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Smallest detectable differences in clinical functional temporomandibular joint examination variables in juvenile idiopathic arthritis

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Structured Abstract

Objective – Temporomandibular joint (TMJ) arthritis in juvenile patients may interfere with optimal joint function and mouth opening patterns. Clinical assessment of maximal mouth opening capacity, laterotrusion and protrusion is critical to TMJ arthritis diagnosis, treatment choice and evaluation of a therapeutic intervention. The aim of the study was to determine the smallest minimal threshold at which differences in maximal mouth opening capacity, laterotrusion, and protrusion between two consecutive observations can be determined.

Setting and Sample Population – Department of Orthodontics, University of Aarhus, Denmark. Forty-two consecutive patients with juvenile idiopathic arthritis.

Material and Methods – Two experienced dentists used a calibrated metallic ruler to measure maximal mouth opening capacity, laterotrusion, and protrusion. Each measurement was carried out thrice by each observer. Intra- and inter-observer variation and the smallest detectable difference were calculated for each variable.

Results – The smallest detectable differences were as follows: maximal mouth opening capacity 4.9 mm, laterotrusion 2.4 mm, and protrusion 2.8 mm (one observer and one measurement). These differences declined when measurements were repeated; maximal mouth opening capacity 3.3 mm, laterotrusion 1.4 mm, and protrusion 1.8 mm (two observers with three measurements each). We found no support for a relationship between measurement variation and patient age, measurement variation and TMJ pain, or between measurement variation and previous/current TMJ arthritis.

Conclusion – The importance of the implementation of a standardized measurement protocol is emphasized including repeated measurements to reduce the smallest detectable difference.

Key words: arthritis; examination; juvenile idiopathic arthritis; mouth opening; temporomandibular joint

Introduction

Temporomandibular joint (TMJ) arthritis in juvenile idiopathic arthritis (JIA) patients may interfere with optimal joint function (1,2). Studies on orofacial pain and dysfunction in JIA suggest that impairments in maximal mouth opening capacity, maximal protrusion, maximal mandibular laterotrusion movements, and pain in the TMJ area are reliable signs of TMJ inflammation in JIA children (1–6).

Maximal mouth opening capacity is a widely deployed outcome variable in interventional studies, and it has been proposed that statistically significant differences between pre- and post-therapeutic outcomes reflect the clinical effect of the intervention. However, observed differences between pre- and post-therapeutic measurements may be biased if the patient is unable to consistently perform the mouth opening procedure, if the examiner fails to consistently deploy the measurement technique, if the patient suffers masticatory muscle pain and because of the natural course of the arthritic condition itself (7,8). Furthermore, the simultaneousness of TMJ symptoms and disability may affect the measurement results. A significant change in an outcome variable in a therapeutic study is, therefore, not tantamount to clinical relevance; and certainly not in the absence of a thorough account of the reliability and reproducibility of the functional maneuvers performed.

The standard error of the measurement (SEM) must be known to evaluate the 'true' intervention success (7–9). Calculation of the smallest detectable difference may provide such information. According to Kropmans et al., the smallest detectable difference is the smallest statistically significant change measured from one time point to another (8,10,11). It is expressed in the same units as those used in the clinical examination. In healthy adult subjects, the smallest detectable difference in maximal mouth opening between two single measurements is 5 mm and in adult patients with temporomandibular disorders, it is 9 mm (8,10). These values have not yet been established in JIA patients.

The primary aim of this study was to calculate the smallest detectable difference in JIA patients' maximal mouth opening capacity, maximal laterotrusion, and maximal mandibular protrusion movement. The secondary aim was to test the hypothesis that the precision of measurements was not affected by the following variables: age, current craniofacial pain or previous/current TMJ arthritis.

Material and methods

Forty-five consecutive patients with JIA according to the ILAR criteria (12) were invited to join the study, which was conducted at the Section of Orthodontics, Aarhus University, Denmark in January and February 2011. All patients were called for routine clinical examination for TMJ inflammation or its treatment. Included were patients with JIA diagnosis below the age of 19: All patients had received their initial JIA diagnosis before the age of 16. Previous or current TMJ arthritis was not a requirement for inclusion.

Prior to the initiation of the study, the two observers (PS and CV) agreed to use a standardized measurement protocol calibrated on seven patients before initiation of the actual study. These patients were not included in the study.

