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# The effectiveness of orthodontic treatment with clear aligners in different thicknesses

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**This study aimed to evaluate the effectiveness, pain, and satisfaction levels of patients treated with different thicknesses of clear aligners among class I maxillary mild crowding cases. Twenty-eight subjects were randomly divided into two groups. Group 1 were treated with 0.5 mm-thick aligners and group 2 were treated with 0.75 mm-thick aligners. Maxillary models were printed using a 3-dimensional printer and aligners were produced using a vacuum thermoforming machine. The amount of orthodontic tooth movement was evaluated by comparing pre- and post-treatment digital models and lateral cephalograms taken at the beginning and end of the treatment. Pain and satisfaction levels were measured before aligner insertion, at the 4th hour, 2nd day, 1st week, 1st month and at the end of the treatment. Increases in maxillary intercanine, interpremolar, and intermolar widths, and dental arch perimeter were significantly higher in group 2 ($p < 0.05$). The pain levels peaked at T1 and decreased gradually in both groups; group 2 demonstrated greater pain levels. Group 1 reported significantly greater satisfaction levels ($p < 0.05$). Aligner thickness is a key determinant of the extent of orthodontic tooth movement. Treatment with a 0.5 mm-thick aligner provides enhanced comfort for patients, but a 0.75 mm-thick aligner yields more efficient treatment results.**

**Trial registration: The trial was registered on https://ClinicalTrials.gov retrospectively with the registrat ion number of NCT06504498, on 16/07/2024.**

**Keywords** Clear aligner, Aligner thickness, Orthodontic tooth movement, Pain, Patient satisfaction

In previous decades, many important developments have occurred in modern orthodontics with the advancement of new materials and techniques[1]. Current developments have focused on aesthetics and have led to dramatic changes in interest in orthodontic treatment in all age groups[1,2]. Clear aligner treatment (CAT), which is an aesthetic alternative to traditional appliances for the treatment of low-grade malocclusions, has gained significant popularity among clinicians and patients with aesthetic concerns[3]. In contrast to orthodontic treatment with conventional fixed appliances, CAT has been reported to be more comfortable, less painful, to facilitate oral hygiene, and is preferred by patients due to its efficacy[1].

The advance of aligner technology can be attributed to the introduction of Kesling's ground-breaking technique in 1945, after which plastic-based tooth aligners have been used for correcting minor malocclusions[4]. Following the introduction and evolution of computer-aided design/computer-aided manufacturing (CAD/CAM) technologies in dentistry, Invisalign® clear aligners (CAs) were launched by Align Technology (San Jose, California) in the latter part of the 20th century as the first digitally designed aligner system[5]. The working principle of 3-dimensional (3D) printing integrated with CAD/CAM technologies in the field of dentistry consists of 3 stages: digitalisation, design, and manufacturing[6]. 3D printing in dental and orthodontic offices has gained popularity by offering various advantages such as rapid manufacturing, high accuracy, and increased patient comfort[7]. The success of CAT depends on multiple parameters such as crown and root morphology, tooth movement types, shape and position of the attachments, thickness of the CAs, and patient- and operator-related factors[8–11]. Based on the literature and information of several manufacturers, CA material thickness varies from 0.5 mm to 1.5 mm[12,13]; margin height to the gingival zenith differs from 0 to 4 mm[14]; and gingival margin shapes are classified as scalloped or straight[11]. These differences may have clinical importance, affecting aligner seating, force application, and amount of orthodontic tooth movement (OTM)[12].

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Modern orthodontics is aimed at providing patients with comfortable and satisfying treatments and subsequent increases in quality of life[3]; any pain and discomfort associated with orthodontic treatment will ultimately negatively influence that quality of life[15]. Above all, the primary factor in the success of CAT is patient compliance[16]. Questionnaires may be useful for evaluating patients' goals and expectations to help clinicians offer personalised treatment and optimise outcomes[2]. Numerous studies have investigated differences in treatment effectiveness, quality of life and patient satisfaction between treatment with CAs and fixed appliances[1–3,16–20]. Most of these studies demonstrate that patient satisfaction during CAT is higher than during fixed orthodontic treatment. As we know, few studies have compared different CA systems and materials against each other[21–23]. While several studies have assessed tooth movement, and biomechanical and clinical effects according to the design of attachments[24–26], studies investigating the thickness of the CAs are limited[11,27]. Although some studies have been conducted with in-house CA methods[28], as per the current literature, the majority of published studies on CAT comprises non-randomised controlled trials, retrospective studies, case reports, finite element analysis, and in vitro studies, which do not contribute significantly to evidence-based treatment modalities[11,24,27–29]. It is therefore essential to improve the standard of available evidence in this regard. Studies conducted with in-house CA methods have reported varying results on the accuracy of OTM and the effectiveness of CAs[28]. The purpose of the current research was therefore to investigate the effectiveness, pain, and satisfaction levels of patients with Class I maxillary mild crowding treated with different thicknesses of CAs. The null hypothesis stated no clinical differences in effectiveness, pain, and satisfaction levels resulting from the use of different thicknesses of CAs. The alternate hypothesis stated that the thicker the CA, the higher the orthodontic force exerted, subsequently affecting OTM, pain, and satisfaction levels of patients.

