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Development and validation of a novel screening instrument to prioritize the orthodontic referral of developing malocclusion in children: The index for interceptive orthodontics referral

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Objective: The absence of a guideline to refer to developing malocclusions appropriately, may be a contributing factor to the inadequacy of timely interceptive orthodontics provision. This study aimed to develop and validate a new orthodontic grading and referral index to be used by dental frontliners to prioritize the orthodontic referral of developing malocclusion in children based on its severity. **Methods:** A cross-sectional study involving clinical assessment with 413 schoolchildren aged between 8.1 and 11.9 years was conducted in 2018. All the presenting malocclusion was listed and graded based on a few dental guidelines to produce the draft index. The validity and reliability of the draft index were tested using twenty study models. Face and content validation was carried out using the content validation index and Modified Kappa Statistics. **Results:** Fourteen dental and occlusal anomalies were identified as components of malocclusion and three grades of referral (monitor, standard, urgent) were included in the final index. The scale-level content validity index average value of 0.86 and 0.87 was obtained for content and face validation, respectively. There was moderate to excellent agreement in the Modified Kappa Statistics for both validations. Excellent inter- and intra-assessor agreement was obtained. The new index displayed valid and reliable scores. **Conclusions:** The Index for Interceptive Orthodontics Referral was developed and validated for the dental frontliners to identify and prioritize the developing malocclusion in children based on its severity and refer for orthodontic consultation to increase the possibility for interceptive orthodontics.

Key words: Orthodontic index, Early treatment, Diagnosis and treatment planning, Paediatric dentistry

INTRODUCTION

Interceptive orthodontics is an economical measure to correct a developing malocclusion or simplify future treatment.[1] Children in the late mixed and early permanent dentition were found to have numerous dental and occlusal anomalies. Crowding and clinically missing teeth were the highest occlusal and dental anomalies screened respectively, and therefore, early orthodontic screening was recommended.[2] The developing malocclusion begins to manifest in the mixed dentition, which commences when the first permanent tooth erupts at around five to six years and ends at around twelve to thirteen years of age with the exfoliation of the last deciduous tooth.[3] Although orthodontic treatment has numerous benefits including improvements in dental health, function and esthetics, it carries significant risks that need to be considered to yield maximum benefit and minimum risk.[4] It is crucial to recognize and refer timely the malocclusion for suitable interceptive orthodontics as almost 15% of developing dental problems can be fully corrected and 49% can be improved with a simple interceptive treatment.[5] This proves that with proper selection of developing malocclusion, interceptive orthodontic treatment may negate or simplify future treatment.

The dental frontliners involved in orthodontic screening of the children population include the general dental practitioners (GDPs), dental nurses (DNs) and dental therapists (DTs). It is crucial for them to be able to identify the developing malocclusion and refer timely to the orthodontists, who will be able to consult and provide the necessary treatment. The lack of diagnostic accuracy in orthodontic referral amongst the GDPs and DNs was still apparent with the use of the popular Index of Orthodontic Treatment Need (IOTN).[6] The frequently used IOTN was inadequate to assist the frontliners to decide on the developing skeletal abnormalities and dental malocclusion, such as, hypoplastic maxilla contributing to a Class III skeletal pattern, midline diastema, poor prognosis of the first permanent molars, and crowding, because the IOTN does not include these abnormalities in its grading system.

The absence of an orthodontic referral guideline resulted in marked variation in the referral process among DTs, largely due to their differences in age, qualification and work sector.[7] This void has to be addressed as malocclusion imposes a negative impact on oral health-related quality of life, mainly on the psychological discomfort domain.[8] The absence of a guideline or index specifically for developing malocclusions has contributed to this phenomenon.

