

## Adaptational changes in clear aligner fit with time: *A scanning electron microscopy analysis*

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### ABSTRACT

**Objectives:** To analyze adaptational changes in clear aligner fit after intraoral usage at different sets of time.

**Materials and Methods:** Eight Invisalign appliances (Align Technology, San Jose, California, USA) were collected after intraoral usage. Acrylic imprints of the lower incisor region were constructed for each appliance at T0 (unused appliance). Two appliances were then used intra-orally for each of the following defined periods of time: 3 days, 7 days, 10 days, or 15 days. Used aligners were adapted on its T0 imprint and both were sectioned buccolingually from the distal surfaces of each incisor at the attachment area. Eight surfaces were collected for each set of time ( $n = 32$  surfaces). Microphotographs of obtained sections and micrometric measurements of aligner fit were recorded at five different levels using scanning electron microscopy (SEM). Mean values of the fit changes (gap width) and group comparisons were statistically analyzed using analysis of variance and Tukey's post hoc tests. Significance level was set at  $P < .05$ .

**Results:** Highly significant differences in aligner fit were found at the different time points assessed ( $P < .001$ ) with the least mean gap width at 15 days ( $176 \pm 98 \mu\text{m}$ ) and the highest at 7 days ( $269 \pm 145 \mu\text{m}$ ). Significant differences in aligner fit at different attachment levels were also found ( $P < .01$ ) with the least mean gap width at the middle of the labial surface of the attachment ( $187 \pm 118 \mu\text{m}$ ).

**Conclusions:** The 15-day period of intraoral aligner wear might still be recommended as it showed the best adaptation and least gap width between the aligner and the attachment. (*Angle Orthod.* 2022;92:220–225.)

**KEY WORDS:** Change analysis; Invisalign; Mechanical properties; Orthodontics; SEM

### INTRODUCTION

Clear aligner therapy (CAT) is becoming an essential treatment modality in orthodontics especially with increasing demands in adult orthodontics. They are made of thermoplastic materials, mainly polyurethane. They move teeth by having a series of customized removable clear plastic appliances that move the teeth in stages according to a predefined plan that is

translated into computer algorithms by a virtual three-dimensional software program.<sup>1</sup> Improvements in attachment design, aligner materials, as well as adding auxiliaries has made substantial advances in aligner biomechanics, biomaterials, and engineering with more precise and predictable outcomes.<sup>2,3</sup> Multiple studies have shown acceptable results when using clear aligners in treating crowding,<sup>2–4</sup> proclination,<sup>4</sup> distalization,<sup>5,6</sup> and open bite cases.<sup>7</sup> However, more complex movements such as deep bite,<sup>8,9</sup> rotations, and torquing require precise planning and are more demanding on anchorage units.<sup>10–15</sup>

Appliance material is one of the important factors to consider when assessing the effectiveness of clear aligners in achieving predictable outcomes.<sup>16–18</sup> Clear aligners are made of polyurethane material that have shown aging changes within the oral environment.<sup>16–18</sup> The fit of the appliance on the anchorage unit as well as at the teeth requiring movement is also of significant importance to achieve the intended tooth move-

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ment.<sup>3,19,20</sup> Mantovani et al. evaluated the fit of three different aligner systems: Invisalign (Align Technology, San Jose, California, USA), CA-Clear Aligner (Scheu-Dental, Iserlohn, Germany), and F22 (Sweden & Martina, Due Carrare, Italy) on anchorage attachments using scanning electron microscopy (SEM). They found that the three types of aligners had comparable performance in fit on anchorage attachments.<sup>20</sup> Mantovani et al. also evaluated the fit of two aligner systems, Invisalign and CA-Clear Aligner, on different teeth using SEM. They found that Invisalign provided better fit at the gingival edges of aligners, while the CA-Clear Aligner provided better fit on complex occlusal surfaces.<sup>3</sup> Additionally, Pazzini et al. assessed the adaptability of different types of Invisalign materials after intraoral usage: Exceed30 (EX30) and Smart Track (LD30). The appliances were used clinically for 2 weeks for 22 h/d. They found that Smart Track showed better adaptability to the dental arch and had greater consistency in achieving the required orthodontic forces compared to Exceed30.<sup>19</sup> However, both materials showed structural modifications after intraoral usage that resulted in increased hardness and hyperplasticity.<sup>16,20</sup>