The examination was performed with the patients sitting in the dental chair in a 45° position supporting his or her head on the dental chair headrest. All patients were carefully instructed in the correct performance of the specific maneuvers and did mouth opening exercises before the actual measurements. Unassisted maximal mouth opening capacity, maximal laterotrusion measurement, and maximal protrusion ability were measured with calibrated regular 150-mm metallic rulers. The patients were instructed to conduct maximal laterotrusion and maximal protrusion with a consistent contact between teeth in the upper and the lower jaw. The horizontal overjet, vertical overbite and any midline deviation were assessed before the measurements. The clinical points on the incisors used for horizontal overjet and vertical overbite assessment were defined those that would produce the most severe values for the two distances in each individual.

In each patient, all variables were measured thrice by two experienced observers (PS and CV). Maximal mouth opening capacity was measured inter-incisally with the ruler positioned on the incisal edge of the lower incisors to record maximal unassisted opening capacity; all mouth opening measurements were adjusted for the vertical incisal overbite. During this maneuver, all patients were verbally emphasized to 'open as much as possible'. Maximal protrusion ability and laterotrusion movements were measured in the same fashion. The points used for these measurements were identical to those used for horizontal overjet and vertical overbite assessment. All the first observer's measurements were finished before the second observer initiated his/her measurements. The order of the observers was determined by randomization. The results of the first observer were blinded to the second observer until they both had performed all measurements. Patients were also assessed in terms of: 1) present TMJ/muscular pain, 2) previous TMJ arthritis history, 3) present TMJ arthritis based on clinical and radiological TMJ examinations, 4) present treatment with functional appliance, 5) peripheral joint arthritis, and 6) current medication.

TMJ functional examination complied with current national regulations for clinical pediatric orthodontic examinations. The protocol was approved by the local scientific committee, and the study procedures are in accordance with the Helsinki Declaration. All included JIA patients and their parents gave their informed consent before their inclusion into the study.

Statistics

All variables were tested for normal distribution. *Intra*-observer bias was evaluated by paired *t*-tests between the first and third measurement to check for systematic time trends. *Inter*-observer bias was evaluated by *t*-tests between the individual observer mean scores for each of the variables examined. The mean score of observer PS was plotted against the mean score of observer CV to visualize any observer bias and data variation (13).

Analyses of variances were used to estimate variance components of patients, observers, and repetitions together with their two-way interactions: observers and patients (observer*patients), repetitions, and patients (repetition*patients), observers and repetitions (observer*repetitions), and residual random errors. For each variable, the total estimated variance was calculated by the summation of all variance components with at least one random factor. In cases of repeated measurements, the relevant variance components were divided by the number of repetitions. The *inter*-individual variance component of patients was excluded from the total estimated variance of each variable addressed because the measurement model assumes that the measurement is performed in a fixed individual by random observers. The corresponding *inter*-individual variance component of patients therefore does not contribute to the total estimated variance of each measurement.

The variances of the measurements were estimated, and the appertaining SEMs were found by the square roots of the estimated variances. With a level of significance of $\alpha = 0.05$, the smallest detectable difference was estimated for each of the variables of interest: smallest detectable difference $= 1.96 \times (\sqrt{2}) \times$ SEM (8,14). The estimation of variance components was performed using SAS 9.2, PROC MIXED,

Table 1. **Cohort Characteristics**

Characteristics	Total cohort n = 42
Females	31 (73.8%)
Mean age, years (std.dev)	12.8 (3.2)
Current arthritis activity in other joints†	18 (42.9%)
History of TMJ arthritis	24 (57.1%)
Unilateral	11 (26.2%)
Bilateral	13 (31%)
Current TMJ arthritis activity	10 (23.8%)
Unilateral	4 (9.5%)
Bilateral	6 (14.3%)
Craniofacial pain present	8 (19.1%)
VAS intensity, mm (SD)‡	34.9 (17.8)
Current orthodontic treatment	22 (52.4%)
Functional appliance	20 (47.6%)
Full fixed appliance	2 (4.8%)
Medication	
NSAID	15 (35.7%)
Paracetamol	5 (11.9%)
Methotrexate	9 (21.4%)
IACI§	2 (4.8%)
Systemic steroid	1 (2.4%)
Biologics	7 (16.7%)

TMJ: temporomandibular joint, VAS: visual analogue scale, NSAID: non-steroidal anti-inflammatory drugs, IACI: intraarticular corticosteroid injection.

†in other joints than the TMJs based on examination conducted by a pediatric rheumatologist.

‡Average intensity on a 100-mm visual analogue scale.

