Effect of functional appliance therapy on the quality of life in skeletal Class II malocclusion

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Introduction: A Class II malocclusion is a common orthodontic problem that may affect social acceptance and the self-esteem of the patient. The aim of the present study was to evaluate the effect of functional appliance therapy on the oral health-related quality of life (OHRQOL) of patients presenting with a skeletal Class II malocclusion due to mandibular deficiency.

Methods: Forty-nine patients (11 to 14 years old) with a Class II malocclusion due to mandibular deficiency were included as the experimental group. A control group of 49 subjects was selected from school children without malocclusion. The Child Oral Impact on Daily Performance (Child-OIDP) index was administered, repeated and differences were evaluated following functional therapy using the Clark Twin Block appliance.

Results: At baseline, the most common oral impact on daily performance in the experimental group was emotional stability (35 patients, 71.4%) and smiling without shame (34 patients, 69.4%), which respectively decreased to 12.2% (six cases) and 20.4% (10 cases) after functional therapy. The mean (±SD) of the Child-OIDP Overall Impact score in the experimental group at baseline was 25.94 (±17.84), which significantly decreased to 2.77 (±2.09) after therapy (p < 0.001).

Conclusion: Functional therapy using the Clark Twin Block appliance had a significant effect in improving OHRQOL of children presenting with mandibular deficiency.

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Introduction
Quality of life (QOL) is the sense of wellbeing that arises from a person’s satisfaction with his/her life.1 In contemporary times, facial aesthetics has become an increasing field of interest as personal appearance has the potential to affect life qualities such as interpersonal relationships, popularity, and social contacts.2 Oral health-related quality of life (OHRQOL) is a complicated issue that can define the effect that oral health or diseases may have on daily performance, mental health, self-confidence, and satisfaction.3 Psychologists suggest that a malocclusion may affect a patient’s self-satisfaction with his/her face, in which case, mental responses such as anger, loss of self-confidence, introspection, and depression might result.4,5 Recently, the effects of fixed orthodontic treatment on OHRQOL have been investigated,6,7,8 and it has been concluded that, in children, OHRQOL is of higher importance. The patient’s view regarding their malocclusion may be different from the dentist’s perspective, and might not necessarily be related to the severity of the problem but affected by personality traits and mental factors.2,3,5,6 An awareness of a patient’s viewpoint improves the patient-dentist relationship and provides data to improve a future health care system.9

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The assessment of QOL is complicated and there are few research instruments available for this purpose. The Child Perception Questionnaire (CPQ), Child Oral Health Impact Profile (COHIP), and Child-OIDP (Child-Oral Impact on Daily Performances) provide the most valid questionnaires currently used for assessing the OHRQOL in children. Of these, the child-OIDP has the advantage of defining the oral conditions that cause discomfort for the child, and therefore can be used to determine the child's treatment needs.

A Class II malocclusion is a common orthodontic problem that occurs in 20–30% of children and may be difficult to treat. The effects of wearing headgear or functional appliances on a child's performance have been evaluated in several studies. However, the effect of functional appliances on children's OHRQOL has not been sufficiently assessed. The purpose of the present study was to evaluate the effect of functional appliance therapy on the OHRQOL of patients who presented with a skeletal Class II malocclusion as a result of mandibular deficiency.

Materials and methods
The present study recruited 98 patients of a mean age of 11.5 years (range, 11 to 14 years). Following informed consent, the cohort was divided into experimental and control groups (49 patients in each group). The experimental group consisted of patients possessing a Class II skeletal pattern (ANB > 4º) caused by a mandibular deficiency (SNB < 76º), manifesting intra-orally as a bilateral Class II molar relationship, an overjet of at least 5 mm, but a normal mandibular plane angle (Go-Gn/ SN = 32±2º). This group received functional appliance treatment. The control group included school children with a bilateral Class I molar relationship and a normal overjet along with proportionate faces. No intervention was performed in this group. The exclusion criteria were an inability to communicate verbally and answer questions, any previous orthodontic treatment, facial deformities such as cleft lip/palate, systemic diseases, mental disorder or disability, and physical disability.