## Materials and methods

### Participants

This study was reviewed and approved by the Clinical Research Ethics Committee of the University of Gaziantep (Approval Number: 2020/428) and performed in accordance with the Declaration of Helsinki. The trial was registered on ClinicalTrials.gov retrospectively with the registration number of NCT06504498, on 16/07/2024. The study followed the CONSORT guidelines for reporting clinical trials, and all procedures were performed in accordance with the relevant protocols. The sample size was computed to detect differences in the amount of OTM between groups (G*Power, version 3.1.9.2, University of Dusseldorf, Germany). The calculated sample size was 14 for each group, similar to previously published study (effect size = 0.8, $\alpha = 0.05$, and $1 - \beta = 0.80$)[28]. A total of twenty-eight patients were selected and none of the patients were lost to follow-up. Before participating, subjects were given a brief explanation of the study and provided written informed consent. The patients were recruited from the Department of Orthodontics, Faculty of Dentistry, Gaziantep University between May 2021 and January 2022. The following inclusion criteria were applied: (1) Angle Class I malocclusion without skeletal discrepancy; (2) patient older than 18 years old, with full permanent dentition without supernumerary, missing or impacted teeth except for 3rd molars; (3) non-extraction cases with mild crowding in maxillary arch (2–5 mm); (4) good oral health without periodontal disease or caries; (5) no previous orthodontic treatment; (6) not taking pain medications.

Lateral cephalograms were taken for all patients using an X-ray device (PM 2002 EC Proline; Planmeca OY, Helsinki, Finland) in the Department of Oral and Maxillofacial Radiology, University of Gaziantep. Images were taken by the same radiology technician, with a natural head position, and under standard conditions. Cephalograms of patients were traced to determine whether patients were in a skeletal Class I relationship; tracings were performed using Dolphin software, version 10.5 (Patterson Dental Supply, Chatsworth, USA). Twenty-eight patients (17 females, 11 males; mean age 20.14 ± 1.58 years) fulfilling the inclusion criteria were randomly divided into two equal groups based on aligner thickness. Using a computerized algorithm (https://www.graphpad.com/features/power-analysis, GraphPad Software Inc., version 9.2.0, Boston, MA), we randomly assigned participants to either group in a 1:1 ratio. To maintain confidentiality of group assignments, identical, sealed, opaque envelopes were used. An independent researcher assigned a unique study identifier to each randomly generated number to create the allocation sequence. This allocation sequence was kept confidential until the completion of data analysis. To ensure concealment of allocation, sealed opaque envelopes were shuffled by an independent staff member, and participants selected one at random prior to treatment initiation. CAs with thicknesses of 0.5 and 0.75 mm were used (Duran®; Scheu-Dental GmBH, Iserlohn, Germany). Patients in Group 1 (9 females, 5 males, mean age: 20.07 ± 1.54 years) were treated with 0.5 mm-thick CAs; patients in Group 2 (8 females, 6 males, mean age: 20.21 ± 1.62 years) were treated with 0.75 mm-thick CAs. The Little's Irregularity Index (LII), which measures the horizontal linear deviation between the anatomical contact points of the incisors in the labiolingual direction from the mesial surfaces of the right and left canines, were calculated with intraoral scanner (IOS), using OrthoAnalyzer software (3Shape, Copenhagen, Denmark) to standardise the amount of maxillary anterior crowding at the beginning of the treatment[30].