Malocclusions such as impacted teeth, supernumerary and crossbite detected in adulthood that should ideally have been identified earlier in childhood and intercepted with simpler measures may not have been sent for an orthodontic consultation by the dental frontliners due to lack of confidence in referring, absence of a referral guideline and high load of patients to be screened during their scheduled clinics.[7] An orthodontic consultation can ensure that orthodontic treatment is provided based on severity and treatment need, while those with little need will be safeguarded from potential risks. This end result of being consulted by the orthodontist heavily depends on the referral by the frontliners, mainly under the government dental healthcare systems. Interceptive orthodontics may negate or simplify future treatment, indirectly facilitating the management of the long orthodontic waiting list.[6] Delayed referral of some of the developing malocclusion results in the establishment of the malocclusion, leading to a more complex orthodontic treatment, increased cost and a long waiting list,[9] because the malocclusion was not prioritized earlier based on dental development and feasibility of interceptive treatment.

The IOTN has been utilized to grade orthodontic treatment need vastly around the world. However, it was coined using the study population that included children between the ages of eleven and twelve years. Furthermore, the criteria for the school samples were determined beforehand.[10] This study population could not have displayed all the possible developing malocclusion as most developing malocclusions begin to manifest from a much younger age. The IOTN also highlights Class II malocclusion and deprives the significance of Class III and anterior open bite, although both categories may present itself at a younger age and affect the child functionally and socially. Facial features and deformities are not included in this index and there is a lack of correlation between the malocclusions and the extent of its improvement in quality-of-life post-treatment between grades.[11]

Several inappropriate referrals, such as incorrect grading and referral timing, from the GDPs were apparent with the use of IOTN alone, mainly due to its complexity and limitations in its content.[12] The IOTN may be useful to prioritize orthodontic provision in a population that depends on its government-funded health system. However, it does not always equate the higher grades to the complexity of the treatment of some malocclusion.[13] Currently, the increase in demand for an orthodontic treatment among children, may not be coherent with the need prescribed by indices such as IOTN. There is a need for a standardized approach that may be accepted by both the orthodontic profession and the community.[13] Hence, there appears to be a deficiency in the global dental education system that needs to be addressed. Although the IOTN remains to be used by many around the world, its complexity and limitations in addressing

some developing malocclusion and its severity create a discrepancy that it may not be an ideal tool to be used in solitary during orthodontic screening, especially in children.

At present, the absence of a guideline to prioritize the presenting malocclusion and refer for timely interceptive orthodontics provision contributed to the delay in the management of any significant developing malocclusion in children. This leads to delayed treatment provision, which necessitates more complex and compromised orthodontic management in adulthood.

Therefore, the aim of this study was to generate a novel orthodontic grading and referral index that can be utilized by the dental frontliners to prioritize the orthodontic referral of the developing malocclusions presented in children based on its severity. Hence, these referred malocclusions will have the opportunity to be consulted by an orthodontist, who would decide the feasibility and success of timely interceptive orthodontics.

MATERIALS AND METHODS

Ethical approval was obtained from the Research Ethics Committee Universiti Teknologi MARA (600-IRMI 5/1/6; 29th March 2017). This study was conducted in accordance with the ICH Good Clinical Practice Guidelines and the Declaration of Helsinki. Written permissions from the Ministry of Education Malaysia and Sungai Buloh District Education Office (DEO) were obtained prior to securing permission from the shortlisted school's administrative offices. Children who had submitted written informed consent from parents were included in this study. The study was conducted in accordance with the approved guidelines and declarations.

Study design and study population

A cross-sectional study was executed among schoolchildren aged between 8.1 and 11.9 years. The list of national primary schools in the district of Sungai Buloh was retrieved from the DEO, from which, seven schools were selected randomly. The children's enrollment list was obtained from each school's administrative office.

Based on a previous study,[14] the power was set at 95% with 5% significance level. The sample size was estimated as 374, using a single proportion formula. However, it was increased by 10% to account for the possible dropouts in overall participation. The sample size was segregated according to the population in Malaysia. According to the Department of Statistics, the Malaysian population included 69% Malays, 23% Chinese, 7% Indians and 1% other ethnicities. Therefore, the research sample population was selected using a stratified random sampling method according to the ethnic distribu-

tion of Malay, Chinese and Indians, to reduce the selection bias.