Intervention
A Clark Twin Block appliance was inserted into each member of the experimental group and continued until a Class I molar relationship was achieved and the overjet was corrected. All of the patients were instructed to wear the twin block appliance throughout the day except when eating or exercising. The active phase was completed in 7–11 months, depending on the patient’s cooperation and on determination of when the molars were in a Class I occlusion and an edge-to-edge incisor relationship was achieved. During the later stages of treatment, selective grinding was directed at the appliance bite plates to promote better inter-digitation of the teeth. The retention phase was conducted at night by the same appliance for an average duration of six months.

After the completion of treatment, but during the retention phase, an interview was conducted again to assess the treatment results and their effect on the child's quality of life. The questionnaire for the control group was completed at the same time as those of the study group and all were delivered by the same examiner.

Research tool
The Child-OIDP questionnaire was introduced in 2004. At baseline, the patients were contacted and the questionnaire completed by a face-to-face interview. Cavand et al., in a cross-sectional study, confirmed the validity and reliability of the Farsi (Persian) translation of the Child-OIDP. The questionnaire requests demographic information such as gender, parental educational level and oral/dental problems over the previous three months. In a second part, the chart of the Child-OIDP index was completed by the interviewer. The children were asked to indicate the daily performances affected by dental/oral problems over the previous three months. The daily performances were selected from eight daily performances presented by the Child-OIDP index and included chewing, speaking, cleaning teeth, sleeping, smiling without shame, emotional stability, doing school work, and social contact. The following part of the questionnaire considered the severity and frequency of each problem using a Likert scale (possible scores of 1–3) for frequency (1–2 times/month was 1, ≥ 3 times/month was 2, and 1–2 times per week was 3) and severity (little effect was 1, moderate effect was 2, and severe effect was 3). The frequency and severity scores for each performance were multiplied to produce a resultant score range of zero to nine and called the Performance Score. The scores of the eight performances were totalled (a possible maximum
score of 72) and finally divided by 72 and multiplied by 100 to produce a total percentage score called the Overall Impact score.

**Reliability**

In order to determine the reliability of the Child-OIDP, two weeks after enrollment, the questionnaire was completed for a second time by 30 patients (15 in the experimental and 15 in control group). The intraclass correlation coefficient (ICC) index was 0.926, which is considered excellent according to the Cicchetti classification.17

**Statistical analysis**

The Kolmogorov-Smirnov test was used to assess the normal distribution of the Child-OIDP Overall Impact scores, which showed a non-normal distribution of this score in the experimental and control groups. The median (interquartile range, IQR) as well as mean (±standard deviation, SD) was used to describe the Child-OIDP Overall Impact scores. In order to compare median Child-OIDP Overall Impact scores between experimental and control groups at baseline and after the functional therapy, the Mann Whitney U test was applied. To determine the changes of Child-OIDP Overall Impact scores before and after the functional appliance therapy in the experimental group, the Wilcoxon test was applied. In determining the comparison of the Child-OIDP Overall Impact scores in subgroup analyses (according to gender and parental educational level), the Student t-test was used. A significance level was set at 0.05. The data were analysed using the SPSS statistical package (Ver.16.0, SPSS Inc., USA).

**Ethics**

The present study was approved by the ethics committee of Kermanshah University Dental School Research Deputy. The details of the study were explained to the children and their parents, who were assured about the privacy of the information, and written informed consent was obtained.

**Results**

There were 25 girls (51%) and 24 boys (49%) in the experimental group, and 19 girls (39%) and 30 boys (61%) in the control group. The mean (±SD) ages in the experimental and control groups were 11.26 (±1.61) and 11.88 (±0.48) years, respectively.