### Models prototyping

Initial records were taken at the beginning of the treatment using an IOS (Trios 3®, 3Shape, Copenhagen, Denmark). Scanned data was converted to standard tessellation language (STL) files which were modified to create virtual setups for OTM using OrthoAnalyzer software. Virtual setups were imported into a slicing software for model preparation before printing (Masitte Slicer, Masitte 3D Printing Technologies, Gaziantep, Türkiye). A stereolithographic (SLA) 3D printer (Masitte 3D printer, Masitte 3D Printing Technologies, Gaziantep, Türkiye) and liquid photopolymer (Masitte 3D Printing Technologies, Gaziantep, Türkiye) were used to print resin models. All models were printed with the occlusal plane parallel to the build platform's base; layer thickness was set at 50 µm, the optimum layer thickness for the prototyping of orthodontic models for CAs[31,32]. These models were used as moulds for the thermoforming of the aligners using a vacuum-thermoforming device (Model

No: 202, Keystone Industries, Myerstown, USA). All aligners were manually cut with straight trim lines at the gingival zenith to provide better comfort for the patients.

## Treatment protocol

At the initial appointment, attachments were placed according to the software measurements and interproximal reductions (IPRs) were performed. All patients were instructed to wear their CAs for 22 h per day, except during meals and brushing, and to replace them with new CAs on average every 2 weeks. In both groups, IPRs were performed in areas of crowding, with careful control of final expansion and protrusion, within the constraints of the virtual tooth movements required to achieve the ideal occlusion as defined by the digital treatment plan. The required IPRs for each patient were carried out by the same operator (SMC) using oscillating diamond strips under water-rinsing according to the virtual treatment plan; the amount of IPRs was checked with a metal gauge. Patients were followed up at 4-week intervals and were asked to use aligner chewies for 15–20 min a day to seat the aligners. After the first set of CAs, additional CAs were used to complete treatment goals and correct slight orthodontic details. Pre- (T0) and post-treatment (T5) digital models were collected using an IOS from all patients. At the end of the treatment, all attachments were removed, and bonded lingual retainers and in-house thermoformed retainers were applied.

## Treatment evaluation

The primary aim was to evaluate pre- and post-treatment changes in OTM. Maxillary cephalometric parameters were calculated on lateral cephalometric radiographs and maxillary dental parameters were measured using OrthoAnalyzer; pre- and post-treatment values were compared (Table 1)[33]. The secondary aim was to assess the pain and satisfaction levels of patients. A Visual Analogue Scale (VAS) was used to assess pain intensity before the insertion of the aligner (T0), at the 4th hour (T1), 2nd day (T2), 1st week (T3), 1st month (T4), and at the end of the treatment (T5). All responses were recorded on a 10-cm VAS using "no pain" and "severe pain" as anchor descriptions. To evaluate satisfaction levels, "Patient Satisfaction Evaluation Form 1" was used at T1, T2, T3, and T4, and "Patient Satisfaction Evaluation Form 2" was used at T5; the forms consisted of 15 and 17 questions, respectively. These forms consisted of the same questions and were applied to evaluate changes in patient satisfaction during and at the end of the CAT. These questionnaires were used to analyse the level of impact of CAs on daily life, encompassing routine limitation, social and psychological disability, discomfort in appearance, eating, speaking, and temporomandibular joint (TMJ) restrictions. These items were summarised to assess oral health-related quality of life (OHRQoL). The entire workflow was performed by one operator (SMC), who had proper training in this treatment modality.

## Statistical analysis

Statistical analysis, including mean and standard deviation (SD) values of all groups, were performed using SPSS software (SPSS version 22.0, SPSS IBM, Armonk, NY, USA) and Microsoft Excel 365 (Microsoft Office 365, Microsoft Corporation, Redmond, WA, USA). The normality of data distribution was assessed using the Shapiro–Wilk test. Non-parametric statistical tests were employed due to the non-normal distribution of the data. The Wilcoxon signed-rank test was used for intragroup comparisons of continuous variables. The Mann–Whitney U test was employed to compare the distributions of two parameters between groups. Intragroup comparisons of categorical variables were performed using the McNemar test. The Chi-squared analysis was performed to determine differences in categorical variables between groups. Statistical significance was defined as $P < 0.05$ for all analyses. For intraexaminer reliability, measurements of 10 randomly selected patients were repeated after 4 weeks to avoid potential sources of bias. Intraclass correlation coefficient (ICC) and Dahlberg's formula were performed to assess systemic and method errors.

| **Maxillary cephalometric parameters** | |
|---|---|
| SNA (°) | Angle of the anteroposterior position of the maxilla relative to the cranial base |
| U1-SN (°) | Angle of the upper incisor with the SN plane |
| U1-PP (°) | Angle of the upper incisor with the palatal plane |
| U1-NA (°) | Angle of the upper incisor with the NA plane |
| U1-NA (mm) | Horizontal distance of the upper incisor tip to the NA plane |
| **Maxillary dental parameters** | |
| Maxillary intercanine width (mm) | Linear distance between the cusp tips of the upper right and left canines |
| Maxillary interpremolar width (mm) | Linear distance between the cusp tips of the upper right and left first premolars |
| Maxillary intermolar width (mm) | Linear distance between the mesiobuccal cusp tips of the upper right and left 1st molars |
| Maxillary dental arch perimeter | Distance from the mesial contact point of the upper right 1st molar through mesial and distal contact points of 6 anterior teeth to the mesial contact point of the upper left 1st molar |

