

# Comparison of Short-Term Oral Impacts Experienced by Patients Treated with Invisalign or Conventional Fixed Orthodontic Appliances

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## Significance of the Study

- This study was aimed at comparing the oral health-related quality of life of patients during thermoplastic clear aligner therapy (Invisalign<sup>®</sup>) and conventional fixed orthodontic appliances using a previously validated questionnaire.
- Clear aligner therapy appears to be tolerated better, but in the short term affects pronunciation and speech delivery.

## Keywords

Invisalign · Braces · Fixed appliance therapy · Dentistry · Orthodontics · Patients · Oral impacts · Oral health-related quality of life

## Abstract

**Objectives:** Our objective was to test the hypothesis that thermoplastic clear aligners (Invisalign<sup>®</sup>; Align Technology, Santa Clara, CA, USA) are more pleasant for patients than conventional fixed orthodontic appliances. **Subjects and Methods:** This was an observational retrospective study in which subjects were matched for age, treatment modality, and the treating orthodontist. A total of 60 adult patients (30 in the Invisalign group and 30 in the conventional buccal fixed appliance group) who met the inclusion criteria completed a validated self-reporting questionnaire, rating their experience after appliance activation in regard to oral im-

pact experience and satisfaction of both treatment modalities. Categorical variables were compared using the  $\chi^2$  test, Fisher's exact test, and the Z test. Continuous variables such as pain level and age were analyzed using the 2-sample *t* test. **Results:** Patients on clear aligner therapy reported significantly more difficulty in speech ( $p = 0.035$ ) necessitating change in speech delivery ( $p = 0.003$ ). In addition, they reported better chewing ability ( $p < 0.001$ ), no restrictions on amounts or types of food ( $p = 0.02$ ), and less mucosal ulcerations ( $p = 0.01$ ). Effects on daily routine, use of analgesics, and overall treatment satisfaction were not significantly different between the 2 groups. **Conclusion:** Clear aligner therapy is not necessarily more pleasant, but it is more tolerable as it satisfies patient needs over food consumption and absence of mucosal ulcerations. However, clear aligners affect pronunciation and speech delivery in the short term.

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## Introduction

Recent developments in the field of orthodontics have led to major changes in patients' interest in orthodontic therapy. A new system of thermoplastic clear aligner therapy, Invisalign® (Align Technology, Inc., Santa Clara, CA, USA), was introduced to the field of orthodontics in 1997 [1]. It combines basic principles proposed by multiple orthodontic pioneers suggesting the use of a removable thermoplastic appliance to achieve orthodontic movement [2]. Invisalign aligners consist of a series of clear, removable, plastic appliances that the patient wears sequentially to achieve the final result [3]. The Invisalign system uses a computer-based online software to plan the treatment ahead of time and the orthodontist can share the expected final results with the patients [4]. Invisalign aligners were introduced to offer not only the advantage of better esthetics but also the convenience of removal during consumption of food and beverage, less pain, as well as better oral care. [5]. There seems to be a general agreement that it is not indicated to manage orthodontic cases with skeletal disharmonies or severe crowding [6, 7]. The website of Align Technology Inc. reports that an estimated 7.5 million people have been treated with this appliance [8], while older studies have reported that it has been used to treat 300,000 people worldwide [9, 10]. Most of Invisalign users are above 19 years of age [11]. A predominance of 20- to 30-year-old females selected the clear appliance over buccal or lingual fixed appliances as it satisfies esthetic and functional considerations [12]. More adults and teenagers nowadays are requesting a more esthetic option; thus, the orthodontist should be well versed to answer their questions regarding what to expect.