§In other joints than the TMJ within the past 2 months.

(SAS Institute INC. Cary, NC, USA). To evaluate how age and previous/current TMJ arthritis diagnosis affected measurement precision, two graphs were produced where the mean standard deviation of the six measurements (2×3) on each individual was plotted against age and previous/current TMJ arthritis diagnosis.

Results

Forty-two of 45 JIA patients accepted participation and completed the study. Two declined participation without further explanation and one failed to comply because her craniofacial symptoms grew worse during measurements. The patients' mean age was 12.8 years (range 3.5–18). Cohort characteristics are presented in Table 1.

Intra-observer variation

Both observers' mean recorded values rose from the first to the third measurement in 3/4 of the variables. Observer PS recorded a significant increase in mean maximal mouth opening ($p < 0.05$; 0.61 mm; SD 1.51 mm), an increase in mean leftward laterotrusion (0.20 mm; SD 0.8 mm), a decrease in mean rightward laterotrusion (−0.12 mm; SD 1.01 mm), and an increase in mean protrusion (0.27 mm; SD 0.73 mm). For observer CV, mean maximal mouth opening decreased −0.53 mm (SD 2.63 mm), mean leftward laterotrusion increased significantly ($p < 0.05$) 0.24 mm (SD 0.68 mm), mean rightward laterotrusion increased 0.17 mm (SD 0.78 mm), and mean protrusion increased 0.21 mm (SD 0.7 mm).

Inter-observer variation

Table 2a features the average of the three measurements. Observer PS's average score was plotted against observer CV's average score for each individual to visualize the *inter*-observer bias (graphs not shown). Observer CV systematically measured significantly higher maximal mouth opening ($p < 0.05$, 1.06 mm, SD 1.89 mm) and protrusion ($p < 0.05$, 0.42 mm, SD 1.25 mm) values than observer PS. *Inter*-observer agreement was seen for the variables laterotrusion to the left (0.09 mm, SD 0.89 mm) and laterotrusion to the right (−0.26 mm, SD 1.05 mm).

Variance components

Variance components are illustrated in Table 2b. Patient variance (*inter*-individual variation) accounted for most of the variation. However, this variation was not included in the calculation of the total estimated variance for each of the four variables. Observer–patient interaction accounted for the largest variance among the components included in the total estimated variance calculation.

Table 2. **(a) *Inter*-observer variation. Depiction of observer mean values of the three measurements conducted for each variable addressed. *Inter*-observer difference was evaluated with *t*-tests. (b) Variance components for each of the variables addressed. Main effects of patients, observers and repetitions are illustrated together with the two-way interactions of observers and patients, repetitions and patients, observers and repetitions and residual random errors.**

(a)

	Mean (SD) observer PS/mm	Mean (SD) observer CV/mm	Mean difference (SD)/mm	95% CL of mean difference/mm	Significant
Maximal mouth opening	47.66 (9.61)	48.72 (8.93)	1.06 (1.89)	0.46–1.64	$p < 0.05$
Laterotrusion left	8.59 (1.92)	8.68 (1.76)	0.09 (0.89)	−0.19–0.37	n.s.
Laterotrusion right	8.45 (2.23)	8.19 (2.28)	−0.26 (1.05)	−0.58–0.08	n.s.
Protrusion	7.78 (2.06)	8.20 (2.38)	0.42 (1.25)	0.03–0.81	$p < 0.05$

(b)

	Max. mouth opening	Laterotrusion left	Laterotrusion right	Protrusion
Source				
Patients	83.52	2.84	4.33	4.03
Observer	0.51	0	0.02	0.07
Repetition	0.05	0	0	0.01
Observer*patients	1.43	0.33	0.44	0.71
Repetition*patients	0.02	0.04	0	0
Observer*repetition	0	0	0	0
Residual	1.09	0.20	0.33	0.23

SD: standard deviation, CL: confidence limit.

Smallest detectable differences

The smallest detectable differences for single and repeated measurements are presented in Table 3; this table also illustrates the random factors, standard error of the measurements, and the confidence limits. According to Table 3, the smallest detectable differences were as follows: maximal mouth opening capacity 4.9 mm, laterotrusion 2.4 mm, and protrusion 2.8 mm (one observer and one measurement). The smallest detectable differences were reduced if repeated measurements were conducted; maximal mouth opening capacity 3.3 mm, laterotrusion 1.4 mm, and protrusion 1.8 mm (two observers with three measurements each). For a change between two independent observations to be characterized as statistically/clinically significant, it must at least exceed the smallest detectable difference of the measurement procedure for the variable in question.