The recruitment period was between January and November 2018. Schoolchildren without any major illnesses were included, while those who were undergoing orthodontic treatment, previously treated with orthodontics, diagnosed with any craniofacial anomalies and without parental consent were excluded.

Intervention and data collection

A thorough orthodontic clinical assessment was carried out for all the participants, followed by study model fabrication, which was used for future reference. To replicate an orthodontic screening process, only clinical assessments were conducted, without any radiographic investigations.

To ensure inter-assessor reliability, calibration of the examiner was carried out against an orthodontist for the assessment of dental and occlusal anomalies using twenty study models. Intra-assessor reliability was tested ten days later.

The dental and occlusal anomalies seen in the schoolchildren were tabulated as the components of malocclusion with three grades of referral (monitor, standard referral, and urgent referral). The description of the grades was segregated using the IOTN,[10] crowding classification,[15] incisor classification[16] and clinicians' experience. Several other studies were also referenced before finalizing the cut-off between grades.[17,18] The draft index was devised, and validation was carried out.

Any new index should be validated prior to its use. Index validity refers to the accuracy of the index, whether it measures what it was intended to measure.[19] Face validity assesses the degree to which the test respondents view the content of the test and its item relevance to the context of the test administered, which must be done by the people who will be involved in the test-taking.[20] Conversely, content validity is the degree to which elements of an instrument are relevant and representative of the particular construct,[21] which will usually be undertaken by experts who ensure the index is relevant and appropriate.

The index was presented to six independent specialists in the fields of orthodontics, paediatric dentistry, and dental public health for qualitative face validation. Thereafter, the index underwent some minor adjustments to its content and wordings.

Six orthodontic specialists[22] with comprehensive experience in orthodontics were then invited to participate in the content validity assessment comprising ten assessment items. Each assessor received a copy of the draft index and a content validity assessment form. The assessors were asked to independently evaluate the relevance of all the items. It was designed according to the

principles of content validity using a four-point ordinal scale (i.e., 1 = Not relevant, 2 = Item need some revision, 3 = Relevant but need minor revision, and 4 = Very relevant).[23,24] Scales 3 and 4 were rated as agreed items, while scales 1 and 2 were rated as non-agreed items.

The quantitative content and face validity of the draft index were analyzed using the content validity index (CVI)[25] and Modified Kappa Statistics (K*),[26] which was based on the proportion of agreement.[15,24] The individual-level CVI (I-CVI) was calculated by determining the proportion of assessors who agreed with the individual items. In contrast, the scale-level CVI average (S-CVI/Ave) was determined by computing all the I-CVI values and the total scores averaged by the total number of assessment items. Any dissent among the assessors was discussed to reach a consensus prior to adjustment. As the number of assessors for content validity was six, the acceptable score of S-CVI/Ave must be at least 0.83.[24] At this point, the index would be considered to have content validity.

Twelve assessors from various dental specialties and designations were invited to participate in the quantitative face validity assessment. The assessors were provided with a copy of the draft index and a face validity assessment form to assess the draft independently. A dichotomous scale with categorical options of "yes" and "no" based on eight items of assessment was provided for face validity assessment.[27] Discussions were carried out to elucidate the comments made by the twelve assessors. Modifications were made to the wording and descriptions of the index to reflect the comments. As the number of assessors for face validity was twelve, the acceptable score of S-CVI/Ave must be at least 0.83.[24] At this point, the index would be considered to have face

validity.

Statistical analysis

The data were analyzed statistically using the SPSS version 21.0 (IBM Co., Armonk, NY, USA). The level of significance was set at $p < 0.05$. Index validity was determined based on the CVI (I-CVI and S-CVI) and Modified Kappa Statistics (K*). The index reliability was analysed according to Kappa Coefficient Analysis using Stata Version 14.2 (STATA Corp., College Station, TX, USA).