There are many factors to consider when choosing between Invisalign aligners and conventional bracket-based treatment. Previous studies compared the use of Invisalign aligners and conventional fixed appliances with regard to esthetics, cost, technical and dental health characteristics, in addition to patients' experiences. The ability to remove the clear aligners make it easier for patients to maintain good oral hygiene, but studies have shown conflicting results related to pain and discomfort experienced by patients during orthodontic treatment [13]. Miller et al. [14] reported that the Invisalign caused more discomfort, whereas Shalish et al. [15] concluded that patients on conventional fixed therapy experienced more discomfort. Moreover, some studies reported more eating disturbance among patients treated with conventional fixed orthodontic appliances compared to Invisalign

therapy [16, 17]. The aim of our study was to compare patients' experience with thermoplastic clear aligners and conventional fixed orthodontic appliances in terms of limitations to daily routine or food consumption, oral symptoms, treatment satisfaction, or pain and consumption of analgesics.

## Materials and Methods

Participants were selected based on certain inclusion criteria. These included: treatment involved both jaws, treatment did not involve tooth extraction, crowding or spacing limited to 1–4 mm, Angle Class I molar relationship without skeletal discrepancy, absence of vertical or transverse discrepancy, absence of periodontal disease, and full complement of dentition except for 3rd molars.

Sixty adult patients between the ages of 18 and 50 who satisfied the inclusion criteria were recruited. The patients were assigned to 2 groups based on the treatment modality used but not the treatment stage or the type of dental movement due to the retrospective nature of the study. The Invisalign group consisted of 30 patients (20 females, 10 males; mean age 32.9 years) and the conventional fixed group included 30 patients (21 females, 9 males; mean age 23.6 years) The demographic characteristics of both groups are shown in Table 1.

This observational study was conducted using the previously structured and validated oral health-related quality of life (OHRQoL) questionnaire [18–20] (see Appendix). It also assesses pain severity and the use of pain-relieving medications. The degree of pain was assessed using a visual analog scale of 1–10 with 1–3 representing mild pain, 4–7 moderate pain, and 8–10 severe pain. Analgesic consumption was based on patients' self-reports. Patients were asked to fill out the questionnaire 1 week after their routine orthodontic visit. This approach was chosen because the reactivation periods of the 2 appliances differ. The Invisalign group changed their aligner every 2 weeks, while the conventional fixed appliances had a 1-month reactivation interval. The fixed appliance treatment protocol included the following wire sequence in an 0.022 bracket slot size: 0.014 Nitinol wire followed by 0.016 Nitinol, then 19 × 25 Nitinol, and finally 19 × 25 stainless steel wires were used. Other parameters recorded were limitations to daily routine, limitation to food consumption, oral symptoms, and treatment satisfaction. The selected sample was analyzed with regards to demographics, particularly age, gender, income, educational level, and area of residence. The data were collected from the participants through self-reported questionnaire after their routine appointment. An informed consent was attached to the questionnaire clearly stating the importance of patient privacy and the confidential information provided. The questionnaire was divided into 2 sections. The first section involved questions about demographics, whereas the second section included questions about limitations to daily routine, disturbances to eating, presence of oral symptoms, treatment satisfaction, pain, and analgesic use. The questions used have been employed in previous studies [14]. Most of the questions were obtained from the validated OHRQoL questionnaire, providing a set of answers that classified the frequency of the experienced incidence according to the 5-point Likert scale [16].

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS, Armonk, New York, NY, USA). Categorical variables were compared using the  $\chi^2$  test, Fisher's exact test, and the Z test. Continuous variables such as pain level and age were analyzed using the 2-sample *t* test. The results were dichotomized into 2 categories of "yes" and "no" to allow for statistical analysis. The "yes" category involved people who answered "always," "often," and "sometimes".

## Results

### Demographics

The data were normally distributed. Gender distribution, governorate of residence, educational level, and income showed no significant difference between the 2 groups. Mean age of the 2 groups showed a significant difference ( $p < 0.001$ ) but we do not believe that this difference would have affected their responses as both groups consisted of young adults (Table 1).

### Limitations to Daily Routine

Significantly more patients in the Invisalign aligner group reported limitations in the desired way of speech ( $p = 0.003$ ) and changes in speech delivery ( $p = 0.035$ ). When assessing daily routine in respect to malaise or fatigue, limitation to daily rest and sleep, daily activities, social relationships, and job/school attendance, no statistically significant differences were found between the 2 groups (Table 2).

