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Original research article

Effects of fixed functional devices on patients' oral health-related quality of life

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Abstract

Objective: To determine treatment expectations of patients and parents, and the initial effects of fixed functional devices on oral health-related quality of life.

Materials and Method: The study comprised 50 patients (39 female, 11 male, mean age 16.24 years) with Angle Class II,1 malocclusion, who were planned to be treated with forsus fatigue resistant device (FFRD). Treatment expectations of the patients and their parents/legal guardians were assessed before the treatment. The Oral Health Impact Profile (OHIP-14) was assessed 1-month after bonding (T1), and repeated 1-month after placement of FFRD (T2). Statistical analysis included Wilcoxon Signed Rank test for the evaluation of the differences in scores between treatment periods and Mann-Whitney U test for the evaluation of gender differences. Results: Main motivation for seeking orthodontic treatment was to improve dental appearance for the patients, and facial esthetics for their parents. Results declared that girls took their orthodontic problems more seriously than boys ($p<0.05$). The highest mean scores in OHIP-14 were achieved for "difficulty in eating", and "feeling pain". No significant difference between treatment periods was noted.

Conclusion: This study highlighted the lack of serious adverse effects of the use of fixed functional devices on patients' quality of life, and that patients might probably experience problems about physical status, mainly for functional limitations, rather than psychological status and social interactions. The findings may assist clinicians in understanding the concerns about these appliances.

Keywords: Orthodontics; orthodontic appliances, functional; quality of life

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Introduction

Health-related quality of life has gained attention with an increased emphasis on patient-based outcome measures.[1] It was emphasized that experiences of the patients and their parents contributed to the efficacy of the treatment.[2] Gift & Redford[3] presented that impairments in oral health might have an adverse effect in functions, appearance, and social relationships. Therefore, oral health contributes to the quality of life at both biological and social psychological levels.[4]

In recent years, due to the increased demand for better facial appearance and dental esthetics, the impact of malocclusion on patients' well-being has become important.[5,6] Thus, evaluations related to oral health-related quality of life (OHRQoL) and malocclusion has become popular.[5] The most common instruments used in the assessment of OHRQoL is the Oral Health Impact Profile (OHIP), in which the original version consisted of 49 items with seven domains,[7] and the short-form included 14 items.[8]

Angle Class II division 1 malocclusions are one of the most frequent problems in orthodontic practice, which require different treatment modalities. Among these, Forsus Fatique Resistant Device (FFRD) is a non-compliance, fixed hybrid functional appliance which was reported to be effective in the treatment of Angle Class II malocclusions.[9] A recent study examined patient experiences with this device and found that patients adapted to the device after a certain period of time.[10] In general, quality of life measures have been assessed especially for orthognathic patients rather than conventional orthodontic treatments.[11,12] This

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shows that further quantitative data is needed to evaluate the patients' responses to conventional orthodontic treatment. It has also been pointed out that perception of malocclusion can differ among patients and is not related with its severity.[13] Thus, evaluating patient expectations before treatment could be beneficial during treatment. Taken together, the objective of this study was to find out the treatment expectations of patients and their parents/legal guardians, and to assess the self-reported initial effects of fixed functional devices on patients' OHRQoL.

Materials and Method

The study comprised patients with Angle Class II division 1 malocclusion, who were planned to be treated with fixed functional devices at the University clinic. Ethical approval was obtained from the Ethical Committee of Gazi University (protocol number: 77082166-604.01.02). Patients and their parents/legal guardians were informed that this was a voluntary participation, and if they decided to refuse participation, this would not change their treatment service. All participants gave written informed consent at the beginning of the study. Sample size estimation was carried out in relation to a previous report,[14] estimating a sample size of 48 subjects for a significant change in quality of life with an 80% probability of power, an effect size of 0.5 and 0.05 level of significance. Thus, the sample size was determined to be 50 patients to compensate possible drop-outs or refusals during study.