RESULTS

Demographic distribution of the participants

A total of 413 schoolchildren from seven schools, aged between 8.1 and 11.9 years, were assessed. The inter- and intra-assessor reliability measurements were in excellent agreement (Kappa coefficient score = 1.00). The demographic data of the sample population is shown in Table 1.

The prevalence of malocclusion was 76%, with Class II malocclusion predominance, followed by Class I and Class III (Table 2). However, there was no statistical significance between gender and malocclusion distribution ($p = 0.76$) or orthodontic treatment need ($p = 0.84$).

Development and validation of the draft index

All the malocclusion identified from the clinical assessment and study model was listed as components of malocclusion. The British Standards Institution classification, IOTN and clinician experience were used to finalize the referral grading. A draft index was tabulated with fourteen rows of components of malocclusion and three columns of referral grades comprising monitor, standard referral, and urgent referral.

From the content validity assessment, seven items scored excellent agreement and three items scored substantial agreement in I-CVI. However, the S-CVI/Ave was 0.86, which was rated as excellent. The three items were discussed among the assessors and improvised. The modified Kappa statistics showed moderate to excellent agreement (Table 3). From the face validity assessment, seven out of eight items scored excellent agreement in I-CVI and the S-CVI/Ave was 0.87, which was also rated as excellent. The one item which scored less was discussed between the assessors prior to adjustment. The modified Kappa statistics showed substantial to excel-

Table 1. Demographic data of the study population

Variable	Number of subjects
Sex	
Female	223 (54.0)
Male	190 (46.0)
Race	
Malay	276 (66.8)
Chinese	82 (19.9)
Indian	55 (13.3)

Values are presented as numbers (%).

Table 2. Distribution of malocclusion in the study population

Variable	No malocclusion	Malocclusion				Total
		Class I	Class II division 1	Class II division 2	Class III	
Number, n	99	109	106	22	77	413
Percentage, %	24.0	26.4	25.7	5.3	18.6	100

Table 3. Content validity items

Content validity items	I-CVI[25]	Modified Kappa Statistics[26]
Name of the index	1.00	1.00
Components of the index	1.00	1.00
Grades of the index	1.00	1.00
Description of each component in relation to each grade	0.66	0.56
Overall content of the index	0.66	0.56
Convenience of using the index	0.66	0.56
Simplicity of the index	0.83	0.82
Overall coverage of developing malocclusion	1.00	1.00
The index as a tool for quick orthodontic screening for children	0.83	0.82
The index will benefit in simplifying or negating future orthodontic treatment	1.00	1.00
S-CVI/Ave	0.86	-

I-CVI, individual level content validity index; S-CVI/Ave, scale-level content validity index average.

Table 4. Face validity items

Face validity items	I-CVI[25]	Modified Kappa Statistics[26]
Do you think the presentation is appropriate?	1.00	1.00
Do you think the language used is appropriate?	0.92	0.92
Do you think the words used are suitable for all levels of qualification?	0.58	0.62
Do you think the structure of sentences is easy to understand?	0.83	0.82
Do you think the description of each component and grade is adequate?	0.83	0.82
Do you think the content is clear and unambiguous?	0.83	0.82
Do you think the grades for each component are distinct?	1.00	1.00
Do you think the index is relevant to your practice?	1.00	1.00
S-CVI/Ave	0.87	–

I-CVI, individual level content validity index; S-CVI/Ave, scale-level content validity index average.

lent agreement (Table 4).

All the assessors' comments for the validation of the draft index were pertaining to the word selection, overall presentation, and sequence of the components of malocclusion.

