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RESEARCH ARTICLE

Perception of Pain Intensity and Quality in Patients Treated with Conventional Fixed Orthodontic Appliances Versus Clear Removable Aligners: A Pilot Study

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Abstract:

Objectives: The main objective of this study was to compare the perception of pain intensity between patients treated with fixed orthodontic appliances and those treated with clear removable aligners. The secondary objective was to investigate the pattern and quantities of analgesics use immediately after orthodontic adjustment visits and correlate this with the intensity and quality of the perceived pain.

Methods: Two hundred participants, 100 treated with fixed orthodontic appliances (G1) and 100 with clear removable aligners (G2), filled the Short-form McGill Pain Questionnaire (SF-MPQ), the Numeric Pain Rating scale (NPRS), and the Present Pain Index (PPI) at baseline (before orthodontic adjustment or changing to a new aligner) and 24-hours post-adjustment visit.

Results: The mean change in the NPRS values from baseline to 24-hour post-adjustment showed significantly higher pain intensity in G1 (3.15±2.47) compared to G2 (1.58±1.74) (p<0.0001). There was also a statistically significant difference in the frequency of reporting of SF-MPQ pain descriptors between G1 and G2, with more pain associated with G1. The PPI 24-hours post-adjustment showed that 94% of G1 reported some form of pain compared to only 79% in G2. At the 24-hour post-adjustment visit, 34 participants in G1 and only 8 participants in G2 reported the use of analgesic medications (p < 0.0001).

Conclusion: Overall, patients treated with fixed orthodontic appliances reported higher pain perception compared to patients treated with clear removable aligners during the first 24 hours following the adjustment visit.

Keywords: Pain perception, Fixed orthodontic appliances, Clear removable aligners, Short-form McGill Pain Questionnaire (SF-MPQ), Numeric Pain Rating scale (NPRS), Present Pain Index (PPI).

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1. INTRODUCTION

1.1. Background

According to the International Association for the Study of Pain, pain is defined as "an unpleasant sensory

and emotional experience associated with, or resembling, actual or potential tissue damage" [1]. Pain is frequently associated with dental care, with orthodontics being one of the procedures known to aggravate lingering pain and discomfort that may last for days or weeks [2, 3].



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Regardless of the techniques and modalities used, most studies have shown that the majority of patients report peaking pain and discomfort during the first few days after orthodontic adjustment visits [2, 3]. Pain has also been reported as a dominating reason for orthodontic treatment discouragement and non-compliance [4].

Orthodontic appliances, either fixed or removable, represent foreign objects introduced to a physiologically and neurologically sensitive area of the body [5]. The mechanisms whereby the application of orthodontic forces causes pain are still not fully understood. However, these two interrelated and dependent biological events are outcomes of a cascade of self-limiting inflammatory, vascular, neural, cellular, and immunological reactions that act in an orchestrated manner [6]. It is important to bear in mind that the association between the orthodontic force being applied and the subsequent pain is not proportionally correlated [7]. This reflects the complexity and multidimensionality of pain perception that can be influenced by several factors, such as fear, culture, and past experience [8-10].

Shape memory polymers, used in the removable aligners, are innovative contemporary materials with the capacity to have their shape modified by external stimuli while maintaining the ability to revert back to their original forms. This emerging technology has been widely utilized in the field of medicine, including regenerative medicine, neuro medicine, orthopedics, and drug delivery systems, given their biocompatibility with human tissues, biodegradability, cost-effectiveness, and ease of fabrication. With the increased demand for aesthetic orthodontic appliances nowadays, the use of clear removable aligners has gained great popularity. Despite the minor oral constraint reported by patients (i.e., slight and temporary speech and swallowing difficulties), clear removable aligners are deemed aesthetic and nonrestrictive for patients' diet and oral hygiene practice [11]. Regardless, investigations providing a head-to-head comparison of pain perception between patients receiving conventional fixed orthodontic appliances and clear removable aligners using validated and reliable pain inventories remain scarce.