The influence of age, TMJ pain, and previous/current TMJ arthritis

Figure 1A shows the relationship between age and measurement variance of maximal mouth opening. Figure 1B shows the relationship between previous/current TMJ arthritis diagnosis and maximal mouth opening measurement variance. The graphical presentations indicate the absence of relationship between measurement variance and age, measurement variance and current craniofacial pain, or measurement variance and previous/current TMJ arthritis.

Table 3. **Smallest detectable difference in maximal mouth opening, laterotrusion left, laterotrusion right, and protrusion.**

	Random Factors				
	Observer(s)	Repetition(s)	SEM/mm	95% CL/mm	SDD/mm
Max. Mouth Opening					
Single measurement	1	1	1.76	±3.45	4.9
Repeated measurements	1	3	1.52	±2.99	4.2
Repeated measurements	2	3	1.20	±2.34	3.3
Translation left					
Single measurement	1	1	0.76	±1.49	2.1
Repeated measurements	1	3	0.64	±1.26	1.8
Repeated measurements	2	3	0.46	±0.46	1.3
Translation right					
Single measurement	1	1	0.89	±1.73	2.4
Repeated measurements	1	3	0.75	±1.47	2.1
Repeated measurements	2	3	0.53	±1.04	1.4
Protrusion					
Single measurement	1	1	1.01	±1.98	2.8
Repeated measurements	1	3	0.93	±1.82	2.6
Repeated measurements	2	3	0.66	±1.29	1.8

SEM: standard error of measurement, CL: confidence limit, SDD: smallest detectable difference.

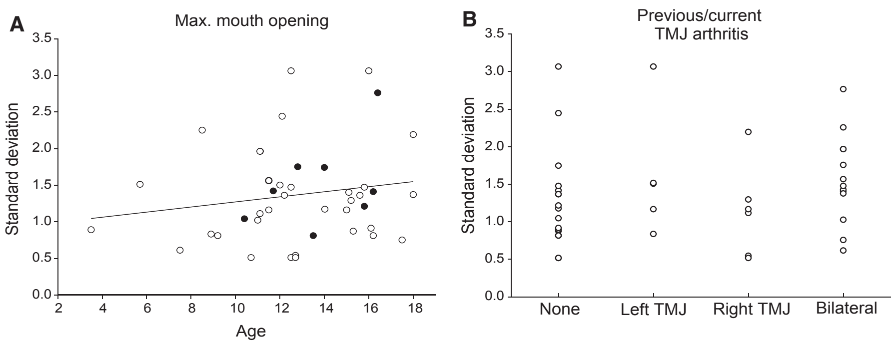

Fig. 1. (A) Relationship between age and measurement variance of maximal mouth opening. Individual measurement standard deviation plotted against the patient´s age. Dots filled with black colour represent the JIA patients with craniofacial symptoms at the time of the measurements. (B) Relationship between previous/current TMJ arthritis diagnosis and maximal mouth opening measurement variance. Individual measurement standard deviation plotted against previous/current TMJ arthritis status.

Discussion

The present study estimated the smallest detectable differences in maximal mouth opening capacity, maximal laterotrusion, and maximal protrusion in patients with JIA and thus provides the clinician with information to determine whether a statistically significant change has occurred between two observations. Repeated measurement caused the smallest detectable differences to decline for all variables examined. This emphasizes the importance of repeated measurement and use of a thorough, standardized measurement protocol to optimize reliability and reproducibility in daily clinical examinations and experimental clinical research.

In terms of reliability, our results are consistent with previous research on maximal mouth opening capacity in healthy adults and adult patients with temporomandibular dysfunctions (8,10,15); the previously published estimated values for the smallest detectable differences are 5 mm for healthy adult patients and 5–9 mm for adult patients with painfully restricted mandibular function. The difference in the values for adult patients with painfully restricted mandibular function is explained by diverse methods used and the duration between the measurement procedures. Our study supports previous findings describing no difference in the smallest detectable difference between healthy individuals and patients with a temporomandibular dysfunction (8).