The inclusion criteria included patients between 13 and 18 years of age, presence of Angle Class II division 1 malocclusion, Class 1 or Class 2 skeletal pattern or both (ANB, 2°-6°),[15] indication for non-extraction fixed orthodontic treatment together with a fixed functional device, presence of moderate crowding, no need for extra-oral appliances/mini-implants, no presence of transversal deficiency, tooth loss, caries, periodontal disease, or any craniofacial deformities. The exclusion criteria included patients with any cognitive disorders, hearing loss, speech disorders, mental retardation, history of any previous orthodontic treatment, and presence of severe skeletal Class 2 pattern in which orthognathic surgery is needed.

The study included 50 voluntary patients (39 female, 11 male) with a mean age of 16.24 years. Initially, finding out the treatment expectations were intended, so the first questionnaire, adapted from previous studies,[16,17] was conducted (Table 1).

Orthodontic treatment has been initiated with the placement of fixed appliances with Roth metal brackets (0.018-inch slot size prescription, Dentaurum, Ispringen, Germany). Patients were seen every 4 weeks. After leveling, 0.017× 0.025-inch stainless-steel archwires were inserted to both arches, and FFRD (3M Unitek Corp, Monrovia, CA, USA) were placed. Patients were informed about the usage instructions of FFRD before wearing it. The rods were attached from the buccal tubes of the upper first molar bands to the archwire distal to the lower canines in all patients. Patients were invited to complete the OHIP-14 questionnaire, which was translated into Turkish in accordance with cross-cultural adaptation guidelines to produce validated Turkish version,[18] at the first month control appointment after bonding of the fixed appliances (T1), as well as 1 month after the placement of FFRD (T2). The questionnaires were completed with face-to-face interviews. OHIP-14 contains 7 domains (two items per domain) for functional limitation, physical pain, psychological dis-

Table 1. *The questionnaire for demographic data and treatment expectations*

Age:			
Gender:		(please circle one)	
		Female	Male
Who fills the form?		(please circle one)	
		Patient	Parent/legal guardian
What is your present educational degree?		(please circle one)	
Elementary school	High school	University	Master/PhD
Please answer the following questions:			
1. Which was the most important issue for you referring for orthodontic treatment?			
a. Straightening of my/my child's teeth			
b. Having a better facial esthetics			
c. Having a better chewing function			
d. Having a better speech quality			
e. Other			
2. How will you score this orthodontic problem relative to your/your child's overall health?			
(Please score 1 to 10, where 1 is the least and 10 is the most important problem)			
(1) (2) (3) (4) (5) (6) (7) (8) (9) (10)			
3. Who referred you/your child to see an orthodontist?			
a. Myself			
b. My family members/relatives			
c. A dentist advised me			

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comfort, physical disability, psychological disability, social disability, and social handicap. Responses to each item is scored on a five-point Likert scale; 0, never; 1, hardly ever; 2, occasionally; 3, fairly often; 4, very often or every day. High total scores indicated negative impact on OHRQoL.[7,8]

Statistical analysis

Statistical analyses were performed by using SPSS Version 24.0 for Windows (Statistical Package for Social Sciences, SPSS Inc., Chicago, IL, USA). Descriptive statistics of data were calculated. Kolmogorov-Smirnov was used to evaluate the normality. The differences in scores between treatment periods was evaluated with Wilcoxon Signed Rank test, gender differences and the differences for the responses of patients and their parents were calculated by Mann-Whitney U test. Statistical significance was accepted as $p<0.05$.

Results

None of the participants refused to complete completing the questionnaires or discontinued the treatment, and no appliance breakage was reported. Education status assessments showed that 62% of the patients were at high school, 36% were at elementary school, and the rest were undergraduate students. The majority of the parents/legal guardians (38%) high school graduates, 36% primary school and 26% University/PhD graduates.

Assessment of treatment expectations

The majority of the patients (68%) declared that straightening and alignment of teeth was the most important issue for them, while 50% of the parents/legal guardians stated that having a better facial esthetics was their main concern. There was a statistically significant difference between patients and their parents/legal guardians ($p<0.05$). Mean scores related to the participants' rates for the importance of orthodontic problem relative to overall health showed statistically significant difference (patients' mean score: 5.98 ± 1.12; parents/legal guardians' mean score: 7.62 ± 1.34, $p<0.05$). Female patients presented higher scores than male patients (6.51 ± 1.14, 5.10 ± 1.06, respectively, $p<0.05$).