Clear aligners require full-time wear to achieve the required movements.<sup>3</sup> However, as with all removable appliances, wear time is highly dependent on patient compliance. In their earlier years, clear aligners were recommended to be worn for a minimum of 22 h/d for 2 weeks to be effective.<sup>10,21</sup> However, this was considered to be a long period that could cause patients to become fatigued and lead to less than optimal results.<sup>22</sup> This has caused practitioners and companies to consider combining aligner treatment with devices that would accelerate tooth movement such as AcceleDent (OrthoAccel Technologies, Houston, Texas, USA)<sup>23</sup> and OrthoPulse (Biolum Research Ltd., Vancouver, Canada).<sup>24–26</sup> This would allow patients to obtain results faster and thus improve practice efficiency.<sup>22</sup> Some studies recommended the use of clear aligners for 10 days.<sup>15,27</sup> However, since 2016 and with the advances in aligner technology, the Align company recommended the wear of each aligner for 1 week only, which would reduce treatment time by 50%.<sup>1,22,28</sup> Lately, with the advances of Align Technology materials, wear of aligners was suggested to be reduced to 3–4 days especially when combined with corticotomy or piezosession or OrthoPulse for accelerated tooth movement.<sup>24,25,27,29</sup>

As mentioned in the literature, there are many factors to consider when deciding total wear time and duration for each aligner appliance to achieve predicted outcomes.<sup>3,10,15–22,27</sup> No previous study compared the actual adaptational changes in aligner fit between different durations of wear time. Thus, the aim of the

present study was to assess the adaptational changes in clear aligner fit with intraoral usage after 3, 7, 10, and 15 days, using SEM.

## MATERIALS AND METHODS

### Study Design

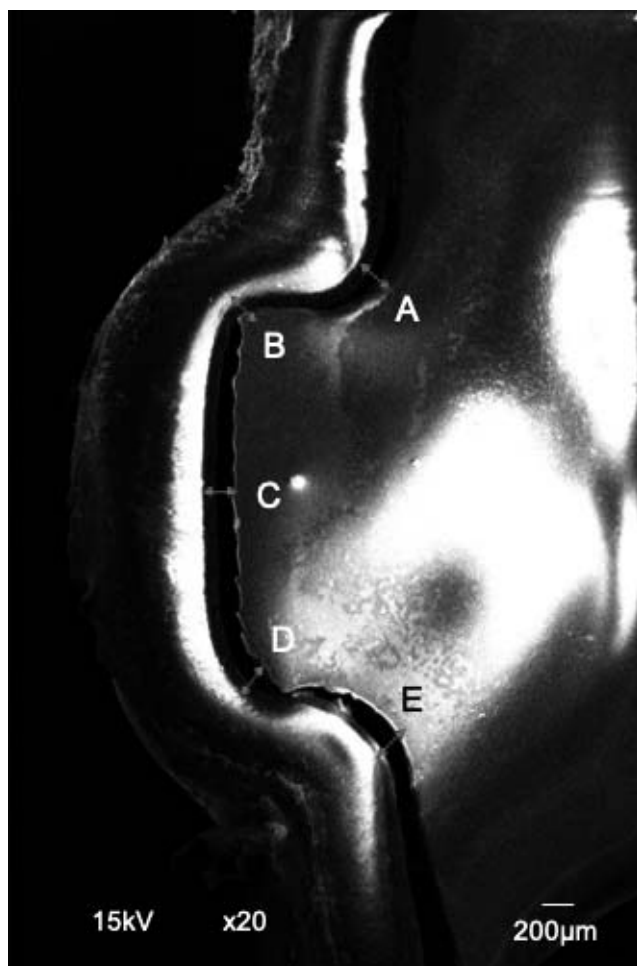
This was an ex-vivo experimental study. The study was approved by the ethical committee at the Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia [Ethical no.: 104-06-19]. The study hypothesis was that there would be no significant difference in the adaptational changes of clear aligner fit after intraoral usage between the four durations of wear time: 3, 7, 10, and 15 days. The study outcome was the micrometric gap width between the appliance and the attachments at five points of contact.