1.2. The Validated Arabic Version of the Short-form McGill Pain Questionnaire

The McGill Pain Questionnaire (MPQ), developed and published by Melzack in 1975, has revolutionized pain research [12]. It upgraded pain investigations from being limited to measuring pain intensity and included multidimensional pain descriptors to illustrate sensory, affective, and evaluative qualities of the pain experience. The modified short-form MPQ (SF-MPQ) is a shorter version of the original MPQ that was developed later to evaluate the sensory and affective qualities of pain [13]. Iwasakia *et al.* validated the use of MPQ in measuring orthodontic pain by modifying the original form [13]. Fifteen descriptors with 4-point Likert severity response scale (*i.e.*, no pain, mild, moderate, severe) were incorporated, and the pain perception was quantified by the total score of those 15 descriptors. Only 11 descriptors of the 15 descriptors were discriminating for orthodontics (*i.e.*, pressure, aching, throbbing, tight, strange, pulling, uncomfortable, sore, frustrating, annoying, miserable). Satpal S. Sandhu *et al.* confirmed the two-factor structure of the SF-MPQ, as proposed by Iwasaki *et al.* 2013 [13]. Hence, two dimensions, the sensory and affective model of the SF-MPQ, seem to be the most appropriate and informative in assessing orthodontic pain [14].

The Arabic version of the SF-MPQ was developed and validated by Terkawi *et al.* [15]. A two-stage systematic translation process was undertaken. A backward translation back to the English language was accomplished and validated against the original SF-MPQ to ensure that the translated Arabic questionnaire reflected the same item content as the original English questionnaire. For all translators (English and Arabic), the source language of the questionnaire was their mother tongue, and they were totally unaware of the concepts being explored in the SF-MPQ.

1.3. Aims of the Investigation

This investigation aimed to provide a head-to-head comparison of the perception of pain intensity using the validated Arabic version of the modified SF-MPQ in patients treated with fixed orthodontic appliances and those treated with clear removable aligners. The secondary aim was to investigate the pattern and quantity of analgesics use immediately after orthodontic adjustment visits and correlate this with the intensity and quality of the perceived pain.

2. METHODOLOGY

2.1. Ethical Considerations

Ethical review was conducted in accordance with the Declaration of Helsinki [16] and approved by the King Abdul Aziz University Faculty of Dentistry Research Ethical Committee (Proposal #183-12-20; Approval #4263833; Date: January 17, 2021). The pain question-naire was accompanied by a cover letter to explain the purpose of the investigation to the participants, reassure respondents of the confidentiality of their responses and obtain their informed consent. Participation in the study was voluntary, and a consent form was obtained from all participants prior to accessing the pain questionnaire.

2.2. Participant Recruitment

This is a prospective observational investigation comparing self-reported pain intensity and pain quality by patients receiving conventional fixed orthodontic appliances *versus* clear removable aligners. Study participants were recruited from the Department of Orthodontics at the University and from the orthodontics practice at one private clinic. Patients were identified through the CPT codes registered in the electronic billing system and the electronic medical charts of the identified patients were reviewed to confirm their potential eligibility to be considered in the study. The study team personally approached all participants once they arrived at their orthodontics visits. The investigation details were provided to the participants and their permissions for voluntary enrollment were obtained.

2.3. Inclusion and Exclusion Criteria

The inclusion criteria of the subjects were 1) patients currently undergoing orthodontic treatment, 2) patients aged 15-65 years old, and 3) patients with no previous orthodontic therapy. Exclusion criteria included 1) patients with a history of clinically confirmed neurological, rheumatological, or psychological disorders (per physician's report), 2) patients with preexisting chronic orofacial pain condition (either odontogenic or non-odontogenic), 3) patients on continuous analgesic, steroid, or neurological therapies, and 4) patients who were unable to read, understand and/or fill out the modified SF-MPQ.

2.4. Study Design and Data Collection

Participants in this investigation were divided into two comparison groups: Group 1 (G1), defined as patients treated with fixed orthodontic appliances, and Group 2 (G2), defined as patients treated with clear removable aligners. For the sake of standardization, all removable

aligners were constructed by Invisalign[®]. The web link for the pain questionnaire was sent to the participants' mobile devices twice, once at baseline (*i.e.*, at the beginning of the adjustment orthodontic visit before changing the wires, in the conventional fixed appliances group, or switching to a new tray, in the removable clear aligners group) and once at 24-hour post-adjustment visit to collect follow up data. Study identification numbers were provided for each participant to link the answers of both the baseline and the post-adjustment visit SF-MPQ.