To our knowledge, our study is the first of its kind in children with JIA. The hypothesis that sparked our study was that reliability would be affected by the children's age, their current craniofacial symptoms and any previous/current TMJ arthritis. It is a straightforward anticipation that the understanding of the specific mouth opening maneuvers and the ability to conduct them consistently could be difficult in young children. However, we found no evidence in support of our hypothesis. Nor did we find any indication of a relationship between current craniofacial symptoms and increased maximal mouth opening variation. This is in keeping with a study on adult patients with painfully restricted TMJ function (10) where no relationship was found either between current craniofacial pain and reliability of maximal mouth opening assessment or between current craniofacial pain intensity and the precision in maximal mouth opening capacity measurements.

One limitation of the present study is our inability, for practical reasons, to repeat measurements on a second day and hence address the issue of *inter*-day variance. According to Kropmans et al., the variance components of patients and days (patients*days) and patients, days and observer (patients*days*observer) are substantial.

This affected the reliability of maximal mouth opening capacity measurements in their patients (10). This may explain why their reported values for the smallest detectable differences in maximal mouth opening capacity in adults were larger than those presented in this study. Another potential limitation to our study is the measurement method used to for the assessment of the smallest detectable differences; it could be argued that a more correct basis for the calculation is to use the greatest value of the three measurements instead of calculating the smallest detectable differences based on the mean value of the 3 measurements. However, in order to facilitate comparison between our data and previous studies, we chose to calculate the smallest detectable differences based on mean values because previous studies have used this methods (8,10).

Our findings also invite a discussion of a more general nature. Significant *intra*-observer and *inter*-observer biases were seen even if measurements were performed on the same patients and on the same days. We would therefore expect the measurements to be identical and not to differ significantly from each other as seen in Table 2a. However, this study reveals that the issue of reliability must be addressed in clinical studies that involve these kinds of measurements. Clinical studies may draw incorrect conclusions based on statistically significant differences between pre- and post-therapeutic values if an evaluation of the results does not take into consideration the concept of the 'smallest detectable difference of the measurement'. It is important to realize that to demonstrate clinical relevance, clinical intervention must satisfy two equally important requirements: 1) a statistically significant difference between the pre- and post-therapeutic measurement values must be established; 2) any significant change in the value scores must be comparable to or exceed the smallest detectable difference of the specific outcome variable examined. Obviously, one must also consider if the statistically significant change in the specific measurement value is, indeed, clinically relevant.

We also need to address the issue of a proper TMJ 'warm-up'; a need that springs from two factors. First, the observation of a statistically significant difference between the first and the third value obtained by observer PS in mean maximal mouth opening capacity and by observer CV in leftward laterotrusion. Indeed, values rose from the first to the third measurement in six of eight variables measured by both observers. Second, clinical observation has indicated that patients' complaints about TMJ stiffness and craniofacial symptoms in JIA patients with TMJ arthritis seem to subside during the day. As long as we do not know if there is a relationship between TMJ function and the time of the day the TMJ examination is performed, we recommend that pre- and post-therapeutic TMJ examinations in interventional studies are conducted at the same time of the day to avoid any bias associated with TMJ morning rigidity. Intervention studies should follow a detailed protocol to reduce any variation in TMJ measurements. Commercial products that may assist the examiner in measuring maximal mouth opening capacity are available on the marked. Alternatively, the clinician may deploy a 'finger measurement approach' of the maximal opening capacity; a popular approach in clinical settings (16). However, to our knowledge, no previous study has evaluated the reliability and reproducibility of these devices and measurement methods in children.

Conclusion

Evaluation of maximal mouth opening and mandibular excursions are used to recognize early joint disability with the purpose of early diagnosis and treatment planning. In the present study, we found no support for a relationship between measurement variation and patient age, measurement variation and TMJ pain, or between measurement variation and previous/current TMJ arthritis; however, future studies involving more patients are needed to confirm these findings. Additionally, the present study identifies important issues and aspects of motion examination that must be duly catered for in clinical decision making and research. It emphasizes the importance of the implementation of a standardized measurement protocol including repeated measurements to reduce the smallest detectable difference.

Clinical relevance

Temporomandibular joint (TMJ) arthritis in (JIA) patients may lead to mandibular growth disturbances, unstable occlusion, disturbed TMJ and masticatory function causing asymmetric loading of joints and muscles, TMJ pain and a compromised esthetic appearance. Orthopedic treatment of TMJ arthritis and mandibular growth disturbances proceeds over a long period and involves substantial intervention. Arguments in favor of instituting early intervention have been presented, which emphasize the importance of early diagnosis. The present study offers new knowledge about clinical examination parameters important for TMJ arthritis diagnosis, treatment choice, and evaluation of a therapeutic intervention.

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