### Sample Distribution

Based on the study hypothesis, sample size calculation was done using G\*power 3.1. The minimum sample size required to detect an effect size of 0.6 for the micrometric gap width between the appliance and the attachments was at least eight surfaces for each duration at 80% power and  $\alpha = 0.05$ .

### Sample Preparation

A Class I deep bite malocclusion patient was selected for the study. The lower arch had mild crowding and deep curve of Spee. The treatment plan was to level curve of Spee by proclination of lower incisors and, thus, the constructed aligners had attachments on all four lower incisors. The patient followed a standardized protocol for appliance wear and removal as well as brushing and exposure to chemicals. Eight samples of Invisalign lower arch appliances (Align Technology, San Jose, California, USA) were collected after intraoral usage. Acrylic imprints of the lower arch were constructed for each appliance at its T0 (before usage) and the full fit of the appliances on the anchorage attachments was assured to establish reference points. Then, two appliances were each worn for one of the following defined durations of time: G1: 3 days; G2: 7 days; G3: 10 days; and G4: 15 days of usage. After being worn for its intended time, each appliance was adapted on its own T0 imprint with the anchorage attachments properly fitted and then it was sectioned buccolingually from the distal surfaces of the four lower incisors with a cutting machine (Well Diamond Wire Saw Inc., Norcross, GA, USA). The samples were oriented so that sectioning was parallel to the long axis of the teeth and passing through the attachment area using a mold taken for the imprint of the lower incisor region of one of the



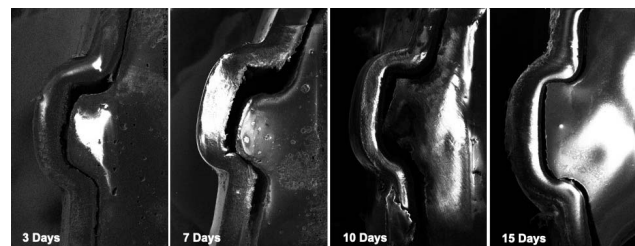
**Figure 1.** Scanning electron microscope image showing the micrometric measurements for the distance between the appliance and attachment (gap width) at five levels: (A) Level 1: occlusal end of attachment; (B) Level 2: occlusal corner of attachment; (C) Level 3: labial middle of attachment; (D) Level 4: gingival corner of attachment; and (E) Level 5: gingival end of attachment. (cross-section, 20× magnification).

appliances and then sectioned buccolingually to standardize the area of cutting among the different appliances. Eight surfaces were collected and assessed for adaptational changes (gap width) for each duration of time (total  $n = 32$  surfaces).

### Measurements

Micrometric measurements were obtained by a SEM, JSM-6490LA (JEOL Inc., Peabody, MA, USA) at 20× magnification, using microphotographs of the obtained sections, and adaptational changes of aligner fit were recorded at each duration of time.

Similar to the study of Mantovani et al. (2018),<sup>3</sup> the micrometric measurements for the distance between the appliance and the attachment of the T0 imprint (gap width,  $\mu\text{m}$ ) for each surface were taken at five levels as



**Figure 2.** Representative SEM images for aligner fit at the different durations of aligner wear assessed: 3, 7, 10, and 15 days (cross-section, 20× magnification).

follows (Figure 1): Level 1: Occlusal end of attachment; Level 2: Occlusal corner of attachment; Level 3: Labial middle of attachment; Level 4: Gingival corner of attachment; Level 5: Gingival end of attachment. Thus, a total of 160 micrometric measurements were obtained and analyzed.