No significant difference was found between treatment expectations, rates for the importance of orthodontic problem, and education status ($p>0.05$). Fifty-six percent of the patients attended for treatment with their own request, while 26% pointed out that their parents noticed the orthodontic problem, and 18% declared that their dentists suggested reference for orthodontic treatment.

Assessment of OHIP-14 scores

Table 2 shows the mean total score, and the mean item scores for each domain, revealing no significant difference between T1 and T2. The highest mean scores were found as "difficulty in eating" (T1, 1.78 ± 1.79; T2, 2.06 ± 2.06), and "feeling pain" (T1, 2.28 ± 2.24; T2, 2.52 ± 2.54). There were no significant gender differences in mean OHIP-14 scores.

Table 2. *OHIP-14 questionnaire and the comparison between treatment periods*

Domains and questions	T1 (n=50) Mean±SD	T2 (n=50) Mean±SD	p
Functional limitation			
Q1. Difficulty in saying words/pronounciation	0.94±0.93	1.10±1.10	0.159
Q2. Mouth sore/worsening sense of taste	0.38±0.33	0.52±0.50	0.341
Physical pain			
Q3. Feeling pain in teeth/mouth	1.78±1.72	2.06±2.00	0.131
Q4. Difficulty in eating/chewing foods	2.28±2.24	2.52±2.50	0.195
Psychological discomfort			
Q5. Problem in self-confidence	0.24±0.20	0.32±0.30	0.329
Q6. Feeling tense	0.54±0.52	0.42±0.42	0.157
Physical disability			
Q7. Unsatisfactory diet	1.04±1.00	1.30±1.30	0.192
Q8. Interrupted meals	0.72±0.70	0.90±0.87	0.070
Psychological disability			
Q9. Difficulty in feeling relax	0.66±0.62	0.96±0.93	0.193
Q10. Feeling embarrassed	0.24±0.22	0.34±0.31	0.131
Social disability			
Q11. Feeling irritable/nervous towards others	0.26±0.22	0.42±0.40	0.227
Q12. Difficulty for performing usual job	0.22±0.22	0.28±0.28	0.247
Social handicap			
Q13. Life less satisfying	0.54±0.50	0.50±0.49	0.163
Q14. Unable to function completely	0	0	1.000
Total OHIP-14 score	9.84±3.50	11.64±4.50	0.121

T1, one month after bonding fixed appliances; T2, one month after placement of Forsus Fatique Resistant Device (FFRD); SD, standard deviation; score scale; 0, never; 1, hardly ever; 2, occasionally; 3, fairly often; 4, very often; non-significant, p>0.05.

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Discussion

The increasing demand for orthodontic treatment might be associated with the self-perception of facial appearance.[19] Improvements in dentofacial esthetics and self-image are the major motivations for patients to search for orthodontic treatment.[16,20] Similarly, our results showed that primary reason of the patients for seeking orthodontic treatment was the desire for achieving better dental appearance. However, the current results demonstrated that facial esthetics was more important for their parents. Participants were also invited to give a score to their level of concern for the existing orthodontic problem, and results pointed out that parents were more concerned about their children's orthodontic problems, than the patients themselves. We believed that this finding might depend on the desire of parents to deserve an access to the orthodontic treatment. It has also been noted that patients and their parents share similar treatment expectations, but parents reported more realistic prospects.[21] Decision for referring to an orthodontist was mainly based on the patients themselves and their parents in our study group. This result was in line with the findings of Uslu & Akcam.[16] Again, McKiernan *et al*.[22] emphasized that parental influences for dental esthetics may direct the patients' desire for orthodontic treatment. Dann *et al*.[23] demonstrated that the severity of malocclusion is not as effective as esthetic factors in orthodontic treatment decision. While there are numerous aspects to this subject, concerns for esthetic appearance strongly influences the demand for treatment, as confirmed in this study. Similarly, a recent study revealed the importance of dental appearance on social reinforcement among adolescent orthodontic patients.[24]

When the gender differences are considered, the results confirmed that female patients indicated higher concern for their existing orthodontic problem than male patients. Likewise, in the study of Al Omiri & Ahaija[25], the larger role of esthetic concerns for women's motivation to undergo orthodontic treatment was noted.