The prevalence of oral impact on daily performances is presented in Table I. In the experimental group, the most common oral impacts on daily performances at baseline were emotional stability (71.4%) and smiling (69.4%), which respectively decreased to 12.2% and 20.4% after functional therapy. Smiling without shame was the most frequent problem in the control group (14 patients, 28.6%).

Table I shows the prevalence of oral impacts on daily performance with respective severity, frequency, and performance score for each performance before and after the intervention. In the experimental group,

| Performance | Experimental group (baseline) | Experimental group (after the intervention) |
|-------------|-------------------------------|---------------------------------------------|
|             | No. (%) Severity Frequency Performance score | No. (%) Severity Frequency Performance score |
| Eating      | 17 (34.7%) 1.88 (0.85) 2.35 (0.78) 4.76 (3.09) | 0 - - - |
| Speaking    | 7 (14.3%) 2 (0.57) 2.29 (0.48) 4.57 (1.98) | 2 (4.1%) 1 (0) 1 (0) 1 (0) |
| Cleaning teeth | 0 - - - | 0 - - - |
| Sleeping    | 25 (51%) 2.56 (0.65) 2.68 (0.55) 7.16 (2.67) | 4 (8.2%) 1.25 (0.5) 1.25 (0.5) 1.75 (1.5) |
| Emotional stability | 35 (71.4%) 2.34 (0.68) 2.37 (0.69) 6 (2.97) | 6 (12.2%) 1.17 (0.4) 1.33 (0.51) 1.66 (1.21) |
| Smiling without shame | 34 (69.4%) 2.29 (0.67) 2.26 (0.66) 5.56 (2.83) | 10 (20.4%) 1 (0) 1 (0) 1 (0) |
| Doing schoolwork | 4 (8.2%) 2 (1.15) 2 (1.15) 5 (4.61) | 1 (2%) 1 1 1 |
| Social contact | 25 (51%) 1.88 (0.78) 2.2 (0.7) 4.44 (2.75) | 1 (2%) 1 1 1 |

Data are presented as mean (standard deviation)

9 After the functional therapy only one patient reported difficulties in doing schoolwork and maintaining social contact and the data presented are for one patient.
the most common daily performance was emotional stability (35 patients, 71.4%), followed by smiling without shame (34 patients, 69.4%), social contact (25 patients, 51%), and sleeping (25 patients, 51%). In the control group, the most prevalent effects on daily performance were eating (one patient, 2%), speaking (six patients, 12.2%), cleaning teeth (three patients, 6.1%), sleeping (two patients, 4.1%), emotional stability (nine patients, 18.4%), smiling without shame (14 patients, 28.6%), and social contact (three patients, 6.1%). None of the subjects in the control group mentioned difficulty with the daily performance of ‘doing schoolwork’.

The Child-OIDP Overall Impact scores decreased significantly after the intervention in the experimental group (Table II). The mean (±SD) of the Child-OIDP Overall Impact Score in the experimental and control groups at baseline were respectively 25.94 (±17.84) and 12.76 (±7.29), \( p = 0.005 \). In the experimental group, this score decreased to 2.77 (±2.09) after the intervention (\( p < 0.001 \)).

### Subgroup analysis

According to the level of parental educational, the patients were divided into two groups: (1) high school diploma and lower levels, (2) higher education at college/university. Table III presents the Child-OIDP Overall Impact scores before and after the intervention in the experimental group in males and females and according to the level of parental educational. The change in the Child-OIDP Overall Impact scores after the intervention was statistically significant in both genders. Similarly, the improvement in the Overall Impact scores were significant in the groups based on paternal and maternal educational level.

