

## A randomized clinical trial comparing mandibular incisor proclination produced by fixed labial appliances and clear aligners

Joe Hennessy<sup>a</sup>; Thérèse Garvey<sup>b</sup>; Ebrahim A. Al-Awadhi<sup>b</sup>

### ABSTRACT

**Objective:** To compare the mandibular incisor proclination produced by fixed labial appliances and third generation clear aligners.

**Materials and Methods:** Patients underwent a course of orthodontic treatment using either fixed labial appliances or clear aligners (Invisalign). Mandibular incisor proclination was measured by comparing pretreatment and near-end treatment lateral cephalograms. Eligibility criteria included adult patients with mild mandibular incisor crowding (<4 mm) and Class I skeletal bases (ANB, 1–4°). The main outcome was the cephalometric change in mandibular incisor inclination to the mandibular plane at the end of treatment. Eligible patients picking a sealed opaque envelope, which indicated their group allocation, was used to achieve randomization. Data was analyzed using a Welch two-sample *t*-test.

**Results:** Forty-four patients (mean age, 26.4 ± 7.7 years) were randomized in a 1:1 ratio to either the fixed labial appliance or the clear aligner group. Baseline characteristics were similar for both groups: Fixed appliance mean crowding was 2.1 ± 1.3 mm vs clear aligner mean crowding, 2.5 ± 1.3 mm; pretreatment mean mandibular incisor inclination for the fixed appliance group was 90.8 ± 5.4° vs 91.6 ± 6.4° for the clear aligner group. Fixed appliances produced 5.3 ± 4.3° of mandibular incisor proclination. Clear aligners proclined the mandibular incisors by 3.4 ± 3.2°. The difference between the two groups was not statistically significant (*P* > .05).

**Conclusion:** There was no difference in the amount of mandibular incisor proclination produced by clear aligners and fixed labial appliances in mild crowding cases. (*Angle Orthod.* 2016;86:706–712.)

**KEY WORDS:** Clear aligners; Fixed appliances; Tooth movement

### INTRODUCTION

Fixed appliances have been the gold standard in orthodontics for many years; however, the esthetic demands of patients have encouraged the development of clear aligners. In addition to improved esthetics, it has been reported that clear aligners are less painful, allow for improved oral hygiene, and cause less root resorption than conventional fixed appliances.<sup>1–4</sup> Over the years, these appliances have

evolved in an attempt to achieve improved tooth alignment and occlusion.<sup>5</sup> The first generation aligners were solely reliant on the removable appliance to move teeth. Following this, a second generation of aligner depended more on attachments being bonded to teeth. The most recent, third generation, has been modified to place different types of attachments automatically where difficult tooth movements are required.

Despite over 15 years of commercial availability and many millions of cases treated worldwide, very little research has assessed how clear aligners achieve their results. From the available studies, clear aligners would appear to have poorer clinical results compared with fixed appliances.<sup>6</sup> The aligner's ability to extrude, derotate, and torque teeth has also been questioned.<sup>6–9</sup> As a result of these tooth-movement concerns, many clear aligner treatments are completed without extractions. This may put an increased emphasis on mandibular incisor proclination to relieve crowding during clear aligner treatment.

<sup>a</sup> Specialist Orthodontist, St James' Hospital, Dublin, Ireland.

<sup>b</sup> Consultant Orthodontist and Senior Lecturer, Dublin Dental University Hospital, Dublin, Ireland.

Corresponding author: Dr Joe Hennessy, Specialist Orthodontist at St James' Hospital, James' St, Dublin 8, Ireland (e-mail: joehenno@hotmail.com)

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**Table 1.** Studies Comparing Mandibular Incisor Proclination Produced by Different Orthodontic Appliances

Study	Type of Appliance	Proclination (Mean $\pm$ SD)	Result
Gill and Lee, <sup>9</sup> 2005	Twin Block (TB) vs mini-block (MB) functional appliances	TB = $1.3^\circ \pm$ (not given) MB = $2.4^\circ \pm$ (not given)	NS <sup>a</sup>
Toth and McNamara, <sup>12</sup> 1999	TB vs Frankel II (FR II) functional appliances	TB = $2.8 \pm 5.4^\circ$ Fr II = $1.1 \pm 3^\circ$	NS
Pandis et al., <sup>10</sup> 2010	Self-ligating (SL) vs conventional (C)	SL = $3.1 \pm 8.0^\circ$ C = $5.5 \pm 6.7^\circ$	NS
Scott et al., <sup>11</sup> 2008	SL vs C	SL = $1.73 \pm 4.06^\circ$ C = $2.34 \pm 3.72^\circ$	NS

<sup>a</sup> NS indicates not statistically significant.