### Limitation and Disturbances in Eating

Patients with conventional fixed appliances reported restriction in the amount and types of food they were comfortable consuming and more limitation in chewing when compared to patients using the removable clear aligner ( $p = 0.020$  and  $0.001$ , respectively). There were no significant differences in enjoyment of food or swallowing difficulties among patients in the 2 groups (Table 2).

### Oral Symptoms

Patients with conventional fixed appliances reported more mucosal ulcerations ( $p = 0.01$ ). No significant differences were found between the 2 groups for other symptoms such as halitosis, bleeding, swelling, bruising, or difficulty in opening the mouth (Table 2).

### Treatment Satisfaction

Patients with Invisalign reported more satisfaction with the appearance of their appliance in comparison to patients with the buccal fixed appliance; however, the dif-

**Table 1.** Demographics

Variable	Invisalign aligner (n = 30)	Fixed appliance (n = 30)	p value
Age, years	32.9±6.9	23.6±5.3	<0.001 <sup>a</sup>
Gender			
Female	20 (66.7)	21 (70.0)	
Male	10 (33.3)	9 (30.0)	0.781
Governorate			
Capital	17 (56.7)	12 (40.0)	
Hawally	11 (36.7)	12 (40.0)	0.269 <sup>b</sup>
Others	2 (6.7)	6 (20.0)	
Educational level			
College and above	29 (96.7)	24 (80.0)	
High school	1 (3.3)	6 (20.0)	0.103 <sup>b</sup>
Monthly income			
KWD <1,000	6 (20.0)	7 (23.3)	
KWD 1,000–2,000	13 (43.3)	17 (56.7)	0.432 <sup>b</sup>
KWD >2,000	11 (36.7)	6 (20.0)	

Data are presented as *n* (%) or mean ± SD as appropriate. KWD 1,000 is about USD 3,297.07. <sup>a</sup> *t* test used to obtain *p* value. <sup>b</sup> Fisher's exact test used to obtain *p* value.

ference was not significant ( $p = 0.052$ ). Patients in both groups felt that they would recommend the treatment they received to others and showed no interest in trying other options (Table 2).

### Pain and the Use of Analgesics

Participants reported their experienced pain according to the visual analog scale. Most patients in both groups exhibited pain for a few days. Patients with Invisalign experienced more pressure-like pain compared to other types of pain like sharp or throbbing pain ( $p = 0.016$ ), whereas patients with conventional fixed appliances reported more throbbing and dull pain ( $p = 0.037$  and  $0.019$ , respectively). The difference in pain duration was insignificant ( $p = 0.052$ ). Although the mean value of pain level in both groups was almost the same, patients with conventional fixed appliances reported higher consumption of analgesics than the other group ( $p = 0.062$ ; Table 3).

## Discussion

Our study followed an observational design using a survey with the objective of comparing 2 common modalities of orthodontic therapy. There was a significant difference in the age distribution, indicating that adults of

**Table 2.** Limitations to daily routine

Variable	Invisalign aligner (n = 30)	Fixed appliance (n = 30)	p value
Limitation to daily routine			
Speaking difficulty	16 (53.3)	8 (26.7)	0.035
Desired way of speech	16 (53.3)	5 (16.7)	0.003
Malaise or fatigue	4 (13.3)	6 (20.0)	0.731 <sup>a</sup>
Daily rest and sleep	4 (13.3)	3 (10.0)	1.000 <sup>a</sup>
Daily activities	1 (3.3)	2 (6.7)	1.000 <sup>a</sup>
Social relationships	1 (3.3)	1 (3.3)	1.000 <sup>a</sup>
Work or school attendance	0 (0.0)	1 (3.3)	1.000 <sup>a</sup>
Limitations and disturbance in eating			
Kind or amount of food	12 (40.0)	21 (70.0)	0.020
Chewing food	6 (20.0)	23 (76.7)	<0.001
Enjoying food	0 (0.0)	3 (10.0)	0.237 <sup>a</sup>
Comfortable swallowing	1 (3.3)	0 (0.0)	1.000 <sup>a</sup>
Oral symptoms			
Mucosal ulceration	11 (36.7)	21 (70.0)	0.010
Bad taste or smell	5 (16.7)	10 (33.3)	0.136
Bleeding, swelling, bruising	4 (13.3)	3 (10.0)	1.000 <sup>a</sup>
Difficulty in mouth opening	3 (10.0)	2 (6.7)	1.000 <sup>a</sup>
Treatment satisfaction			
Pleased and satisfied	29 (96.7)	23 (76.7)	0.052 <sup>a</sup>
Recommend it to others	29 (96.7)	30 (100)	1.000 <sup>a</sup>
Willingness to repeat treatment modality	27 (90.0)	27 (90)	1.000 <sup>a</sup>