### Discussion

Oral health-related quality of life has become an important index in the evaluation of the treatment needs and priorities for oral and dental health planning.\(^{18}\) The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have

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**Table II.** Comparison of the Child-OIDP Overall Impact scores at baseline and after the functional therapy between the experimental and control groups.

| OIDP overall impact score | Baseline (Experimental) | After functional therapy (Experimental) | After functional therapy (Control) | \( P \) value |
|---------------------------|--------------------------|------------------------------------------|-----------------------------------|----------------|
|                           | 25.94 (±17.84); 25 (26.39) | 2.77 (±2.09); 1.38 (2.43) | - | < 0.001† |
| Control                   | 12.76 (±7.29); 11.11 (12.5) | 12.76 (±7.29); 11.11 (12.5) | - | - |
| \( P \) value             | 0.005†                   | -                                        | -                                 | < 0.001† |

Data are presented as mean (±standard deviation); median (IQR)

† Wilcoxon test; † Mann-Whitney test

**Table III.** Comparison of the Child-OIDP Overall Impact score in the experimental group before and after the intervention, based on gender and parental educational level.

| Gender | Baseline (Experimental) | After the intervention (Experimental) | \( P \) value† |
|--------|--------------------------|---------------------------------------|----------------|
| Male (N = 21) | 27.97 (±21.74) | 3.96 (±2.71) | 0.018 |
| Female (N = 23) | 24.09 (±13.61) | 1.85 (±0.69) | 0.008 |
| \( P \) value† | 0.47 | 0.08 |

| Father education | Baseline (Experimental) | After the intervention (Experimental) | \( P \) value† |
|------------------|--------------------------|---------------------------------------|----------------|
| High school and lower (N = 17) | 25 (±17.43) | 3.76 (±2.74) | 0.018 |
| University (N = 27) | 26.54 (±18.4) | 2 (±1) | 0.008 |
| \( P \) value† | 0.78 | 0.14 |

| Mother education | Baseline (Experimental) | After the intervention (Experimental) | \( P \) value† |
|------------------|--------------------------|---------------------------------------|----------------|
| High school and lower (N = 20) | 30.97 (±19.58) | 3.03 (±2.39) | 0.003 |
| University (N = 24) | 21.75 (±15.44) | 2.22 (±1.24) | 0.04 |
| \( P \) value† | 0.08 | 0.49 |

Data are presented as mean (±standard deviation)

† Wilcoxon test; † Student t-test
designed laws based on the necessity of surveys of patients related to improvement of OHRQOL for the confirmation of drug products.\textsuperscript{19,20} OHRQOL indicates the level to which a person is satisfied with his/her oral and dental status and how it might affect their daily performance.\textsuperscript{21}

The OHRQOL is important in children because oral and dental diseases are more common in the paediatric age group. Hence, the related problems could have a negative effect on their lives and adversely affect their daily activities.\textsuperscript{10,22}

Previously, parents’ opinions were required to evaluate a child’s health status, since it was considered that children were not a valid source for providing relevant information. Evaluating the effect of oral health on children’s QOL requires special methods as children differ from adults in two ways. The first and more important is that children have fewer decision-making abilities regarding their oral health. The second is related to their experience and their ability to understand problems.\textsuperscript{23}

At the age range of 11–12 years, the idea of health becomes a complex, multidimensional concept for children, and up to the age of 14, individuals can evaluate OHRQOL according to its effect on their daily performance.\textsuperscript{24} Therefore, in evaluating the treatment needs of children or the effectiveness of a therapeutic intervention, the child’s opinion must be properly assessed and considered along with records of clinical examination.\textsuperscript{25} Many studies have shown the effect of fixed orthodontic treatment on OHRQOL,\textsuperscript{3,5,8,26} but research performed on paediatric skeletal Class II malocclusions is limited to studies that evaluate the effect of the presence of functional appliances and the patient’s irritation and discomfort.\textsuperscript{9,12} Kadkhoda et al.\textsuperscript{9} evaluated the effect of headgear and functional appliances on QOL of children, and showed that during treatment, the effects on daily life were no different. According to the high prevalence of Class II malocclusion in children, the present study evaluated the effect of functional treatment on the quality of life in children presenting with mandibular deficiency. The Clark Twin Block functional appliance has been widely used and arguably promotes mandibular growth. Other than guiding the mandible to a forward position, by selectively adjusting the bite planes, guidance of tooth eruption can be achieved. The wire components and jack screw in the upper arch appliance and the ramps in the upper and lower jaw appliances facilitate three-dimensional occlusal control.\textsuperscript{27,28}