**Table 1**. Measurements used for this study.

| Variable | Period | Group 1 ($n=14$) | | Group 2 ($n=14$) | | |
|---|---|---|---|---|---|---|
| | | Mean ± SD | $p^a$ | Mean ± SD | $p^a$ | $p^b$ |
| SNA (°) | T0 | 83.80 ± 4.32 | 0.490 | 83.47 ± 4.22 | 0.706 | 0.841 |
| | T5 | 83.60 ± 2.95 | | 83.24 ± 3.04 | | 0.755 |
| Change | | −0.20 ± 1.44 | | −0.23 ± 1.28 | | 0.730 |
| U1-SN (°) | T0 | 98.47 ± 4.18 | 0.490 | 99.39 ± 2.97 | 0.706 | 0.358 |
| | T5 | 100.82 ± 3.55 | | 102.45 ± 2.86 | | 0.190 |
| Change | | 2.35 ± 1.06 | | 3.05 ± 0.90 | | 0.073 |
| U1-PP (°) | T0 | 105.74 ± 3.16 | 0.010* | 106.14 ± 3.17 | 0.001* | 0.741 |
| | T5 | 108.53 ± 3.74 | | 109.66 ± 3.08 | | 0.392 |
| Change | | 2.79 ± 2.68 | | 3.52 ± 0.75 | | 0.581 |
| U1-NA (°) | T0 | 14.65 ± 3.56 | 0.001* | 15.90 ± 4.93 | 0.001* | 0.441 |
| | T5 | 14.28 ± 3.38 | | 15.61 ± 4.74 | | 0.808 |
| Change | | −0.36 ± 0.28 | | −0.29 ± 0.12 | | 0.851 |
| U1-NA (mm) | T0 | 2.52 ± 1.58 | 0.001* | 2.94 ± 2.22 | 0.001* | 0.535 |
| | T5 | 2.27 ± 1.50 | | 2.66 ± 2.14 | | 0.505 |
| Change | | −0.24 ± 0.13 | | −0.27 ± 0.09 | | 0.241 |

**Table 2**. Comparison of maxillary cephalometric measurements. $p^a$: Wilcoxon Signed Rank, $p^b$: Mann-Whitney U test. *Statistically significant at $P<0.05$.

| Variable | Period | Group 1 ($n=14$) | | Group 2 ($n=14$) | | |
|---|---|---|---|---|---|---|
| | | Mean ± SD | $p^a$ | Mean ± SD | $p^a$ | $p^b$ |
| Maxillary intercanine width (mm) | T0 | 29.54 ± 2.25 | 0.001* | 29.50 ± 1.52 | 0.001* | 0.963 |
| | T5 | 31.12 ± 1.92 | | 33.54 ± 1.55 | | 0.003* |
| Change | | 1.58 ± 0.47 | | 4.04 ± 0.53 | | 0.001* |
| Maxillary interpremolar width (mm) | T0 | 33.35 ± 1.69 | 0.001* | 33.64 ± 1.97 | 0.001* | 0.854 |
| | T5 | 35.79 ± 1.72 | | 37.50 ± 1.48 | | 0.011* |
| Change | | 2.26 ± 0.62 | | 3.86 ± 0.84 | | 0.001* |
| Maxillary intermolar width (mm) | T0 | 43.27 ± 2.06 | 0.001* | 43.36 ± 3.04 | 0.001* | 0.982 |
| | T5 | 45.48 ± 1.79 | | 47.15 ± 2.33 | | 0.063 |
| Change | | 2.20 ± 0.91 | | 3.78 ± 1.03 | | 0.001* |
| Maxillary dental arch perimeter | T0 | 69.02 ± 4.42 | 0.001* | 68.25 ± 3.53 | 0.001* | 0.312 |
| | T5 | 72.87 ± 4.11 | | 73.82 ± 2.53 | | 0.335 |
| Change | | 3.85 ± 1.04 | | 6.57 ± 1.59 | | 0.001* |

**Table 3**. Comparison of dental model measurements. $p^a$: Wilcoxon signed-rank, $p^b$: Mann-Whitney U test. *Statistically significant at $P<0.05$.