Data are presented as n (%). <sup>a</sup> Fisher's exact test used to obtain p value.

**Table 3.** Pain and analgesics

Variable	Invisalign aligner (n = 30)	Fixed appliance (n = 30)	p value
Any pain	29 (96.7)	30 (100)	1.000 <sup>a</sup>
Pain in the first week after appointment	29 (96.7)	30 (100)	1.000 <sup>a</sup>
Pain duration			0.052 <sup>a</sup>
Lasted for a few days	27 (93.1)	23 (76.7)	0.166 <sup>b</sup>
Pain type			0.008 <sup>a</sup>
Pressure like pain	23 (79.3)	14 (46.7)	0.016 <sup>b</sup>
Throbbing	2 (6.9)	8 (26.7)	0.037 <sup>b</sup>
Sharp	4 (13.3)	3 (10.0)	0.688 <sup>b</sup>
Dull	0 (0.0)	5 (16.7)	0.019 <sup>b</sup>
Use of analgesics	3 (10.3)	9 (30.0)	0.062 <sup>a</sup>
Pain level	5.4±1.8	5.4±2.0	0.941 <sup>c</sup>

Data are presented as n (%) or mean ± SD as appropriate. <sup>a</sup> Fisher's exact test used to obtain p value. <sup>b</sup> Z test used to obtain p value. <sup>c</sup> t test used to obtain p value.

older ages are seeking a more esthetic option. This might have affected patients' experience with treatment, and thus can be considered a confounding factor. The Invisalign groups included a higher percentage of females; this is to be expected since, in general, females seek orthodontic treatment more often than males. It is important to mention that the patients included were not matched for the treatment stage nor the type of tooth movement. Therefore, the data should be interpreted with care.

Our findings show that patients with Invisalign aligner reported significantly more limitations and difficulties in the desired way of speaking, a common finding with removable appliances [12]. However, no significant disruptions were reported in other aspects of daily routine, including social relationship, and work or school attendance. Shalish et al. [15] have reported similar findings. Our clear aligner group reported more comfortable eating and chewing compared to conventional fixed appliances, which was also reported by Flores-Mir et al. [21], who showed that 47% of patients with Invisalign reported 100% satisfaction while eating and chewing compared to 24% of the bracket-based treatment group. This is not surprising due to the fact that subjects with Invisalign have the ability to remove their appliance temporarily during meals. However, when food enjoyment and swallowing ability was compared between the 2 groups no significant differences were found ( $p = 0.23$  and  $1.0$ , respectively). Moreover, conventional fixed orthodontic appliances showed higher prevalence of mucosal ulceration ( $p = 0.01$ ) as their treatment involves the use of metal brackets, wires, and bands which increases the risk of mucosal irritation compared to the plastic material used in clear aligners.

Furthermore, the ability to remove the appliance as in the Invisalign group makes brushing and flossing easier, which contributed to the better hygiene and oral health indices [22, 23]. However, published data regarding the 2 modalities of hygiene maintenance are inconsistent, showing that the plaque scores in the 2 groups are similar in both children and adults [24]. Gingival health was reported to be indistinguishable between the 2 groups, although the plaque accumulation in the standard fixed bracket group was more evident [25]. In our study, no significant difference in halitosis was found between the 2 appliances ( $p = 0.13$ ).