The results of the present study indicate that, after orthodontic treatment, oral disorders reduced significantly. Previous studies have shown that OHRQOL improved after fixed orthodontic treatment.\textsuperscript{26,29} A lower QOL in patients with a malocclusion has also been reported.\textsuperscript{9,28} It appears that aesthetic problems and the related mental issues have immense destructive effects on patients’ quality of life. As a result, a common reason for seeking orthodontic treatment is an improvement of oro-dental aesthetics and of a patient’s self-confidence.\textsuperscript{5,30-34} Orthodontists should be aware that, following orthodontic treatment, patients expect an improvement in aspects of their lives mainly related to aesthetics, self-confidence, social situations, work and interpersonal relationships.\textsuperscript{3,8} Occasionally patients have expectations beyond reality that may also vary from professional opinion, and so using OHRQOL may be helpful as part of the information gathering process and initial diagnosis.\textsuperscript{3,5}

The median Child-OIDP score for the experimental group was higher than the control group at baseline. After functional appliance treatment, this score decreased in comparison with the control group, which indicated an improvement in patients’ quality of life after orthodontic treatment. Feu et al. reported the effect of fixed orthodontic treatment on the OHRQOL in adolescents by using the OHIP-14 questionnaire. It was shown that after treatment the quality of life improved significantly.\textsuperscript{6} This finding was supported by additional studies.\textsuperscript{3,7} The Oral Health Impact Profile (OHIP-14) questionnaire was initially prepared for application in adults; however, it has also been used effectively for assessing oral health problems in adolescents.\textsuperscript{6}

Alternative methods are available to assess the effect of treatment on a patient’s quality of life. Several studies have used general health questionnaires such as the 16-item Short-Form (SF16), which is more commonly used in medical research.\textsuperscript{35} Taylor et al.\textsuperscript{36} employed three questionnaires including the Youth Quality of Life (YQOL), Children’s OHRQOL, and Treatment Expectations and Experiences and reported that after the completion of orthodontic treatment the patients’ performance and appearance improved without significant changes in their QOL. Azuma et al.\textsuperscript{37} used the general health and oral health related questionnaire for assessing quality of life and found
an improvement in QOL after orthodontic treatment, while the general oral health questionnaire showed insignificant changes.

Three main questionnaires used frequently in studying paediatric QOL include the CPQ, COHIP, and child-OIDP. In the present study, the child-OIDP was selected since it specifies oral problems resulting in discomfort in children, and can be used to determine the child’s therapeutic requirements.10,11

It was observed that the OIDP index decreased significantly after functional appliance therapy without significant gender difference. This is in agreement with former reports.5 However, the literature shows controversial results regarding the different effects of a malocclusion on QOL of females and males. Some investigators have reported that a malocclusion has a more prominent effect on the QOL of female patients, which may be due to cultural differences.31,32,37,38

The results of the present study showed that orthodontic treatment significantly reduced the OIDP index, regardless of the patients’ social class defined by parental educational level. In contrast to the present results, Masood et al.31 concluded that the effect of a malocclusion on OHRQOL intensified in those with higher educational levels. This difference seems to be related to the multifactorial aspect of OHRQOL. It has been shown that factors such as culture, race, nationality, education, and age can affect a person’s perception regarding aesthetic issues. These factors are not interdependent and separating them could result in confusion.25

Conclusion

According to the results of the present study, the prevalence of oral disorders in skeletal Class II patients presenting with mandibular deficiency is higher than in children without skeletal malocclusion. These disorders may have a destructive effect on aesthetics and ultimately on the mental aspects of a patient’s life. After the completion of orthodontic treatment with functional appliances, significant reductions in oral disorders occurred, regardless of gender, and resulted in a consequent improvement in the child’s quality of life.

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