Mandibular crowding can be resolved by interproximal reduction (IPR) or proclination of the mandibular labial segment. Excessive proclination can cause poor esthetics, gingival recession, and unstable results. It is important to ascertain how much proclination an individual orthodontic appliance produces. Many studies have assessed this sequel<sup>10–13</sup> (Table 1); however, the effect of clear aligners on incisor proclination has yet to be determined.

The aim of this study was to compare the mandibular incisor proclination produced by fixed appliances and third generation clear aligners (Invisalign) when treating patients with mild mandibular crowding.



**Figure 1.** Downs' method of measuring mandibular incisor inclination.

## MATERIALS AND METHODS

### Trial Design

This was a parallel-group, randomized, prospective clinical trial with a 1:1 allocation ratio.

### Sample Size Calculation

Similar studies have not reported sample-size calculations.<sup>10,11,13</sup> Means and standard deviations were ascertained from previous research.<sup>11</sup> A minimum sample size of 17 participants in each group was proposed for 80% power with a significance level of 0.05%. The sample size was calculated using a two-sample, *t*-test power calculation. The power calculation was carried out using the R software version 2.11.1 (Vienna, Austria. ISBN 3-900051-07-0, URL <http://www.R-project.org>)

### Participants, Eligibility Criteria, and Settings

Sixty participants were recruited during October and November 2013. The following selection criteria were applied: no caries or periodontal disease, mild mandibular crowding (<4 mm) assessed using the Nance brass-wire technique,<sup>14</sup> required nonextraction orthodontic treatment, and an anteroposterior skeletal pattern within the average range (ANB, 1–4°). Participants also had to be  $\geq 18$  years old, and they were excluded if they had complex medical histories or were pregnant. Patients had to be willing to be assigned to either treatment modality. Forty-four patients who met the inclusion criteria were included in the research.

The Joint Research Ethics Committee at St James' Hospital, Dublin, Ireland, granted ethical approval for this research (Ref. 2013/11/Chairman). The participants were fully informed about the study, and written consent was obtained.

### Interventions

Each participant had a pretreatment digital lateral cephalogram (Proline 2002 PM CC, Planmeca Oy, Helsinki, Finland) taken with the patient in the natural head position (looking into their own eyes in a mirror) immediately prior to commencement of treatment. Lateral cephalograms were repeated near the end of treatment.

**Table 2.** Descriptive Statistics for Demographic and Clinical Characteristics of Pretreatment Study Groups (n = 44)

	Mean $\pm$ SD		
	Total	Invisalign Group	Fixed Appliance Group
Age (y)	26.4 $\pm$ 7.7	29.1 $\pm$ 7.5	23.7 $\pm$ 7.0
Crowding (mm)	2.3 $\pm$ 1.3	2.5 $\pm$ 1.3	2.1 $\pm$ 1.3
Incisor inclination ( $^{\circ}$ )		91.6 $\pm$ 6.4	90.8 $\pm$ 5.4

Twenty-two fixed appliance patients were treated by a single postgraduate student using self-ligating, preadjusted edgewise brackets with an MBT prescription and 0.022  $\times$  0.028-inch slot (Forestadent, Pforzheim, Germany) under the supervision of a consultant orthodontist. A standard archwire sequence was used (0.014-inch round, 0.018-inch round, 0.018  $\times$  0.025-inch rectangular, martensitic, active nickel-titanium alloys, and 0.019  $\times$  0.025-inch stainless steel). All archwires were cinched back by the operator. Every effort was made to maintain the intercanine width through coordinating the archwires during treatment.

No auxiliary appliances or elastics were used during the study period. IPR, using stainless steel tooth stripping blades (Tooth Stripper Kit, OrthoCare, Saltaire, West Yorkshire, UK), was completed where required by the supervising consultant orthodontist. No restrictions were placed on the amount of IPR that could be used. A Sheridan IPR Gauge (OrthoCare) was used to calculate the amount of IPR. Each patient was seen on a 6-week basis.

The same lead operator treated 22 patients with Invisalign clear aligners (Align Technology Inc, Santa Clara, Calif). The appliances were fabricated using the Invisalign protocol.<sup>15</sup> The authors asked for intercanine width to be maintained. No restrictions were placed on the amount of attachments that could be placed. IPR was performed in an identical manner to that used in the fixed appliance group by the same consultant orthodontist. A conventional etch-and-bond system was used to place Transbond LR (3M Unitek, Monrovia, Calif) optimized composite attachments. Tooth movement commenced from the first aligner. Each patient was seen on a 6-week basis and asked to change aligners every 2 weeks. If required, the Invisalign treatment protocol allowed for a midcourse correction and refinements at the end of treatment.

