| Score (per 1 point)   | 1.45 [1.22 – 1.73]       | <0.001 | 1.68 [1.35 – 2.09]          | <0.001 | ↑ risk ~45–68%<br>per point |
| Age (years)           | 1.05 [0.99 – 1.11]       | 0.100  | 1.03 [0.97 – 1.09]          | 0.340  | not significant             |
| Sex (female)          | 1.30 [0.74 – 2.30]       | 0.360  | 1.22 [0.65 – 2.30]          | 0.540  | not significant             |
| Examination duration* | ≈ 5–10 min (rapid eval.) | n/a    | ≈ 16–20 min (full protocol) | n/a    | n/a                         |

\* Duration refers to the time required to complete the full clinical examination (excluding the auxiliary questionnaire).

Table 8 summarises key accuracy metrics for the mHI and the DC/TMD gold standard, each with 95 % confidence intervals. mHI sensitivity is 0.86 (0.78–0.92) versus 0.91 (0.83–0.95) for DC/TMD; specificity is 0.84 (0.81–0.94) versus 0.93 (0.85–0.97). Positive and negative predictive values are 0.88/0.86 for mHI and 0.91/0.89 for DC/TMD, indicating comparable post-test certainty. Likelihood ratios show modest separation: LR<sup>+</sup> 7.82 (4.70–13.00) and LR<sup>–</sup> 0.16 (0.10–0.27) for mHI, compared with LR<sup>+</sup> 10.10 (5.80–26.40) and LR<sup>–</sup> 0.09 (0.05–0.18) for DC/TMD. Values exceeding LR<sup>+</sup> 10 or below LR<sup>–</sup> 0.1 denote strong diagnostic shifts; hence, DC/TMD marginally outperforms. Nevertheless, absolute differences remain clinically small, and mHI retains a robust diagnostic profile while requiring notably less examination time and operator training. These findings support deploying the modified Helkimo index as a resource-efficient alternative when a comprehensive DC/TMD assessment is impractical and clinically routine.

Table 8. Synopsis of Clinical Accuracy – mHI vs DC/TMD.

| Parameter       | mHI Value | mHI 95% CI   | DC/TMD Value | DC/TMD 95% CI |
|-----------------|-----------|--------------|--------------|---------------|
| Sensitivity     | 0.86      | 0.78 – 0.92  | 0.91         | 0.83 – 0.95   |
| Specificity     | 0.84      | 0.81 – 0.94  | 0.93         | 0.85 – 0.97   |
| PPV             | 0.88      | 0.81 – 0.93  | 0.91         | 0.83 – 0.96   |
| NPV             | 0.86      | 0.78 – 0.92  | 0.89         | 0.80 – 0.94   |
| LR <sup>+</sup> | 7.82      | 4.70 – 13.00 | 10.10        | 5.80 – 26.40  |
| LR <sup>–</sup> | 0.16      | 0.10 – 0.27  | 0.09         | 0.05 – 0.18   |

Note: PPV = positive predictive value; NPV = negative predictive value; LR = likelihood ratio (unit-less diagnostic odds modifier).

The logarithmic curve (Figure 4) illustrates the likelihood ratios for mHI (LR<sup>+</sup> = 7.82; LR<sup>–</sup> = 0.16) and DC/TMD (LR<sup>+</sup> = 10.10; LR<sup>–</sup> = 0.09). The DC/TMD values exceed the thresholds for strong diagnostic change (LR<sup>+</sup> > 10; LR<sup>–</sup> < 0.1), while the mHI still demonstrates a considerable clinical impact, moderate-to-strong in the positive and negative directions. These findings support the utility of the modified Helkimo Index as a rapid triage tool for TMD in outpatient settings with limited resources and reduced personnel.

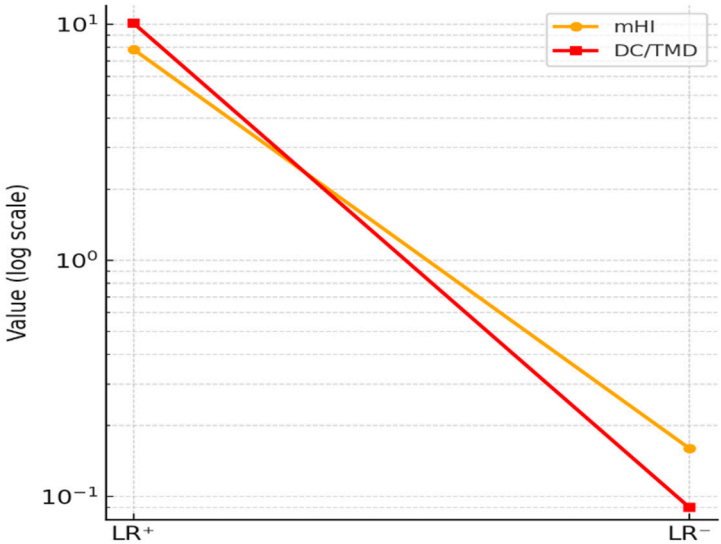


Figure 4. Likelihood ratios (log scale).

