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# Digital treatment planning and clear aligner therapy: A retrospective cohort study

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## Abstract

**Objective:** To investigate the total number of digital treatment plan (DTPs) and aligners manufactured for clear aligner therapy (CAT) by Invisalign® from initial treatment planning to the completion of CAT.

**Design:** A retrospective cohort study.

**Material and methods:** A total of 30 patients, from each of 11 experienced orthodontists, who commenced treatment over a 12-month period, were assessed regarding the number of DTPs and aligners prescribed from initial planning to completion of CAT. Patients were categorised according to the number of aligners prescribed by the initial DTP into mild (<15), moderate (15–29) or severe (>29).

**Results:** After the application of inclusion/exclusion criteria, 324 patients (71.9% women; median age = 28.5 years) undergoing non-extraction treatment with the Invisalign® appliance were assessed. The median number of initial DTPs was 3 (interquartile range [IQR] = 2, 1–9) per patient before acceptance by the orthodontist. Most (99.4%) patients required a refinement phase with a median of 2 (IQR = 2, 2–7) refinement plans recorded. A total of 9135 aligners per dental arch was prescribed in the initial DTP of the 324 patients assessed and 8452 in the refinement phase. The median number of aligners per dental arch, prescribed from the initial DTP was 26 (IQR = 12, 6–78) and from the refinement plans was 20.5 (IQR = 17, 0–132).

**Conclusion:** A median of three initial DTPs and two refinement plans were required for patients undergoing non-extraction treatment with the Invisalign® appliance. Patients were prescribed almost double the number of aligners initially predicted to manage their malocclusion.

## Keywords

clear aligner therapy, digital treatment planning, Invisalign®, orthodontic treatment, refinement

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## Introduction

Clear aligner therapy (CAT) is becoming increasingly popular, with up to 25% of orthodontist caseloads comprising the treatment modality (Meade and Weir, 2022). Numerous advantages have been proposed for CAT including aesthetics, patient management of oral hygiene and superior periodontal health compared with fixed appliance treatment (FAT) (Chhibber et al., 2018; Rosvall et al., 2009; Weir, 2017).

Several potential drawbacks with CAT, however, have been reported. These include sub-optimal patient compliance with wear protocols, reduced efficacy of certain tooth movements and greater relapse potential among those patients treated with CAT compared with those treated with FAT (Blundell et al., 2021; Gaddam et al., 2021; Kuncio et al., 2007; Timm et al., 2021).

The advent of modern CAT, using three-dimensional (3D) technology for treatment planning and the fabrication of aligners, is considered to have been the U.S. Food and

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Drug Administration (FDA) approval of Invisalign® (Align Technology, San Jose, CA, USA) in 1998 (Vlaskalic and Boyd, 2002). Invisalign® is now one of the world's leading aligner providers (Meade and Weir, 2022). 3D digital models of the patient's dentition can be manipulated to move the teeth digitally into the desired position. Align uses a programme called ClinCheck® as an interface with the treating clinician, allowing viewing and modification of tooth position, planning of interproximal reduction and the prescription of bonded composite resin (CR) attachments, until a satisfactory digital treatment plan (DTP) is created (Vlaskalic and Boyd, 2002).

Modifications to the treatment plan can be made directly via ClinCheck® and/or indirectly via communication with an Align technician. Once the clinician approves the ClinCheck® plan, the aligners for the patient are printed and shipped to the clinician.

DTPs fall into two broad categories. The initial DTP is formulated to prescribe the sequence of aligners to obtain a desired or predicted occlusal endpoint. Refinement plans are used to refine the treatment outcome obtained at the completion of the initial prescribed sequence of aligners and involve the fabrication of additional aligners. Refinement may be considered equivalent to the finishing stages of FAT and can be used at any time during treatment. Multiple iterations of each refinement phase may be employed to achieve the clinician's treatment objectives. A feature of Align's terms of service that clinicians may select, is the provision of additional aligners, at no extra cost, for 5 years from the initial treatment plan.

Purported reasons for carrying out refinement, after treatment with the initial phase of aligners, include the reported inaccuracy of the software in predicting tooth movement and poor patient compliance with appliance wear (Arqub et al., 2022; Hansa et al., 2020).