Demographic data, including participants' gender, age, and level of education, were collected. The modified SF-MPQ included three components 1) an 11-point Numeric Pain Rating scale (NPRS) to measure current pain intensity, 2) a measure of severity for 10 qualitative pain descriptors (*i.e.*, pulsating pain, electrical pain, stabbing pain, sharp pain, pressure pain, bite, and touch pain, exhausting pain, disgusting pain, scary pain, and miserable pain) reported on NRS as *zero*= no pain, 1-3=mild, 4-6= moderate, or 7-10= severe, 3) Present Pain Index (PPI) to determine the overall pain severity over the past 24 hours (reported as "no pain", "mild", "discomforting", "distressing", "horrible", "excruciating"), and 4) history of analgesic medications used (*i.e.*, type and frequency).

However, contraction pain in SF-MPQ is not related to orthodontic pain, so it was eliminated from this study.

2.5. Study Outcomes

The primary outcomes included: 1) changes in pain intensity defined as mean difference of the NPRS score (Δ NPRS) from baseline to 24-hours post-adjustment, 2) changes in the frequency of reported severity of the 10 qualitative pain descriptors (*i.e.*, no pain, mild, moderate, severe) from baseline to 24-hours post-adjustment, and 3) changes in the frequency of reported overall PPI over the past 24 hours (no pain, mild, discomforting, distressing, horrible, excruciating,). The secondary outcome was the difference between the two groups in the types and frequency of analgesics used post-adjustment visits.

2.6. Statistical Analysis

Standard descriptive statistics included means and standard deviations as well as frequencies for the measured variables. The bivariate analysis included a t-test and a Chi-square test. Data were analyzed using IBM SPSS statistical software (IBM Corp. Released 2011. IBM SPSS Statistics for Macintosh, Version 20.0. Armonk, NY: IBM Corp.). The significance level was set at $\alpha = 0.05$.

Sample size calculation was done using G power, with a power (1- β) set at 0.90 and α =0.05 (2-tailed), determining a total sample of 172 with 86 subjects per group. Due to the availability of subjects and to ensure that we were able to detect a medium to small effect size, it was decided to go with a total sample of 200 with 100 subjects per group.

3. RESULTS

3.1. Demographic Characteristics

The total sample size was 209 subjects: 104 in G1 (fixed orthodontic appliances) and 105 in G2 (clear removable aligners). Nine subjects, 4 in G1 and 5 in G2 were lost on follow-up (*i.e.*, they did not provide responses for the post-adjustment visit questionnaire). The mean age of the entire sample was 25 years old (SD \pm 5.7), with 111 (55.5%) males and 89 (44.5%) females. Sixty-four (32%) had a high school degree or less, 110 (55%) had a bachelor's degree, and 26 (13%) had a master's degree or higher. Table **1** depicts the demographic characteristics of all study participants.

3.2. Reporting of Pain at Baseline

At baseline (prior to the adjustment orthodontic visit), no statistically significant difference in the NPRS was detected between G1 and G2 (p=0.19) (Table 2). Similarly, the frequency of reporting of SF-MPQ pain descriptors did not show statistically significant differences in the perception of pulsating pain, sharp pain, pain on biting and touching, exhausting pain, disgusting pain, and severe pain (Table 3). Only four of the SF-MPO pain descriptors showed statistically significant differences in the frequency of reporting between the two groups at baseline. Higher reporting of "no pain" in electrical pain, stabbing pain, and scary pain descriptors was detected in G2, while the reporting of "no pain" in the pressure pain descriptor was more significant in G1. Adversely, the reporting of mild or moderate pain was higher in G1 for electrical, stabbing, and scary pains, while pressure pain was significantly more frequent in G2 [electrical pain (p= 0.005), stabbing pain (p=0.03), pressure pain (p=0.006), and scary pain (p=0.035)] (Table 3). There were no statistically significant differences in the frequency of the overall PPI severity between the two groups (Table 4).

4 The Open Dentistry Journal, 2024, Vol. 18

Table 1. Demographic characteristics of the study participants.

| - | | G1 | G2 | P-value | Total | |
|-----------------------|---------------------------|--------------------------------|--------------------------------|---------|---------------------------------|--|
| Mean Age Age Range | | 24.69 (SD±5.12) 15-42 Years | 25.20 (SD±6.23) 15-37 years | 0.53 | 25 yeas (SD±5.7) 15-42 years | |
| Gender | MALE | 66 | 45 | 0.004 | 111 | |
| | Female | 34 | 55 | 0.004 | 89 | |
| | High School | 28 | 36 | | 64 | |
| Educational Level | Bachelor's Degree | 62 | 48 | 0.125 | 110 | |
| | Master's Degree Or Higher | 10 | 16 | | 26 | |

Note: G1: Group 1: defined as patients treated with fixed orthodontic appliance; G2: Group 2: defined as patients treated with clear removable aligners.