When evaluating patients' satisfaction, almost all participants recommended their treatment to others and were willing to repeat the treatment with the same appliance. As our questionnaire was filled 1 week after activation, it is more likely that the satisfaction response of pa-

tients is based on the appliance type and not the final treatment results. It has been documented that patients with Invisalign reported more readiness to repeat the treatment process as they experienced less disturbance in their day-to-day life [24]. It is also important to note that the orthodontist's rapport with patients influences the satisfaction of patients in both treatment modalities [26, 27].

Both groups reported similar levels of pain. However, patients with Invisalign experienced more pressure-like pain ( $p = 0.016$ ), whereas patients with conventional fixed appliances reported more throbbing and dull pain ( $p = 0.037$  and  $0.019$ , respectively). This finding probably explains why the conventional fixed appliance group consumed more analgesics compared to the Invisalign aligner group because pressure-like pain is perhaps more tolerable. Conflicting results are found in the literature in terms of pain and the amount of analgesic consumption.

Several limitations exist in the design and execution of this study. This is a cross-sectional observational study and subjects were not matched for the stage of treatment or the type of dental movement. There was a significant difference in age between participants of the 2 groups. This is considered a confounding factor. The inclusion criteria were not very strict as the availability and willingness of patients to participate were limited. In addition, there is a high probability of recall bias which might have affected the reported results. A prospective randomized assignment of starting patients would be the ideal setup for future research.

## Conclusion

We can conclude with caution that there is a significant difference between clear aligners and fixed appliance therapy in terms of the patient's oral health and quality of life. Clear aligner patients reported more speech disruption, unhindered ability to chew, and no restrictions on amounts or types of food. Patients with conventional fixed appliance experienced more mucosal ulceration without signs of bleeding or bruising. Patients using fixed appliance reported more use of analgesics and the difference approached significance. Patients with Invisalign experienced more pressure-like pain while patients using fixed appliances reported throbbing and dull pain. Invisalign is not necessarily more pleasant but could be more tolerable as it satisfies patient needs of food consumption, absence of mucosal ulcerations, and speech delivery. Long-term differences between these treatment modalities from the patients' perspective are needed.

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## Statement of Ethics

Ethical approval for this study was obtained from the Standing Committee of Coordination of Medical and Health-Related Research, Kuwait Ministry of Health, and the Faculty of Dentistry, Kuwait University.

## Disclosure Statement

The authors declare no conflict of interest.

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## Author Contributions

S.A.: literature review, study design, subject recruitment, data collection, data analysis, and writing and editing of the manuscript. A.S.: literature review, subject recruitment, data collection,

and writing of the manuscript. R.A.-A.: devising the project, overall supervision, study design, subject recruitment, editing, and overall supervision of the manuscript.

## Appendix

### *OHRQoL Questionnaire*

You have received an orthodontic appliance. To improve the quality of care, it is important for us to know how the appliance has affected you. Please take a few moments to complete this survey. Please choose the number that corresponds to your assessment over the last week. Rate the worst pain you have felt during last week on a scale of 1–10 (1 – not at all, 10 – very much). Have you taken any medication to relieve pain? (0 = no, 1 = yes). For the following questions, please use this rating: 1 = no instances, 2 = few instances, 3 = some instances, 4 = several instances, 5 = numerous instances. Has it been difficult to speak? Has it been difficult to swallow? Has it been difficult to open your mouth? Were there any foods that you could not eat? Have you enjoyed your food? Have you noticed a change in your sense of taste? Was it difficult to sleep? Does the appliance disturb you at work or when studying? Has it been difficult to continue your daily activities? Do you have sores on your tongue? Do you have sores on your cheeks? Do you have sores on your lips? Have you had a bad taste or bad smell in your mouth? Has there been any food debris under the appliance?

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