## Outcomes

The main outcome was the mean cephalometric change in mandibular incisor inclination to the mandibular plane at the end of treatment within the fixed appliance and clear aligner groups. Pretreatment and

**Table 3.** Descriptive Statistics for Amount of Mandibular Incisor Proclination Within Both Groups (Fixed Appliance and Invisalign)

Group	Mean $\pm$ SD		
	Pretreatment ( $^{\circ}$ )	Posttreatment ( $^{\circ}$ )	Change ( $^{\circ}$ )
Invisalign	91.6 $\pm$ 6.4	95.0 $\pm$ 6.2	3.4 $\pm$ 3.2
Fixed appliances	90.8 $\pm$ 5.4	96.1 $\pm$ 6.2	5.3 $\pm$ 4.3

near-end treatment lateral cephalograms for all the participants were digitally traced by the lead operator using the Quick Ceph System (Quick Ceph Systems Inc, San Diego, Calif). The tracings were assessed by measuring the angle of the mandibular incisor to the mandibular plane as described by Downs (Figure 1).<sup>16</sup> Each measurement was repeated three times and the mean recorded. The mean angular change within each group was determined by comparing mean pretreatment to mean near-end treatment incisor inclination. The mean angular changes in mandibular incisor inclination of the fixed appliance group and clear aligner group was then compared.

## Randomization

Randomization has not been described in previous similar studies.<sup>10,11,13</sup> Before this research was begun, sealed opaque envelopes indicating group allocation were placed in the reception area of the clinic. A gatekeeper, not involved with the research, asked eligible patients to pick an envelope at random prior to their first treatment appointment. Patients were then assigned to the treatment group dictated by their envelope selection.

## Blinding

Blinding of either patient or operator was not possible due to the visibility of appliances on the radiographs.

## Statistical Analysis

The data were analyzed using R software version 2.11.1. Changes in mandibular incisor inclination within both groups were compared using a Welch two-sample *t*-test.

Intra-examiner reproducibility was assessed by repeating the mandibular incisor inclination measurements, 4 weeks after the original measurements, on 20 randomly selected radiographs. Reliability was calculated using a paired *t*-test comparing the logs of the results. The difference was found to be non-significant (mean difference = 0.0005, *P* = .33).

Interexaminer reproducibility was assessed by two consultant orthodontists, repeating measurements on 20 randomly selected radiographs. The logs of the results were compared with the lead operator's