Table 2. Comparison of the mean Numeric Pain Rating Scale (NPRS) among the study groups.

| - | G1 | G2 | P-value | |
|------------------------------------------|-----------------|-----------------|---------|--|
| Baseline Pain (NPRS) | 0.72±1.33 | 0.51 ± 0.90 | 0.19 | |
| Follow up Pain (NPRS) | 3.87±1.93 | 2.09 ± 1.84 | <0.0001 | |
| Change in Pain from baseline (Δ NPRS) | 3.15 ± 2.47 | 1.58 ± 1.74 | <0.0001 | |

Note: NPRS: Numeric Pain Rating Scale (NPRS); G1: Group 1: defined as patients treated with fixed orthodontic appliance; G2: Group 2: defined as patients treated with clear removable aligners.

Table 3. Comparison of SF-MPQ among the study groups at baseline and follow-up.

| Pain Descriptor | Level | | Baseline | | | Follow Up | | |
|--------------------------------------|---------------|----|----------|---------|----|-----------|---------|--|
| Fain Descriptor | | G1 | G2 | P-value | G1 | G2 | P-value | |
| | No pain | 88 | 92 | | 17 | 74 | <0.0001 | |
| Delection activ | Mild pain | 8 | 6 | 0.594 | 40 | 21 | | |
| Pulsating pain | Moderate pain | 4 | 2 | 0.594 | 43 | 3 | | |
| | Severe pain | 0 | 0 | | 0 | 2 | | |
| | No pain | 89 | 99 | | 35 | 93 | | |
| | Mild pain | 11 | 1 | 0.005 | 53 | 6 | <0.0001 | |
| Electrical pain | Moderate pain | 0 | 0 | 0.005 | 12 | 0 | <0.0001 | |
| | Severe pain | 0 | 0 | 1 | 0 | 1 | 1 | |
| | No pain | 88 | 97 | | 28 | 80 | <0.0001 | |
| | Mild pain | 7 | 3 | 0.02 | 48 | 19 | | |
| Stabbing pain | Moderate pain | 5 | 0 | 0.03 | 23 | 0 | | |
| | Severe pain | 0 | 0 | | 1 | 1 | | |
| | No pain | 90 | 95 | 0.32 | 30 | 71 | <0.0001 | |
| Charm main | Mild pain | 9 | 5 | | 44 | 24 | | |
| Sharp pain | Moderate pain | 1 | 0 | | 26 | 3 | | |
| | Severe pain | 0 | 0 | | 0 | 0 | | |
| | No pain | 87 | 72 | | 24 | 38 | 0.160 | |
| . . | Mild pain | 9 | 26 | 0.000 | 47 | 42 | | |
| Pressure pain | Moderate pain | 4 | 2 | 0.006 | 28 | 19 | | |
| | Severe pain | 0 | 0 | 1 | 1 | 1 | | |
| | No pain | 83 | 80 | | 11 | 31 | 0.001 | |
| D ¹ 1 1 1 1 | Mild pain | 12 | 19 | 0.110 | 44 | 46 | | |
| Bite and touch pain | Moderate pain | 5 | 1 | 0.116 | 38 | 19 | | |
| | Severe pain | 0 | 0 | 1 | 7 | 4 | | |
| | No pain | 85 | 93 | 0.072 | 29 | 53 | 0.004 | |
| Exhausting pain | Mild pain | 11 | 7 | | 51 | 38 | | |
| Exhausting pain | Moderate pain | 4 | 0 | | 17 | 7 | | |
| | Severe pain | 0 | 0 | 1 | 3 | 2 | | |