Data, however, regarding the number of plans formulated before the initial DTP is accepted by the clinician, the number of refinement DTPs required and the total number of aligners produced to treat malocclusions are limited. The current available evidence suggests that several DTPs and additional aligners to that originally prescribed, may be required in comprehensive CAT. A recent survey, for example, found that 81% of Australian orthodontists reported the need for refinement and that the estimated number of refinements was two per case (Meade and Weir, 2022). Hansa et al. (2021) reported that a study of the digital treatment planning from a single orthodontist, found an average of approximately 1.5 refinements. However, no data were provided regarding the initial number of DTPs. It is possible, therefore, that time spent on the design of the initial treatment plan may affect the number and duration of additional aligner orders.

Knowledge in this regard is important as it may provide clinicians with further information regarding the management of CAT protocols. It may help determine practice costs when clinician time, related to digital treatment planning, is included. It may also provide patients with information concerning the likelihood of refinements and the duration of treatment.

The aim of the present study, therefore, was to investigate the total number of DTPs and the total number of aligners manufactured for CAT by Invisalign® from initial treatment planning to the point at which further aligners cannot be ordered without incurring an entire new treatment fee, from Align (i.e. 5 years from the initial treatment planning).

## Material and methods

Institutional ethical approval for this retrospective study was provided by the University of Adelaide Human Research Ethics Committee (HREC-35747). Data for the investigation were derived from the Australasian Aligner Research Database (AARD). AARD contains information related to approximately 11,000 patients, treated by 11 experienced orthodontists, with the Invisalign® appliance between the years of 2013 and 2022. Details regarding every patient treated with the appliance by the contributing orthodontist are contained within the database in order to minimise selection bias. All patients had consented to the use of their treatment information for research purposes before the commencement of their CAT. The investigation involved the selection of 30 consecutively treated patients, from each of the 11 de-identified orthodontists, following the application of the inclusion criteria below:

- Treated, non-extraction, with the Invisalign® appliance only;
- Commenced treatment between 1 June 2016 and 31 May 2017;
- Treatments where additional aligners can no longer be ordered – effectively 5 years from acceptance of the initial DTP; and
- Patients compliant with prescribed Invisalign® wear protocols in the view of the treating clinician.

Exclusion criteria included the following:

- Patients who were undergoing combined orthodontic treatment and orthognathic surgery; and
- Patients who had a medical condition and/or taking medication (such as bisphosphonates) that may have altered bone metabolism.

The following data from the de-identified patients were determined:

- Demographic details related to gender and age;
- Whether CAT included extractions of permanent teeth as part of the orthodontic treatment plan;

- The number of DTPs before acceptance of the initial order of aligners;
- The number of each additional aligner/refinement order(s);
- The initial number of aligners manufactured/prescribed per dental arch patient; and
- The number of individual additional aligners ordered for each additional aligner/refinement order per dental arch per patient.

The patients were categorised as 'mild' (⩽14 aligners), 'moderate' (15–29 aligners) and 'severe' (>29) according to the number of aligners prescribed per dental arch in the initial DTP provided by Invisalign®. The number of aligners ascribed to each category was determined from information regarding the mean number of aligners used in the initial series of aligners in a recent investigation (Hansa et al., 2021).

### Statistical analyses

Descriptive statistics were calculated via GraphPad Prism 9.0 (GraphPad Software Inc., La Jolla, CA, USA). The Shapiro–Wilk test was used to determine normality of all assessed subgroups within the cohort. As all subgroups were non-parametric, the Mann–Whitney and Kruskal–Wallis tests were used to investigate significant differences between the medians of the subgroups. The Spearman correlation test was used to assess the association between subgroups.

## Results

Six patients were excluded from the analysis as they had undergone extraction of teeth as part of their orthodontic treatment. No patient was excluded from the evaluation because of incomplete data. Of the 324 included patients, 238 (73.5%) were girls/women. The median age of the assessed patients was 28.5 years (interquartile range [IQR] = 19.04, 10.33–76.08 years). There was no difference in the median age of the female patients (28.79 years; IQR = 19.96, 10.75–76.08 years) and the male patients (27.54 years; IQR = 18.06, 10.33–68.08 years) ($P = 0.054$).