## Results

The intraclass correlation coefficient (ICC) showed no difference between the two measurements, with a strong correlation (ICC > 0.9); Dahlberg's coefficient showed acceptable values for accuracy and precision. All subjects successfully completed the clinical trial period with no dropout. In general, gender distribution, mean age and severity of malocclusion were well-balanced between two groups ($p>0.05$). Performed IPR amounts were 0.84 ± 0.18 mm in Group 1 and 0.76 ± 0.14 mm in Group 2, showing no significant difference ($p>0.05$). Similarly, median treatment duration did not differ significantly between groups (Group 1 20.28 ± 1.93 weeks; Group 2 20.14 ± 1.95 weeks), ($p>0.05$).

Pre- and post-treatment maxillary cephalometric values, and intragroup and intergroup comparisons are presented in (Table 2). No significant difference was observed in SNA (°) and U1-SN (°) within or between groups ($p>0.05$). As shown in Table 2, there were significant differences in measurements between U1-PP (°), U1-NA (°), and U1-NA (mm) in intragroup comparisons from T0 and T5 ($p<0.05$); conversely, the groups did not differ significantly ($p>0.05$). SNA (°), U1-NA (°), and U1-NA (mm) values decreased in the T0–T5 interval in both groups. Comparisons of dental model measurements are displayed in (Table 3). In both groups, all dental model parameters were significantly increased after treatment and Group 2 exhibited significantly greater maxillary expansion and dental arch perimeter than Group 1 ($p<0.05$).

Table 4 shows the comparison of pain scores on the VAS between groups at different measurement times. Following aligner insertion, VAS scores significantly increased and peaked at T1, but decreased gradually in both groups over the following days ($p<0.05$). Group 2 consistently tended towards greater pain levels than Group 1, however, this difference was statistically insignificant ($p>0.05$).

| VAS | Group 1 ($n=14$) | | | | | Group 2 ($n=14$) | | | | | $p^b$ |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Gap with T0 ($p^a$) | Gap with T1 ($p^a$) | Difference between consecutive periods ($p^a$) | | Mean ± SD | Gap with T0 ($p^a$) | Gap with T1 ($p^a$) | Difference between consecutive periods ($p^a$) | | |
| T0 | 0.00 ± 0.00 | – | 0.001* | – | | 0.00 ± 0.00 | – | 0.001* | – | | 1.000 |
| T1 | 7.21 ± 1.36 | 0.001* | – | T0-T1 | 0.001* | 8.00 ± 0.96 | 0.001* | – | T0-T1 | 0.001* | 0.120 |
| T2 | 4.07 ± 1.59 | 0.001* | 0.001* | T1-T2 | 0.001* | 4.14 ± 1.40 | 0.001* | 0.001* | T1-T2 | 0.001* | 0.685 |
| T3 | 1.21 ± 0.89 | 0.004* | 0.001* | T2-T3 | 0.002* | 2.00 ± 1.24 | 0.001* | 0.001* | T2-T3 | 0.001* | 0.095 |
| T4 | 0.14 ± 0.36 | 0.542 | 0.001* | T3-T4 | 0.004* | 0.21 ± 0.42 | 0.567 | 0.001* | T3-T4 | 0.001* | 0.628 |
| T5 | 0.00 ± 0.00 | 0.565 | 0.001* | T4-T5 | 0.157 | 0.00 ± 0.00 | 0.598 | 0.001* | T4-T5 | 0.083 | 1.000 |

**Table 4**. Comparison of VAS scores. $p^a$: Wilcoxon signed-rank, $p^b$: Mann-Whitney U test. *Statistically significant at $P<0.05$.

| 7. Did you experience any discomfort on your cheeks? | | | Group 1 ($n=14$) | | | Group 2 ($n=14$) | | | $p^b$ |
|---|---|---|---|---|---|---|---|---|---|
| | | | Value | $p^a$ | Gap | Value | $p^a$ | Gap | |
| T1 | No | N | 12 | <0.001* | 1–2,3,4,5 | 12 | <0.001* | 1–2,3,4,5 | 1.000 |
| | | % | 85.7 | | | 85.7 | | | |
| | Yes | N | 2 | | | 2 | | | |
| | | % | 14.3 | | | 14.3 | | | |
| T2 | No | N | 13 | | | 9 | | | 0.065 |
| | | % | 92.9 | | | 64.3 | | | |
| | Yes | N | 1 | | | 5 | | | |
| | | % | 7.1 | | | 35.7 | | | |
| T3 | No | N | 13 | | | 12 | | | 0.541 |
| | | % | 92.9 | | | 85.7 | | | |
| | Yes | N | 1 | | | 2 | | | |
| | | % | 7.1 | | | 14.3 | | | |
| T4 | No | N | 13 | | | 13 | | | 1.000 |
| | | % | 92.9 | | | 92.9 | | | |
| | Yes | N | 1 | | | 1 | | | |
| | | % | 7.1 | | | 7.1 | | | |
| T5 | No | N | 2 | | | 1 | | | 0.029* |
| | | % | 16.7 | | | 7.7 | | | |
| | Yes | N | 10 | | | 12 | | | |
| | | % | 83.3 | | | 92.3 | | | |