### Statistical Analysis

Data were expressed as mean and standard deviation. The normality assumption of the data was evaluated with the Shapiro–Wilk test and homogeneity of the variables with the Levene and Brown–Forsythe tests. Group comparisons were calculated using two-way analysis of variance and Tukey’s post hoc tests. Significance level was set at ( $P < .05$ ).

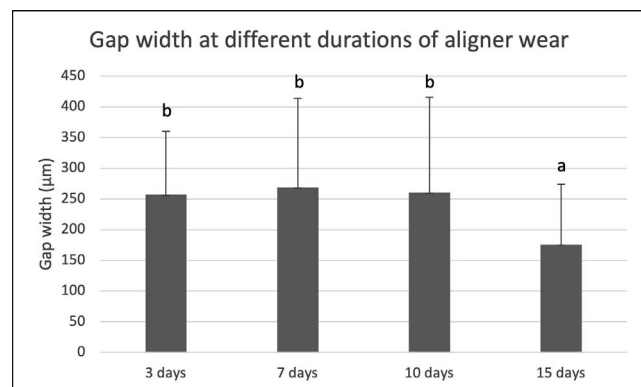
### RESULTS

Figure 2 shows representative images from the scanning electron microscope for aligner fit at the different time durations assessed: 3, 7, 10, and 15 days, at 20× magnification. The least gap width (best fit) was seen at 15 days.

Results revealed highly significant differences in aligner fit at the different time durations assessed ( $P < .001$ ). The least mean gap width was found at 15 days ( $176 \pm 98 \mu\text{m}$ ). The other time durations had almost similar gap widths which were: at 3 days ( $257 \pm 103 \mu\text{m}$ ), at 7 days ( $269 \pm 145 \mu\text{m}$ ), and at 10 days ( $261 \pm 155 \mu\text{m}$ ) (Figure 3).

Significant differences in aligner fit were also observed at the different attachment levels assessed ( $P < .01$ ). The least mean gap width was found at the middle of the labial surface of attachments ( $187 \pm 118 \mu\text{m}$ ). The greatest mean gap widths were at the occlusal corner ( $264 \pm 155 \mu\text{m}$ ), and the gingival corner ( $261 \pm 135 \mu\text{m}$ ) (Figure 4).

Figure 5 shows the mean gap width for each attachment level at the different time durations assessed. All attachment levels had the least mean gap width at 15 days. The occlusal and gingival end levels showed steady changes in mean gap widths over time. On the other hand, the occlusal corner,



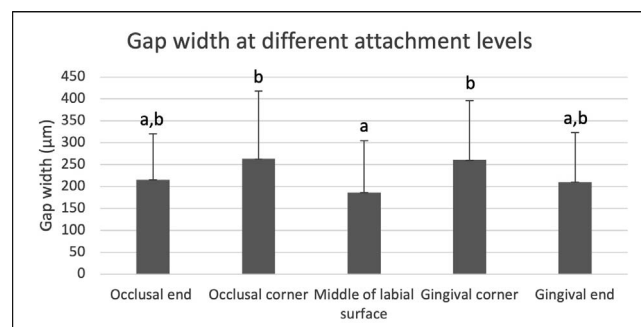
**Figure 3.** Gap width (Mean and SD) at different durations of aligner wear assessed: 3, 7, 10, and 15 days. Different letters indicate significant difference at  $P < .001$ .

gingival corner, and the middle of the labial surface showed variable changes in mean gap widths over time.