Conception of the final index

The final Index for Interceptive Orthodontics Referral (IIOR) in Figure 1, was considered to have face and content validity. It comprised of dental and occlusal anomalies identified from this study. The referral urgency was segregated into three groups and tabulated with descriptions for each grade and malocclusion, for easy reference. The description for the malocclusion and respective grades was short and simple to understand. There were empty boxes at the end of each corresponding malocclusion and grade for the dental personnel to mark if the corresponding malocclusion was present at the time of dental screening. An extra row of 'Others'

was inserted to allow a description of any malocclusion that was not already stated in the index. At the bottom of the table, there was a section for the frontliner to choose the immediate personnel that the patient needed to be referred to accordingly. A flipbook was created containing detailed explanations of each malocclusion and its respective grades.

The Kappa coefficient score showed excellent agreement in the inter- and intra-assessor reliability (Kappa Coefficient Score = 1.00).

DISCUSSION

The prevalence of malocclusion was 76% with Class II predominance, demonstrating the significance of developing malocclusion in children. If this phenomenon is not managed early in a wise manner, it will exhaust the orthodontic waiting list and resources ultimately. This high prevalence of malocclusion found in this study

Grade / Component of malocclusion	1 Monitor	2 Standard referral	3 Urgent referral
Supernumerary		· All teeth well aligned	· Clinically missing permanent teeth · Crowding · Trauma · Displacement of tooth
Clinically missing teeth (excluding permanent canine)	· Contralateral tooth erupting · Spaced arch		· With or without a palpable bulge · Fully erupted contralateral tooth
Clinically missing permanent canine	· Contralateral canine erupting · Presence of 'deciduous canine'	· Labially palpable · Contralateral canine erupted · Not palpable by 10−11 yr	· Palatally palpable
Early loss of deciduous canine	· Presence of contralateral tooth · No dental centreline shift	· Presence of dental centreline shift	
Early loss of deciduous second molar		· Inadequate space for eruption of successor	· Adequate space for eruption of successor
Midline diastema	· Physiological	· >2 mm diastema · Low frenal attachment	· Persistent diastema (>2 mm) · Missing permanent teeth
Carious first permanent molar		· Asymptomatic · Presence of crowding	· Symptomatic · Not restorable · Presence of crowding
Crowding (Cr)	· Cr <4 mm · Over retained deciduous teeth	· 4 ≤ Cr ≤ 8 mm · Over retained deciduous teeth	· Cr >8 mm · Over-retained deciduous teeth
Anterior crossbite		· Present without displacement	· Present with displacement
Posterior crossbite		· Present without displacement · Non-nutritive sucking behaviour	· Present with displacement · Non-nutritive sucking behaviour
Increased overjet (OJ)		· 5 < OJ ≤ 9 mm · Non-nutritive sucking behaviour	· OJ >9 mm · Non-nutritive sucking behaviour
Reversed overjet		· Present without displacement	· Present with displacement
Deep bite	· No palatal mucosa contact	· Complete to palatal mucosa · Non-traumatic	· Complete to palatal or labial mucosa · Traumatic
Open bite		· Absence of non-nutritive sucking behaviour	· Presence of non-nutritive sucking behaviour
Others (please specify)			

Tick ALL the components of malocclusion and the corresponding grades above as screened. Tick the immediate personnel for a referral.

Dental staff nurse	General dental practitioner	Orthodontist	Others (please specify)

Figure 1. Index for Interceptive Orthodontics Referral.

supports previous studies to portray the inefficiency in diagnosing and referring timely,[6] supplemented by the lack of a referral guideline for the dental frontliners. The IOTN was deemed incomplete as it favored Class II over Class III malocclusion.[11] The new IIOR has included the most malocclusions seen in children and may facilitate the screening process to detect any developing malocclusion efficiently. Selective early interception can correct or improve the problem in the future.[5]