| (Table 3) contd | | | | | | | |
|-----------------|---------------|----------|----|-------------------------------------------------------|-----------|----|---------|
| Pain Descriptor | Level | Baseline | | | Follow Up | | |
| | Level | G1 | G2 | P-value | G1 | G2 | P-value |
| | No pain | 92 | 99 | | 36 | 82 | <0.0001 |
| Disgusting pain | Mild pain | 5 | 1 | 0.052 | 49 | 17 | |
| Disgusting pain | Moderate pain | 3 | 0 | 0.052 | 15 | 1 | |
| | Severe pain | 0 | 0 | | 0 | 0 | |
| | No pain | 92 | 99 | 0.035 | 38 | 83 | <0.0001 |
| Coorry noin | Mild pain | 8 | 1 | | 49 | 16 | |
| Scary pain | Moderate pain | 0 | 0 | 0.055 | 12 | 0 | |
| | Severe pain | 0 | 0 | | 1 | 1 | |
| Severing pain | No pain | 93 | 98 | | 35 | 89 | <0.0001 |
| | Mild pain | 6 | 2 | 0.000 | 50 | 8 | |
| | Moderate pain | 1 | 0 | $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | 2 | <0.0001 |
| | Severe pain | 0 | 0 | | | 1 | 1 |

Note: SF-MPQ: Short Form McGill Pain Questionnaire; G1: Group 1: defined as patients treated with fixed orthodontic appliance; G2: Group 2: defined as patients treated with clear removable aligners.

| Table 4. Comparison of the overall PPI amon | g the study groups at baseline and follow-up. |
|---------------------------------------------|-----------------------------------------------|
| | |

| Lorel | | Baseline | | Follow Up | | | |
|---------------------------------|----|----------|---------|-----------|----|---------|--|
| Level | G1 | G2 | P-value | G1 | G2 | P-value | |
| No pain | 78 | 81 | | 6 | 29 | <0.0001 | |
| Mild pain Discomforting pain | 18 | 18 | 0.395 | 44 | 55 | | |
| | 4 | 1 | | 33 | 10 | | |
| Distressing pain | 0 | 0 | | 10 | 5 | | |
| Horrible pain | 0 | 0 | | 7 1 | | | |
| Excruciating pain | 0 | 0 | | 0 | 0 | | |

Note: PPI: Present Pain Index; G1: Group 1: defined as patients treated with fixed orthodontic appliance; G2: Group 2: defined as patients treated with clear removable aligners.

3.3. Reporting of Pain at 24-hour Post-orthodontic Adjustment Visit

The mean NPRS values at 24-hour post-adjustment orthodontic visit showed significantly higher pain intensity in G1 (3.87 \pm 1.93) compared to G2 (2.09 \pm 1.84) (p<0.0001). Comparing the mean change in NPRS from baseline and post-adjustment visit (Δ NPRS) demonstrated a statistically significant difference between G1 (3.15 \pm 2.47) and G2 (1.58 \pm 1.74) (p<0.0001) (Table 2).

There was a statistically significant difference in the

frequency of SF-MPQ pain descriptors reporting between G1 and G2, with more pain associated with G1. The frequency of reporting mild to moderate pulsating pain, electric pain, stabbing pain, sharp pain, and severe pain were significantly higher in G1 compared to G2 (p<0.0001). Similarly, bite and touch pain, exhausting pain, and disgusting pain were significantly higher in G1 compared to G2 (p=0.001, p= 0.004, p <0.0001, respectively). Conversely, there were no statistically significant differences between the two groups in the perception of pressure pain (p=0.160) (Table 3).

Table 5. Comparison of analgesics' use among the study groups at baseline and follow-up.

| Variable | Level | Baseline | | | Follow Up | | |
|------------------------------|---------------|----------|-----|---------|-----------|----|---------|
| Variable | | G1 | G2 | P-value | G1 | G2 | P-value |
| Pain medication | No | 98 | 100 | 0.407 | 66 | 92 | <0.0001 |
| Pain medication | Yes | 2 | 0 | 0.497 | 34 | 8 | |
| Type of pain medication | None | 98 | 100 | | 66 | 92 | <0.0001 |
| | Paracetamol | 1 | 0 | 0.364 | 29 | 5 | |
| | NSAIDs | 1 | 0 | | 5 | 3 | |
| Frequency of pain medication | None | 98 | 100 | | 66 | 92 | <0.0001 |
| | Once/day | 0 | 0 | 0.497 | 10 | 3 | |
| | 2-5 times/day | 2 | 0 | 0.497 | 19 | 5 | |
| | > 5 times/day | 0 | 0 | | 5 | 0 | |

Note: G1: Group 1: defined as patients treated with fixed orthodontic appliance; G2: Group 2: defined as patients treated with clear removable aligners.