**Table 5**. Comparison of the 7th question scores of the patient satisfaction evaluation form. $p^a$: McNemar test, $p^b$: Chi-squared test. *Statistically significant at $P<0.05$.

According to the results of Patient Satisfaction Evaluation Forms 1 and 2, the responses from patients' friends about their clear aligners differed significantly between the groups at T3; Group 1 showed more positive responses ($p<0.01$). Discomfort with the appearance of the aligners was significantly greater for Group 2 at T2 ($p<0.01$), and Group 1 reported better adaptation to the aligners at T4 ($p<0.05$). The level of negative impact of CAT on social life was significantly greater in Group 2 at T1 ($p<0.05$), but in Group 1 at T2 ($p<0.05$). Intensity and duration of pain were also evaluated in this questionnaire and Group 2 exhibited significantly higher intensity and duration of pain at T2 and T3 ($p<0.05$). While the vast majority of patients reported no or very low cheek discomfort during CAT, the incidence of such discomfort was notably greater in Group 2 at T5 ($p<0.05$) (Table 5). The two groups did not differ significantly in terms of impact on daily activities, difficulty in maintaining oral hygiene, orofacial or TMJ pain, restriction in eating, yawning or mouth opening ($p>0.05$). Although most participants reported slight changes in speech, scores on long-term changes in speech were significantly higher in Group 2 at T3 and T4 ($p<0.05$). All patients in Group 1 compared to 71.4% of those in Group 2 stated that they would prefer the same CAs for treatment if they had current knowledge at the beginning of the treatment; this difference was significant ($p<0.05$). Accordingly, the satisfaction levels of patients in Group 1, who received the 0.5 mm-thick aligner treatment, were significantly higher than those in Group 2 ($p<0.05$).

## Discussion

The worldwide introduction of and increasing demands for CAs have led to important changes in daily orthodontic practice[7,9,28,31]. Despite technological developments, further research is required to reach a clear consensus on the effectiveness and predictability of CA systems. Specifically, the properties of materials used, the applied mechanics and ultimately the satisfaction of patients treated with different CAs must be assessed[7,23,34,35]. Although CAs and fixed orthodontic appliances have been compared in terms of treatment effectiveness, quality of life and patient satisfaction[1–3,16–20], according to our current knowledge, a limited number of studies report on the effects of different thicknesses of CA materials on treatment effectiveness and patient perception[21–23]. The thickness of CAs is a critical determinant of the force applied to the tooth and can affect the clinical behaviour of CAs during orthodontic treatment[36]. Considering this, this research was conducted to investigate the effects of different thicknesses of CAs used in the treatment of Class I maxillary mild crowding cases on OTM, pain level, and patient satisfaction.

Although systems offered by manufacturers such as Invisalign® is the current gold standard for orthodontists and patients, advances in 3D intraoral scanners, digital orthodontic treatment planning software, and 3D printers have encouraged clinicians to produce in-house CAs, without the need to contact CA manufacturers. According to the literature and the information of several manufacturers, CA material thickness varies from 0.5 mm to 1.5 mm[12,13], while gingival margin shapes are classified as scalloped or straight[11]. In a previous finite element analysis (FEA) study[27], thicknesses of 0.5 and 0.75 mm were judged to apply enough force to the periodontal ligament (PDL) for orthodontic treatment and correction. It is also well known that the thickness of CAs strongly affects the clinical performance of thermoplastic materials. Careful consideration of aligner thickness and material features is therefore essential for optimal orthodontic treatment. In addition, design differences in trim lines may also alter treatment effectiveness. Aligners with straight trim lines at the gingival zenith were reported to have increased retention and greater efficacy in OTM when compared to scalloped margins[11]. Taking all these factors into account, two thicknesses of aligners (0.5 and 0.75 mm) with straight trim lines at the gingival zenith were used in this study to analyse treatment efficacy. All aligners were trimmed with the same margin design in this study to focus on the effects of material thickness.