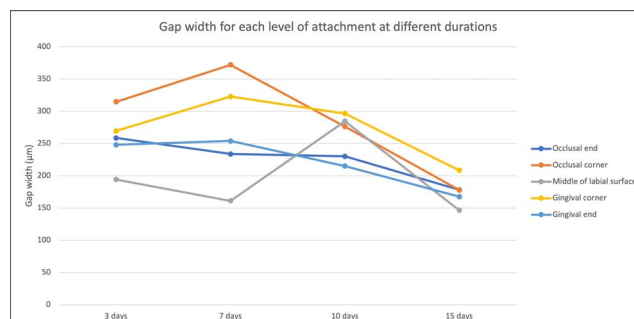
## DISCUSSION

The aim of the present study was to assess the adaptational changes in clear aligner fit after intraoral usage at different durations of wear time including 3, 7, 10, and 15 days using SEM. The results showed significant differences in aligner fit among the different time durations as well as at the different attachment levels assessed. The least mean gap width was found at 15 days and at the middle of the labial surface of the attachments. This might indicate that the aligners get more adapted and fit better with time.

There are many factors to consider when assessing the efficiency and effectiveness of aligners.<sup>3,10,15–22,27</sup> Fang et al. found that changes in the mechanical properties of thermoplastic materials under oral usage were not statistically or clinically significant.<sup>30</sup> Therefore, understanding the biomechanical force systems of the aligner-attachment interaction is more important in explaining the efficiency of aligners based on their



**Figure 4.** Gap width (Mean and SD) at different durations of aligner wear assessed: 3, 7, 10, and 15 days. Different letters indicate significant difference at  $P < .01$ .



**Figure 5.** Group comparison for the mean gap widths of the different attachment levels at the different time durations of aligner wear assessed.

best fit on the attachments.<sup>31,32</sup> It is important to indicate the type of aligner-attachment interaction when explaining the efficiency of aligner fit. Fry conducted a clinical trial on 10 moderately difficult cases and compared the efficacy of three groups of clinical aligner change protocols: biweekly, weekly, and weekly with AcceleDent.<sup>22</sup> It was found that all three groups had similar aligner fit after 12 weeks.

During aligner treatment, attachments are used on the anchorage units as well as on the teeth that require active tooth movement. Treatment of the case in the current study aimed to level the curve of Spee by proclination of the lower incisors and, thus, the constructed aligners had active attachments on all four lower incisors. The active forces that cause tooth movement comes from the intentional predetermined mismatching between the aligner and the attachments on those teeth.<sup>31,32</sup> Thus, proper fit of the appliance on the active teeth indicated that the appliance had finished achieving its programmed tooth movement. The current study showed that 15 days of aligner wear had the best adaptation and least gap width between the aligner and the attachments under SEM. The gap width did not change significantly between 3, 7, and 10 days, but varied in attachment location. Based on previous studies, it can, thus, be proposed that the fit gets better when the tooth movement reaches the programmed goals in the appliances.

Findings of the current study indicated that a protocol 15 days of aligner wear might still be advisable. However, the study had some limitations that reduced the generalizability of its results.

## Limitations

The current study was unique since it used SEM for accurate assessment; however, it still had some limitations. In the current study, one patient was selected with Class I malocclusion, deep bite, and mild crowding in the lower anterior teeth. The patient followed a standardized protocol for appliance wear



and removal as well as brushing and exposure to chemicals. This helped to control variables that might have impacted the adaptation of appliances during tooth movement. The small sample size as well as assessing one type of malocclusion may be considered as reducing the possibility of generalizing the results. However, the actual sample was obtained from 32 surfaces with 160 micrometric measurements. This added strength and credibility to the study results. Further studies are still needed to assess the aligner-attachment fit with a larger sample size and for different tooth movements.

## CONCLUSIONS

- Significant differences were found in aligner fit at the different time durations of aligner wear as well as at the different attachment levels assessed.
- The least mean gap width was found at 15 days and at the middle of the labial surface of attachments.
- The gap width did not change significantly between 3, 7, and 10 days, but varied by attachment location.

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