Commonly, the GDPs, DNs and DTs encounter children in the mixed to permanent dentition during the school dental health program or dental outpatient clinics, prior to being sent to any specialist clinic. This referral pathway highlights the fact that orthodontists have limited opportunity to screen children at first hand and depend on the referrals made by the frontliners. Therefore, the frontliners must be well-equipped to identify the developing malocclusion, and segregate according to its severity and significance at the time of screening, prior to referring for an orthodontic consultation. To encourage them to carry out the screening process accurately, while coping with the high load of patients, the process must be relatively simple and less time-consuming. At present, a screening guideline pertaining to the common developing malocclusion is absent. This resulted in developing malocclusion that would benefit from early interceptive orthodontics, not being referred timely due to lack of guidance, or placed on the standard orthodontic waiting list instead. This further leads to the progression of malocclusion, while waiting to reach the top of the list. Consequently, simpler interceptive orthodontics would have been too late to administer at later life and extensive orthodontic treatment would be necessary. Hence, IIOR may be a tool of reference during screening.

The IIOR consisted of commonly seen developing malocclusion with grades of severity, encompassing those that would necessitate monitoring, standard referral, or urgent referral. Monitoring may be carried out by the frontliners regularly, while the other two grades would need to be referred to an orthodontist, either as a standard or urgent referral. The 'Monitor' refers to mild malocclusion that can be monitored regularly in case it improves or worsens with growth. The 'Standard Referral' means the malocclusion can be put into the regular waiting list as the malocclusion will not benefit from any immediate interception and its progression will not jeopardize the treatment at any timepoint. However, 'Urgent Referral' requires immediate intervention for improved dental health urgently. If placed in a standard referral, it may lose the opportunity to be treated early with simpler mechanics and more treatment options. At the extreme, it may need surgical intervention at adulthood because the ideal time for interceptive orthodontics has passed.

The index was tested for validity and reliability to ensure that the index was meaningful.[28] Validation of the index required both qualitative and quantitative assessments. To assess the face and content validation subjectively, the draft index was presented at two conferences. The judges at the conferences included professionals from dentistry, medicine, and other fields of specialty. Apart from being recognized for its novelty, the IIOR received encouraging remarks, highlighting that the index could play a vital role in improving the management of developing malocclusion.

Quantitatively, the face and content validations were assessed using the CVI and modified Kappa statistics (K*). The content and face validation were assessed by six orthodontists and twelve dental personnel, respectively. It had been suggested that the number of experts involved will determine the implications of the CVI value.[22] The items which scored less than 0.83 was discussed among the researchers and assessors. Suitable amendments were done to reflect the comments by the assessors and to complement the initial objective of this study. The K* was carried out to increase the strength of the CVI result and eliminate any chance of agreement.[23] The final index was reliable as the inter- and intra-assessor agreement portrayed excellent strength.

The IIOR is both valid and reliable as a dental screening tool, that may be introduced in the dental education system to benefit the global community at large in the future. While this study produced significant findings, the IIOR has not been tested on a larger scale for usability and accuracy. This limitation is being overcome by an ongoing study to test the index among dental frontliners.

CONCLUSIONS

• The IIOR has been developed as an orthodontic screening guideline to be used by the dental frontliners. Its novelty is to identify the developing malocclusion based on its severity.
• The IIOR can curb the consequences of delayed referral of developing malocclusion and increase the opportunities for interceptive orthodontics provision. The IIOR may be used in conjunction with other treatment need indices.
• Indirectly, this may increase the number of referrals of developing malocclusion from the dental frontliners to the orthodontist, as the orthodontist relies on the referred population in the referral pathway.

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AUTHOR CONTRIBUTIONS

Conceptualization: SDS, AV. Data curation and Formal analysis: NNZ, AV, SDS. Funding acquisition: SDS, AV, NNZ. Methodology and Investigation: SDS, AV, NNZ. Project administration and Resources: SDS, AV, NNZ. Supervision: SDS, AV. Validation and Visualization: SDS, AV, NNZ. Writing – original draft: SDS, AV, NNZ. Writing - review and editing: SDS.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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