To minimise individual differences, gender distribution, mean age, and malocclusion severity were balanced between the two groups. To standardise the amount of maxillary anterior crowding, the LII was calculated using OrthoAnalyzer software at the beginning of treatment[30]. The predictability of CAT in resolving crowding is a multifactorial phenomenon, influenced by a variety of biological and mechanical factors. A multitude of factors intrinsic to the aligner system, including the treatment protocol, material properties, planning software, and space creation strategies, can impact the predictability of crowding correction[37]. Common methodologies for resolving maxillary crowding in CAT are IPR, buccal arch expansion, incisor protrusion, distalisation, and extraction[38]; here, we used buccal arch expansion, incisor protrusion, and IPR as corrections. The mean amount of executed IPRs in both groups were very similar and did not significantly differ between groups. Several studies have evaluated the effect of attachment design, position, thickness, type or shape on CAT[8,23,25,26,39]. As OrthoAnalyzer software allows for preformed attachment design, rectangular attachments of the same design were used in both groups to achieve proper tooth movement and increase retention of the CAs[8]. As with previous studies[31,32], the models for both groups were printed at 50-µm layer thickness, the optimum layer thickness for the prototyping of orthodontic models for CAs. These models were used as moulds for thermoforming the aligners. Although it has been reported in previous studies that the thermoforming process may reduce aligner transparency and thickness[34,35,40], the use of the same process for our two groups should mitigate any confounding effects on our results. The median duration of treatment was similar for both CA thicknesses. For mild to moderate cases, several cross-sectional studies[20,41,42] report a shorter duration of treatment in CAT compared to fixed orthodontic appliances; however, it was beyond the scope of this study to compare CA with other treatments.

A previous clinical study[28] has reported that overall accuracy and predictability of tooth movement with in-house CAT depends on the type of tooth movement. In the cephalometric evaluations performed in the present study, no skeletal changes were observed in the sagittal direction in either group. Considering that the groups of this study consisted of non-growing patients, the absence of any significant change in SNA (°) is expected. On the other hand, the higher increase in U1-PP (°) and U1-SN (°) in Group 2, although not significant, may be consistent with an FEA study that observed an increase in OTM with 0.75 mm-thick aligners compared to 0.5 mm-thick aligners[11]. We observed significant increases in all maxillary width indicators and dental arch perimeters after treatment in both groups, with a greater change exhibited in Group 2. Increased thickness of CA is reported to increase PDL stress, produce stronger orthodontic forces, and therefore lead to a greater amount of OTM; significant expansion of the maxillary arch has also been demonstrated after CAT[29,33,36]. Our results support these reports, with 0.75 mm-thick aligners yielding greater OTM, maxillary expansion and dental arch perimeter compared to 0.5 mm-thick aligners.

Regardless of treatment method, pain is one of the most common side effects and is affected by many factors such as pain threshold, analgesia, gender, age, and pain history[43]. Even if no wires or brackets are causing frictional forces during CAT, the difference in aligner thickness and the amount of OTM can also affect pain levels. Thicker CAs are also thought to cause more mucosal irritation with resultant pain[3]. In the present study, a 10-cm VAS, a reliable and valid tool for measuring pain, allowed the assessment of the pain level of patients across different time points[44,45]. As expected, patients in Group 2 consistently demonstrated greater pain levels at all evaluation times, as the thicker CA results in more OTM by applying more force to the PDL. Moreover, it was found that following aligner insertion, VAS scores significantly increased and peaked at T1, before decreasing gradually in both groups over the following days. These findings are consistent with previous studies reporting that pain levels peak at 4 h after the initial force generated by the insertion of the orthodontic appliance[46,47]. According to Proffit[48], cellular differentiation in PDL begins at the 4th hour following the application of light

forces and bone remodelling begins on the 2nd day. This process explains why the pain level peaked at T1 and then decreased in both groups in this study as tooth movement begins when osteoclasts and osteoblasts begin remodelling on the 2nd day[48]. Most studies report that the level of pain related to the insertion of the appliance returns to baseline in 7 days[15,49]. Consistent with previous studies[15,48] at our T3 time point, one week after aligner insertion, pain levels were lower than at T1 and T2 due to the patients becoming accustomed to the aligners.