Standardized self-report surveys are emerging as appropriate methods for showing the patient's perspective relative to certain treatments.[1] At this point, clinicians may benefit from the information on the impact of treatment approaches on patients OHRQoL. The results of a systematic review emphasized the existence of a relationship between orthodontic treatment and quality of life.[26] Studies further reported this relationship to be more serious in the first month of treatment.[27, 28] Under this perspective, this study intended to evaluate self-reported difference in OHRQoL between initial placement of fixed appliances and FFRD wear, focusing on the first month. Our results showed that the major initial impacts of fixed appliances and FFRD came up with difficulties in eating and feeling pain. The current OHIP scores after 1-month wear of fixed appliances showed higher score for difficulty in eating/chewing foods than pain. As for fixed orthodontic mechanics, the initial problems experienced by the patients were highlighted as tightness, sensitivity during eating, and pain.[28-30] Chen *et al*.[30] stated that functional limitations and physical pain were affected during the first week of appliance placement, which improved with time. The present OHIP-14 scores (mean total score; 9.84) were lower than a previous result which presented higher scores 6 months after the placement of fixed orthodontic appliances (median total score; 29.3). The authors also noted significant changes for functional limitation, physical pain, psychological discomfort, psychological disability, and social disability domains. The differences between results might depend on several factors, such as different malocclusions, treatment protocols and/or amount of crowding, which were not mentioned in the study.[28]

Although the literature is limited on the effects of fixed and removable functional appliances on quality of life, a meta-analysis presented insufficient evidence to differentiate between fixed or removable functional appliances relative to patient experiences, and quality of life measures.[31] Patients reported that pain was the most common problem with respect to orthodontic appliances.[10,32,33] Čirgić *et al*.[34] investigated the functional and social discomfort experienced with Andresen activator and a prefabricated functional appliance after 1 and 6 months of appliance wear. They reported that 45-55% of the patients complained about pain particularly in the first month of treatment, in line with our results. Heinig & Goz[33] evaluated patient experiences with different Class II treatments including headgear, activator, Class II elastics and fixed functional devices, and they concluded that patients preferred non-compliance devices. Bowman *et al*.[10] noted that most patients had soreness on teeth, lip/cheek, and difficulty in jaw opening with FFRD, but the adverse effects generally diminished with time. The authors used a different survey to assess overall impression of the appliance and advised clinicians to be vigilant about cheek irritations. Recently, Elkordy *et al*.[35] demonstrated the clinical complications faced during the FFRD therapy and encountered complications of FFRD as breakage, separation of parts, spring fatigue, sheared molar tubes, soft tissue swelling, and severe cheek irritation. Subsequently, the authors advised to inform patients before the start of the FFRD therapy. Again, the main source of discomfort associated with FFRD appliances was identified as soreness in the cheeks.[36] With regard to our results, total OHIP score revealed a non-significant increase after one month wear of FFRD, declaring initial discomforts for eating/chewing and pain. The scores revealed that patients noted more issues with mastication than pain. Although the spring of FFRD allows flexibility, this result may suggest that physical pain is highly affected during the initial periods of appliance wear. However, this result was in contrast with a previous report, in which patients reported fewer issues with eating and pain for Forsus Nitinol Flat Spring Device (FNFD).[33]

In a prospective study with fixed and twin block appliances, OHIP scores revealed that pain and diffi-

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culty in eating increased 6 weeks after fitting the appliances,[21] but other domains showed low scores, which is inconsistent with our scores related to FFRD. The authors concluded that quality of life improved regardless of the treatment appliance.[21] Our patients declared no serious impact on psychological and social aspects with FFRD. Similarly, Bowman *et al.*[10] reported FFRD to have very little impact on daily life initially, and the majority of the respondents declared that the side effects decreased over time.