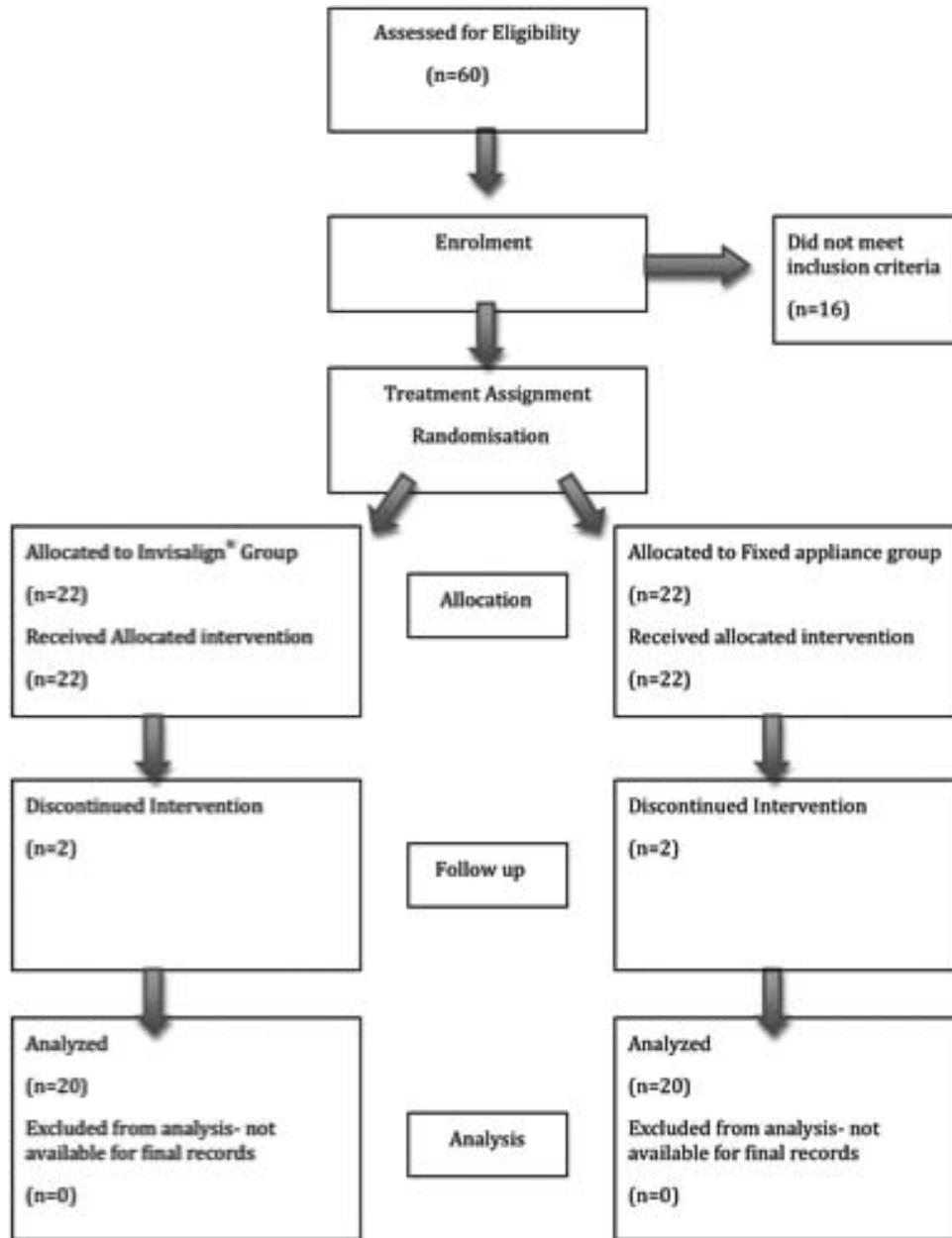


Figure 2. CONSORT flow chart.

measurements using a paired *t*-test. Again, the results were statistically insignificant (mean difference = 0.0011, *P* = .43).

Random error was calculated using the Dahlberg equation  $D = \sqrt{\sum_{i=1}^N \frac{d_i^2}{2N}}$  where  $d_i$  is the difference between the first and second measure, and *N* is the sample size that was remeasured. Random error was also found to be clinically insignificant with 0.7° of random error for cephalometric measurements.

**RESULTS**

**Participant Flow**

Forty-four patients (mean age, 26.4 ± 7.7) were randomized in a 1:1 ratio into either the fixed appliance or clear aligner group. Two patients in the Invisalign group would not comply with appliance wear and discontinued treatment. Two patients in the fixed appliance group were removed from the study due to oral hygiene issues (Figure 2).

## Baseline Data

Baseline characteristics were similar for both groups, thus validating the randomization process (Table 2). More female patients took part in the research with 14 in the clear aligner group and 13 in the fixed appliance group. The mean treatment time was similar for both groups (fixed appliance group, 11.3 months; clear aligner group, 10.2 months). The mean number of aligners used for each patient was 18.

Both groups required similar mean amounts of IPR (Invisalign group,  $1.9 \pm 1.3$  mm; fixed group,  $1.5 \pm 1.2$  mm). No significant intercanine width expansion was measured in either group.

## Numbers Analyzed for Each Outcome

A Welch two-sample *t*-test compared mandibular incisor proclination produced by Invisalign ( $3.4 \pm 3.2^\circ$ ) and fixed appliances ( $5.3 \pm 4.3^\circ$ ; Table 3). The results were not statistically significant ( $P = .14$ ; 95% confidence levels,  $-4.43$ – $0.65$ ).

## DISCUSSION

The aim of this study was to compare the mandibular incisor proclination produced by fixed appliances and third generation clear aligners (Invisalign) when treating patients with mild mandibular crowding. Invisalign produced a mean proclination of  $3.4 \pm 3.2^\circ$ . The fixed appliances produced slight mandibular incisor proclination (Table 3), but the difference was statistically and clinically insignificant ( $P > .05$ ).

Forty-four patients with similar amounts of mild mandibular crowding were treated with either fixed labial appliances or Invisalign aligners. Mandibular incisor proclination was calculated using digital radiographs. Pretreatment assessment revealed that both groups had similar age profiles, crowding, and mean mandibular incisor proclination (Table 2). Most patients were female (61%), which agrees with previous studies that have found women to be the predominant participants in adult orthodontics.<sup>17–19</sup>

This research found that fixed appliances proclined the mandibular labial segment by  $5.3 \pm 4.3^\circ$ . This is in agreement with studies done by Pandis et al. and Scott et al., who compared different types of bracket systems.<sup>11,12</sup> Pandis et al. used similar inclusion criteria and methodology as in our research, although their participants had slightly more crowding ( $5.43 \pm 2.27$  mm).<sup>11</sup> Scott et al. obtained their results from patients who had undergone four first premolar extractions.<sup>12</sup> As mentioned previously, no research had assessed the mandibular incisor proclination produced by clear aligner treatment.