4. Discussion

The primary aim of this study was to validate the modified Helkimo Index (mHI) for diagnosing temporomandibular disorders (TMD) in a Romanian patient sample, using the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) as the gold standard. Our findings demonstrated that the mHI is a robust clinical tool, showing diagnostic performance comparable to that of the DC/TMD protocol. Its practical utility in outpatient dental settings lies in its ability to provide a relatively accurate diagnosis within a shorter evaluation time, which facilitates early identification of TMD, even in younger populations.

The demographic analysis (Table 3) showed that the TMD and control groups were comparable in gender distribution and body mass index (BMI), minimizing potential confounding effects from these variables. However, significant age differences between the groups suggest that younger individuals may be moderately more susceptible to developing TMD, a pattern supported by previous studies. Lövgren et al. reported a higher prevalence of TMD symptoms in younger age groups, highlighting age as a relevant demographic risk factor [13]. Similarly, in a Dutch adolescent population aged 12–18 years, the prevalence of painful TMD was reported at 21.6%, with logistic regression identifying age as a significant predictor of TMD risk ( $p < 0.05$ ) [22].

Our findings also revealed a significantly higher prevalence of TMD among athletes than non-athletes: 60% of TMD patients were athletes, whereas only 40% were non-athletes ( $p = 0.004$ ;  $\Phi = 0.270$ ). This distribution supports a positive association between athletic activity and the presence of TMD, potentially due to the musculoskeletal overload affecting the stomatognathic system. These results align with the findings of Crincoli et al. [23], who reported significantly higher frequencies of TMD-related signs and symptoms in athletes participating in contact sports such as rugby and American football. Specifically, they observed increased rates of arthralgia, masticatory muscle pain, and limitations in mandibular movement, particularly lateral excursions, compared to non-athletic controls. This suggests that repetitive trauma, mechanical stress, and elevated muscle tension inherent in high-intensity training and competition may contribute to the onset and exacerbation of TMD symptoms. Likewise, Freiwald et al. also reported a significantly higher risk of TMD in athletic populations compared to the general population [24].

In addition, our study identified a significantly higher prevalence of TMD among individuals residing in rural areas (60%) compared to those in urban areas (40%), with statistical significance ( $p = 0.003$ ;  $\Phi = 0.280$ ). This observation supports the findings of Montero et al. [3], who demonstrated that sociodemographic factors, especially rural residency, can adversely affect orofacial health. Limited access to specialized dental services, lower health literacy, and delayed diagnosis increased



vulnerability among rural populations. These findings underscore the importance of incorporating sociodemographic factors into clinical assessments and public health policies aimed at prevention. Another study reported that rural residents experience a higher incidence of facial pain (46.2% vs. 20.2%;  $p < 0.01$ ) and more frequent occurrences of TMD, disc dislocations, and degenerative joint disorders compared to their urban counterparts [25].

From a diagnostic performance perspective, the modified Helkimo Index demonstrated a sensitivity of 86% and a specificity of 84%, values closely aligned with those of the DC/TMD protocol (sensitivity 91%, specificity 93%). This similarity confirms the mHI's capacity to discriminate between patients with and without TMD. The strong correlation between mHI and DC/TMD scores ( $r = 0.83$ ), along with a reasonable mean score difference of 4.1 points, suggests that the Helkimo Index can serve as a valid clinical alternative, particularly in settings where the full DC/TMD protocol is impractical due to logistical constraints. In support of these results, Alonso-Royo et al. [17] reported a sensitivity of 86.7% and specificity of 68.1% for the Helkimo Clinical Dysfunction Index compared to the DC/TMD in a clinical sample. These findings reinforce the diagnostic value of mHI and advocate for its broader use, especially in low-resource environments.

The ROC analysis yielded an area under the curve (AUC) of 0.89 for the mHI, which closely approximates the AUC of the DC/TMD protocol (0.95), thereby confirming the excellent discriminative ability of the mHI in distinguishing between positive and negative TMD cases. This performance slightly exceeds previously reported values for the Helkimo score, where the AUC ranged from 0.84 to 0.87 [2,17]. The optimal cutoff point identified ( $\geq 9$  points), along with positive and negative predictive values and likelihood ratios, supports the validity of the mHI as a reliable, rapid, and effective clinical screening tool for TMD, particularly in resource-constrained settings.