In regard to the overall PPI, no pain was reported in 6% in G1 *versus* 29% in G2. Similarly, mild overall pain was reported in 44% of G1 compared to 55% in G2. On the other hand, 33% in G1 *versus* 10% in G2 described the pain as discomforting, 10% in G1 *versus* 7% in G2 described the pain as distressing, and 7% in G1 *versus* only 1% in G2 described the pain as horrible. None of the participants in the two groups described the pain as excruciating (Table 4).

3.4. History of Pain Medication Intake

Analgesic medications were categorized into two groups: paracetamol and NSAIDs. Before the orthodontic adjustment visit, only 2 participants in G1 reported taking pain medications prior to the orthodontic adjustment visit (one paracetamol and one NSAID). At the 24-hour postadjustment visit, 34 participants in G1 and only 8 participants in G2 reported the use of analgesic medications (p<0.0001). The type of analgesics and frequency of intake are detailed in Table **5**.

4. DISCUSSION

This study compared pain perception in patients treated with conventional fixed orthodontic appliances and those treated with clear removable aligners using the validated Arabic version of the SF-MPQ, which included the NPRS, 10 pain descriptors, and the overall PPI [12-14]. While baseline NPRS and PPI showed no statistically significant differences between the two comparison groups, the 24-hour post-adjustment visit NPRS demonstrated a significantly higher pain perception in participants treated with conventional fixed orthodontic appliances. In addition, at 24-hour post-adjustment PPI, "discomforting", "distressing", and "horrible" pains were significantly more frequent in the fix appliance group, while the reporting of "no pain" was higher in the clear aligner group.

Miller *et al.* [2] compared the pain perception at baseline and up to 7 days after orthodontics adjustment. The study demonstrated that the fixed appliances group reported more pain than those treated with clear aligners. Fujiyama *et al.* [3] compared the pain perception between three groups (fixed orthodontic appliances, removable appliances, and both) and concluded that the former group experienced significantly higher levels of pain in comparison to the latter two groups.

The baseline SF-MPQ descriptors showed no statistically significant differences between the two groups in the frequency of reporting of six pain descriptors (*i.e.*, pulsating pain, sharp pain, pain on biting and touching, exhausting pain, disgusting pain, and severe pain). At 24 hours post-adjustment, a higher frequency of reporting of these six pain descriptors was found in the fixed appliances group compared to those receiving clear aligners. On the other hand, four pain descriptors showed significant differences in the frequency of reporting between the 2 groups at baseline. A higher frequency of electrical pain, stabbing pain, and scary pain reporting was detected in participants treated with fixed orthodontic

appliances, whereas frequent reporting of pressure pain was expressed by patients treated with clear removable aligners at baseline. At 24-hour post-adjustment, electrical, stabbing, and scary pains remained highly reported in the fixed appliances groups compared to the clear aligners group. The reporting of pressure pain also became highly reported (but lacking statistical significance) in the fixed appliance group 24-hour postadjustment visit despite its lower frequency in this group at baseline. Although a statistically significant difference on a few of the SF-MPQ descriptors did exist at baseline (i.e., 3 descriptors showing more patients reporting mild pain on the fixed orthodontics appliances group), the reporting of this mild pain at post-adjustment was not restricted to these patients but rather included a steeply higher number. It is important to clarify here that the numbers in Table 3 do not represent the average pain score at baseline, in which statistically significant differences may translate into confounders. Therefore, regression models to adjust for any confounding effects are not applicable. Using the SF-MPQ, Meazzini et al. [17] reported a significantly higher perception of aching, cutting, and tongue/ lips/cheeks pain in the fixed appliances group, while tightness and tension were significantly experienced in the clear aligner group [18].

Several investigations have demonstrated that clear removable aligners have been gaining popularity among patients. Oliver and Knapman *et al.* [19] found that pain and appearance of the fixed appliances are major discouraging factors during treatment that clear aligners may easily mitigate. The tolerability (*i.e.*, minimal pain), esthetics, small size, lack of sharp edges, and ability to be removed during eating and performing oral hygiene enhance the acceptability and preferability of clear aligners [2, 11, 18].