Before this study, it was postulated that clear aligners relieved mandibular labial crowding by proclining and tipping teeth, with moments of force being created away from the centers of resistance of the incisors.<sup>9,20</sup> Krieger et al. used ClinCheck software to assess the accuracy of tooth movements achieved when using Invisalign aligners.<sup>9</sup> They suggested that an increase in arch length was an indication of labial segment protrusion.<sup>9</sup> They commented that 58% of their patients had some increase in mandibular arch length post-Invisalign treatment.<sup>9</sup> Drake et al. compared the tooth movements achieved when changing an aligner weekly or biweekly.<sup>20</sup> They used cone beam computed tomography to measure the movement of the participants' maxillary central incisors for an 8-week period. The authors concluded that most of the movements achieved by the clear aligners were through crown tipping.<sup>20</sup> These results are broadly in agreement with our findings, with 71% of the Invisalign patients having mandibular incisor proclination.

It has been stated that fixed labial appliances align the mandibular labial segment by not only tipping teeth but also, through the use of rectangular archwires, by torquing roots.<sup>21</sup> This implies that clear aligners would procline mandibular incisors more than fixed appliances when treating similarly crowded cases. The fact that this was not a finding from our research may be explained by a number of factors.

First, fixed appliances often apply a protrusive force on teeth during the initial phase of treatment. As mesial canine tip is expressed in the bracket system, the mandibular incisors are proclined.<sup>22</sup> This labial movement can be counteracted in the later stages of treatment; however, this involves a significant amount of "round-tripping" of teeth. Some authors have advocated the use of auxiliary wires or lacebacks to inhibit this mesial movement, but this appears to have limited success.<sup>23</sup> Clear aligners can align teeth individually with one aligner potentially moving only one tooth. This gradual, segmented movement may minimize the proclination that occurs.

The method by which fixed appliances and clear aligners apply forces to teeth may also have had a bearing on our results. According to some investigators, fixed appliances place a force coronal and buccal to the center of resistance of a tooth.<sup>21</sup> This can result in tipping and proclination, particularly in the mandibular labial segment. Clear aligners place a force along the complete length of the crown. This may create forces closer to the center of resistance of the tooth and minimize the amount of proclination that occurs.

A further reason might be the recent developments in clear aligner treatment, that is, the creation of a third generation of aligners. These newer aligners use

accurately placed composite attachments to increase the control of tooth movement; they also have indentations in the polyurethane to place increased pressure on specific points on the crown to produce torque in the root. It is difficult to say whether torquing the anterior mandibular roots prevented excessive proclination in the clear aligner group. Nor is it possible to confirm whether recent aligner developments have contributed to these results, as no previous studies have accurately measured mandibular incisor proclination.

### Limitations

There are a number of limitations of this clinical trial. First, the use of lateral cephalometric radiographs to assess mandibular incisor inclination is not 100% accurate. Baumrind and Frantz<sup>24</sup> described the problems with using cephalometrics to assess angulations. They noted that the mandibular incisor apex, in particular, can be very difficult to locate. We made every effort to reduce the chance of measurement error when tracing the initial and near-end lateral cephalograms. Each measurement was repeated three times and the mean taken. The use of digital radiographs made this process more operator friendly. Intra- and interoperator errors were not significant.

Two patients in the Invisalign group had compliance issues and could not be included in the final results. Two fixed-appliance patients were removed from the research as a result of poor oral hygiene.

### Clinical Significance

Before this research, it had been postulated that clear aligners relieved mandibular arch crowding through excessive proclination of the mandibular labial segment. Many clinicians would have avoided using clear aligners in patients with thin gingival biotypes to limit the risk of developing gingival recession. After this research, it can be proposed that clear aligners procline mandibular incisors to a degree similar to fixed appliances and can be used to treat mild mandibular arch crowding in a way comparable to fixed appliances. Our study opens the door for more complex clinical trials to be completed. These future trials should tell the clinician whether clear aligner therapy is a viable alternative to fixed appliance treatment.

### CONCLUSION

- When we compared mandibular incisor proclination produced by Invisalign and fixed labial appliance treatment in mild crowding cases, we found no difference.

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