Our results regarding the reproducibility of the mHI revealed excellent consistency, with an inter-examiner intraclass correlation coefficient (ICC) of 0.87 and an intra-examiner ICC of 0.91, surpassing conventional thresholds for reliability. These values align with findings by Alonso Royo et al. [17], who reported ICCs ranging from 0.85 to 0.90 for the Helkimo Clinical Dysfunction Index (HCDI) in TMD assessments. Furthermore, a median kappa value of 0.65 observed in our study suggests a good-to-very-good agreement at the item level, comparable to the weighted kappa coefficients reported by Alonso Royo et al., which ranged from 0.43 to 0.77 [17]. These results demonstrate both temporal and inter-observer stability, reinforcing the utility of the mHI in routine clinical practice and epidemiological research without compromising diagnostic rigor.

Multivariate analysis using Generalized Estimating Equations (GEE) highlighted a strong predictive relationship between mHI scores and the likelihood of a positive TMD diagnosis. Every additional point on the Helkimo Index was associated with a 45% increase in adjusted odds. This significant predictive association confirms the internal validity of the mHI. Moreover, the absence of independent effects of age or sex emphasizes the index's symptom-specific nature, indicating that it accurately reflects dysfunction severity regardless of demographic variables. These findings are consistent with those of Yarasca-Berrocal et al. [15], who compared the mHI to the short-form Fonseca Anamnestic Index (SFAI) and reported an AUC of 0.854 for mHI, with a sensitivity of 89.7% and specificity of 77.6%. This reinforces the high discriminative power of the Helkimo score in detecting TMD cases, further validating its utility for rapid clinical screening and epidemiological studies. Hence, the advanced statistical modeling (GEE) and external validation comparisons advocate for the mHI as a pragmatic alternative to more complex diagnostic protocols like the DC/TMD, especially in environments with limited resources.

The optimal administration time of a clinical tool is essential for its efficient implementation in dental outpatient settings. Our findings show that the mHI can be completed in 5–10 minutes, substantially less than the 16–20 minutes required for the full DC/TMD protocol. This time difference is critical, as it reduces both patient burden and examination duration without compromising diagnostic accuracy. Moreover, validation studies, including Alonso Royo et al. [17], affirm that the HCDI is a "simple and rapid test with adequate clinimetric properties." While the brief version of the DC/TMD (bDC/TMD) provides a screening protocol lasting approximately 10 minutes, the complete

Axis II interview can add 10–15 minutes [26]. A recent study validating the Krogh-Poulsen test, a fast, composite screening tool, reported an AUC of 0.93 and a short administration time, making it suitable for primary care settings without specialized staff [27]. Put together, these data suggest that the mHI offers an ideal balance between speed and accuracy, making it a viable solution for early-stage TMD diagnosis with efficient resource use.

#### *Strengths and Limitations*

This study presents a rigorous clinical validation of the modified Helkimo Index (mHI) in a Romanian patient sample, using the DC/TMD protocol as the reference standard. The sample size was sufficient to support robust statistical analyses, and the comparison groups were carefully selected to ensure demographic comparability. The mHI demonstrated excellent diagnostic performance, with 86% sensitivity, 84% specificity, and a strong correlation ( $r = 0.83$ ) with DC/TMD scores. Reliability analyses revealed excellent inter- and intra-examiner agreement (ICC = 0.87 and 0.91, respectively), confirming the tool's stability and reproducibility. In addition, its short administration time (5–10 minutes) offers a significant operational advantage over more complex protocols, supporting its use in clinical environments with limited resources.

Nonetheless, several limitations must be acknowledged. Although the sample size was adequate for statistical analysis, further validation across different age groups and diverse socio-cultural settings would enhance the generalizability of the results. Additionally, the assessments were performed in a specialized clinical context, which may limit the broader applicability of the findings to general dental practice. To fully evaluate the effectiveness of the modified Helkimo Index, future studies should consider extending the analysis to more varied populations and clinical settings.

#### *Clinical Implications*

These findings have significant clinical implications. Validation of the modified Helkimo Index in a Romanian sample provides dental practitioners and researchers with a simple, fast, and effective tool for assessing temporomandibular disorders, complementing the DC/TMD protocol. Implementing this index can improve access to timely and accurate diagnoses, reducing the time and resources required while facilitating early detection and optimal management of this complex condition.

## 5. Conclusions

Our study demonstrates that the modified Helkimo Index (mHI) is a valid, reliable, and operationally efficient clinical alternative to the DC/TMD protocol for diagnosing temporomandibular disorders. Its simplicity and accuracy position the mHI as a front-line diagnostic tool for early TMD detection in general dental settings. The high performance in terms of sensitivity, specificity, and reproducibility, combined with ease of use, supports the broad implementation of mHI in general dental practice and resource-limited settings. These results validate the mHI as a pragmatic tool with genuine potential to optimize triage and early diagnosis of TMD in diverse clinical contexts.

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