Subjects reported the usage of two main medication categories, which were Paracetamol and NSAIDs, with the majority using Paracetamol. Patients in the fixed appliance group demonstrated a statistically higher intake of pain medication after their adjustment visit compared to the removable aligners group. A systematic review by Monk et al. demonstrated the effectiveness of analgesics in reducing orthodontics adjustments-related pain with no difference between systemic non-steroidal anti-inflammatory drugs (NSAIDs) versus paracetamol or topical NSAIDs versus local anesthetic [5]. Similar to the findings in our investigation, Miller *et al.* reported a significantly higher intake of analgesics during the first 24 hours following adjustment visits in patients treated with fixed orthodontic appliances compared to removable aligners [2]. Moreover, the significantly higher analgesic intake in the same group continued throughout the second and third days, after adjustment visits, and then slowed down on days 4 through 7 [2].

5. STUDY LIMITATIONS AND FUTURE DIRECTIONS

Several limitations should be highlighted in this study that will be considered when planning the future longitudinal study. The perception and expression of pain

are influenced by several factors, such as genetic, developmental, psychological, familial, social, and cultural variables [3]. Although this investigation has collected epidemiologic data (*i.e.*, age, gender, educational level) that may influence pain perception, obtaining information pertaining to other influential factors (e.g., genetics, emotional/psychological, cultural, physiological) was beyond the capability of this investigation. It is also worth mentioning that the final study sample in this pilot investigation had a significantly higher number of male participants (due to 9 female participants dropping out after their initial enrolment). Future studies should ensure including a gender-matched participant. If an unavoidable sample attrition occurs, a statistical regression model should be implemented. Reviewing literature published over the past decade, several investigations showed no effect of gender on patient pain perception during orthodontic treatment. In a prospective observational study of 183 patients, Lin et al. demonstrated the lack of sex and age influence on self-reported pain during orthodontic treatment [20]. Furthermore, Machado et al. showed no effect of gender on pain vigilance in 114 patients receiving orthodontic therapy [21]. However, results from the literature should not be taken for granted, and equality in the basic study parameters must be ensured to allow fair comparisons between the study groups.

Furthermore, disclosure of monthly income by study participants was, although intended, could not be achieved. This was due to either refusal to report by the majority of income-making participants or the participation of patients below the age of 21 who are not yet income earners.

The use of categorical pain measures in the SF-MPQ (*i.e.*, no pain, mild, moderate, severe) was another limitation that hindered the quantification of mean pain changes in each pain descriptor. The use of NPRS for each of the SF-MPQ descriptors will be undertaken in the planned future project.

Moreover, the enrollment of patients who have already started their orthodontic treatment has created an effect modifier on the baseline data. Future investigations should measure baseline pain prior to the initiation of any orthodontic therapy to avoid the lingering effect and/or the adaptation to pain caused by prior orthodontic interventions or adjustments. Furthermore, daily reporting of pain, using SF-MPQ, over a one-week period after each adjustment visit for the entire treatment period should be carried out to provide comprehensive data and a clear picture of pain perception, intensity, duration, and analgesic uptake after orthodontic adjustment visits. Finally, exploring the correlation of pain levels with the malocclusion severity score reduction in future longitudinal investigations would allow a better understanding of the factors that may influence pain perception.

CONCLUSION

The results of this study show significant differences in

pain perception between patients treated with fixed orthodontic appliances and patients treated with clear removable aligners during the first 24 hours following the adjustment visit, with removable aligners being more favorable. Additionally, the use of analgesic medications within 24 hours post-adjustment was significantly lower in the removable aligners group. This study provides preliminary data that can be used to educate patients about both treatment modalities and the expected pain experience in each modality. Nonetheless, further investigations should be conducted using quantifiable SF-MPQ data and a larger matched sample with patients completely naïve to orthodontic treatment.

AUTHORS' CONTRIBUTIONS

It is hereby acknowledged that all authors have accepted responsibility for the manuscript's content and consented to its submission. They have meticulously reviewed all results and unanimously approved the final version of the manuscript.

LIST OF ABBREVIATIONS

NPRS = Numeric Pain Rating Scale

PPI = Present Pain Index

SF-MPQ = Short-form McGill Pain Questionnaire

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the King Abdul Aziz University Faculty of Dentistry Research Ethical Committee (Proposal #183-12-20; Approval #4263833; Date: January 17, 2021).

HUMAN AND ANIMAL RIGHTS

All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

Participation in the study was voluntary, and a consent form was obtained from all participants prior to accessing the pain questionnaire.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data and supportive information are available within the article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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