It is difficult to compare the findings between studies since there is no common OHRQoL-measure to ensure consistency of comparing outcomes.[26] Many factors can be effective on the inconsistent results, which might include age, motivation/expectation differences, socio-economic factors, doctor-patient relationships, and even patients' general outlook on life.[29]

There are some limitations related to this study. These can be summarized as the lack of longer term follow-up beyond 1 month. Besides, this study only focused on the evaluation of the self-reported difference between initial placement of fixed appliances and FFRD; thus, recording pre-treatment OHIP scores and self-reported differences between individuals not receiving fixed appliance treatment and those receiving fixed appliance treatment could be useful. This information could provide an interesting base line which could be clarified in future studies. Nevertheless, we can conclude some clinical implications that point to the need to understand the discomfort during orthodontic approaches to improve adherence to doctor-patient relationships and treatment.

Conclusion

The most common initial adverse effects experienced with brackets and FFRD were difficulty in eating/chewing and feeling pain, declaring no difference in quality of life score between these mechanics. Overall, it seems that patients experience problems about physical status, mainly for functional limitations, rather than psychological status and social interactions. Taken together, it might be useful to take sufficient time for understanding patients' expectations and to inform patients about adverse treatment-related effects and to take preventive measures to avoid adverse treatment effects before starting orthodontic treatment.

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Sabit fonksiyonel aygıtların ağızla ilgili yaşam kalitesine etkisi

Özet

Amaç: Bu çalışmada, sabit fonksiyonel aygıt uygulanan hastaların ve ebeveynlerinin tedavi beklentilerini belirlemek, bu aygıtların bireylerin ağızla ilgili yaşam kalitelerine etkisini değerlendirmek amaçlandı.

Gereç ve Yöntem: Angle sınıf II,1 maloklüzyona sahip, ortodontik tedavide forsus fatigue resistant aygıtı (FFRD) kullanımı planlanmış olan toplam 50 hasta (39 kadın, 11 erkek, ortalama yaş 16.24 yıl) çalışmaya dahil edildi. Tedavi öncesi hasta ve ebeveynlerinin tedavi beklentilerine ilişkin bilgiler kaydedildi. Hastaların mevcut ortodontik anomalilerinin genel sağlık durumları üzerindeki algı düzeyini ölçmek üzere tasarlanmış olan Oral Health Impact Profile (OHIP-14) anketi braketlemeden 1 ay sonra (T1) ve sabit fonksiyonel aygıtın yerleştirilmesinden 1 ay sonra (T2) alındı. İstatistiksel değerlendirmede dönemler arası fark analizi için Wilcoxon Signed Rank testi, cinsiyetler arası değerlendirme için Mann-Whitney U testi kullanıldı.

Bulgular: Ortodontik tedavi isteğinde hastaların dişlerinin düzgün sıralanmasını önemli bulduğu; ebeveynlerinin ise yüz estetiğini daha önemli bulduğu belirlendi. Cinsiyetler arası karşılaştırmada, kızların mevcut ortodontik problemlerini daha önemli buldukları görüldü ($p<0.05$). Yaşam kalitesi anket sonuçlarına göre, en yüksek skorlar sırasıyla 'yemek yemede problem' ve 'ağrı hissi' ile ilgili olup; tedavi dönemleri arasında anlamlı düzeyde fark bulunmadı.

Sonuç: Bu çalışma ile; sabit fonksiyonel aygıt uygulamasının hastaların ağızla ilgili yaşam kalitelerine ciddi düzeyde bir yan etkisi olmadığı vurgulanmıştır. Hastalar, psikolojik ve sosyal etkileşimden ziyade fonksiyonel limitasyonlarla karşılaşabilirler. Bu bulgular; ilgili cihazlarla ilişkili endişelerin giderilmesinde klinisyenlere yardımcı olabilir.

Anahtar Kelimeler: Ortodonti; ortodontik aletler, fonksiyonel; yaşam kalitesi

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