Most studies in the literature investigating the effect of CAT on patient satisfaction have compared the treatment with that of commercial aligners or fixed orthodontic appliances, however, this study focused on analysing the impact of CAT performed with different thicknesses of in-house CAs on patient satisfaction[1,3,17,18,20]. In this study, satisfaction was measured via an observational method employing a "Patient Satisfaction Evaluation Form", prepared with the support of a psychologist and previously found to be highly reliable[50–52]. According to the results of this questionnaire, regardless of the CA thickness, the impact of the CAT on daily activities, difficulty in maintaining oral hygiene, orofacial or TMJ pain, and restrictions in eating, yawning, and mouth opening were found to be similar between groups. However, discomfort due to the appearance of the aligners, the level of negative impact of CAT on social life, the incidence of cheek discomfort, and speech changes were all significantly higher in Group 2. Conversely, the level of adaptation to aligners and satisfaction levels were significantly greater in Group 1. These results are not surprising: thick CAs are more prominent and noticeable than thin; thin CAs caused less pain by applying lighter force to the teeth and thus provided a more comfortable treatment experience. Overall, however, the vast majority of patients surveyed were satisfied with the progress and outcome of their CAT, which is consistent with the studies conducted with Invisalign[*][1,2,16,17].

Our study has several limitations. While the sample size of twenty-eight patients was calculated to provide 80% power and there was no loss to follow-up, this number may be considered relatively small for a clinical trial. Given the inherent variability in clinical studies, a larger sample size could provide more robust results and enhance the generalizability of the findings. The findings of the study should be regarded as applicable to a limited extent to different types of malocclusion and different patient populations. However, the study is of clinical importance, evaluating the clinical applications of in-house aligners, which may be particularly advantageous when considering the costs of aligner companies and the production times of the aligners. Notably, due to the high cost of CAT, the study was limited to Class I maxillary mild crowding cases and was conducted with a small sample size. Consequently, future studies could benefit from a larger sample size and a more comprehensive research design. Another limitation of the study is that, since a questionnaire was used, there was a high possibility of recall bias, which may have affected the results. As we know, this is the first clinical study comparing the effectiveness of orthodontic treatment with two different thicknesses of CAs. It should be noted that in-house CAs may vary enormously in terms of attachment design, software, printing process, material, aligner thickness and margin design; these aspects may produce different treatment outcomes. The limitations of in-house aligner production extend to the fully manual process, the need for skilled staff, precision requirements, and the higher costs associated with software and materials. Furthermore, the digital workflow differs significantly from commercial aligners, demanding greater precision. Due to the standardized protocols and uniform thicknesses of commercial clear aligner systems like Invisalign[*], our study opted for in-house aligners for Class I maxillary mild crowding cases. Despite their limitations, in-house aligners were selected for their cost-effectiveness and greater patient acceptance. Although differences between the two tested thicknesses were statistically significant, both aligners were suitable for the treatment of Class I maxillary mild crowding cases. While this study indicates that in-house CAs are useful for mild cases and treatment goals can be achieved at low cost, to increase the effectiveness of CAT, additional studies including other thicknesses of CAs and complex cases are needed. To maintain standardization the scope of this study was restricted to Class I maxillary mild crowding cases which represents another limitation. Consequently, the findings may not be applicable to other malocclusion types, severities, or different patient populations. Furthermore, to better understand the effectiveness and efficiency of treatment with CAs, it is important to compare treatments with in-house CAs and widely available CAs manufactured by well-known companies.

## Conclusions

Considering the limitations of this research, the thickness of CAs affected the magnitude of force applied to the tooth and thereby influenced the amount of OTM. Based on the results of this study, we partly reject the null hypothesis and accept the alternate hypothesis that there is a significant difference in effectiveness, pain, and satisfaction levels between different thicknesses of CAs. A 0.5 mm-thick CA resulted in less pain and greater patient satisfaction. A 0.75 mm-thick CA yielded greater OTM, maxillary expansion and dental arch perimeter. Regardless of aligner thickness, the pain level was at its highest level at the 4th hour of treatment, and the effects on the daily activities of the patients were similar. Both appliances are suitable for the treatment of Class I maxillary mild crowding cases. Better informing patients about possible pain experiences during CAT could considerably help in managing their expectations and adaptation to treatment.

## Data availability

The datasets of the study are available from the corresponding author upon reasonable request.

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## Author contributions
Conceptualization: S.M.C., M.G. Methodology: S.M.C., M.G. Resources: S.M.C., M.G. Data curation: S.M.C. Investigation: S.M.C. Validation: S.M.C. Formal analysis: S.M.C. Writing—original draft: S.M.C. Writing—review and editing: S.M.C. Funding acquisition: M.G. Project administration: M.G. Supervision: M.G. Visualisation: M.G.

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