**Table 1.** Frequency of patients by gender and aligner category (N=324).

| | Initial aligner category | | | Total |
|---|---|---|---|---|
| | Mild | Moderate | Severe | |
| Female | 22 (81.5) | 113 (60.7) | 98 (72.6) | 233 (71.9) |
| Male | 5 (18.5) | 49 (31.3) | 37 (27.4) | 91 (28.1) |
| Total | 27 (8.3) | 162 (50) | 135 (41.7) | 324 (100) |

Values are given as n (%).

Table 1 shows the frequency of patients according to gender and aligner category.

The median number of initial DTPs was 3 (IQR = 2, 1–9) per patient. There was no significant difference between the male (3.00; IQR = 2, 1–8) and female patients (3.00; IQR = 2, 1–9) ($P = 0.76$). Table 2 outlines the median values of the initial DTPs and refinement plans according to aligner number category. Tables 3 and 4 illustrate the frequency of the initial DTPs and refinement plans per initial aligner number category.

Kruskal–Wallis tests indicated that there were no differences between the median values of the three aligner categories for the initial DTPs ($P = 0.55$) and the refinement DTPs ($P = 0.64$).

Two patients did not require refinement, which meant that 99.4% (n = 322) of the patients necessitated additional aligners. The median number of refinement plans per patient was 2 (IQR = 2, 2–7). There was no difference in the median number of refinement plans between male (2; IQR = 1.25, 1–7) and female patients (2; IQR = 1, 0–7) ($P = 0.86$).

A total of 17,587 aligners, per dental arch of the 324 patients assessed, were prescribed in this study, with 9135 prescribed in the initial DTP and 8452 in the refinement phase. The median number of aligners per patient was 47 (IQR = 28, 13–175). There was no difference in the median number of aligners prescribed for male patients (48; IQR = 28.5, 13–135) and female patients (47; IQR = 29, 13–175) ($P = 0.53$).

**Table 2.** Median value of DTPs according to aligner number category.

| | Initial aligner category | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mild | | | Moderate | | | Severe | | |
| | Median | 25%–75% IQR | Range | Median | 25%–75% IQR | Range | Median | 25%–75% IQR | Range |
| Initial DTP | 2 | 2–3 | 1–5 | 3 | 2–4 | 1–9 | 3 | 2–4 | 1–8 |
| Refinement DTPs | 2 | 1–4 | 0–7 | 2 | 2–3 | 1–7 | 2 | 2–3 | 0–7 |

DTP, digital treatment plan; IQR, interquartile range.

**Table 3.** Frequency of initial DTPs per initial aligner number category (N=324).

| Initial DTP | Initial aligner category | | | Total |
|---|---|---|---|---|
| | Mild | Moderate | Severe | |
| 1 | 4 (14.8) | 29 (17.2) | 20 (15.6) | 53 (16.4) |
| 2 | 11 (40.7) | 44 (26.0) | 43 (33.6) | 98 (30.2) |
| 3 | 6 (22.2) | 42 (24.9) | 20 (15.6) | 68 (21.0) |
| 4 | 4 (14.8) | 31 (18.3) | 17 (13.3) | 52 (16.0) |
| 5 | 2 (7.4) | 11 (6.5) | 13 (10.2) | 26 (8.0) |
| 6 | 0 (0) | 5 (3.0) | 5 (3.9) | 10 (3.1) |
| 7 | 0 (0) | 4 (2.4) | 6 (4.7) | 10 (3.1) |
| 8 | 0 (0) | 2 (1.1) | 4 (3.1) | 6 (1.9) |
| 9 | 0 (0) | 1 (0.6) | 0 (0) | 1 (0.3) |
| Total | 27 (100) | 169 (100) | 128 (100) | 324 (100) |

Values are given as n (%).
DTP, digital treatment plan.

**Table 4.** Frequency of refinement plans per initial aligner number category (N=324).

| Refinement plans | Initial aligner category | | | Total |
|---|---|---|---|---|
| | Mild | Moderate | Severe | |
| 0 | 1 (4.5) | 0 (0) | 1 (0.5) | 2 (0.6) |
| 1 | 3 (13.6) | 21 (17.8) | 33 (17.9) | 57 (17.6) |
| 2 | 7 (31.9) | 49 (41.5) | 72 (39.2) | 128 (39.5) |
| 3 | 4 (18.3) | 31 (26.3) | 36 (19.6) | 71 (21.9) |
| 4 | 2 (9.1) | 12 (10.2) | 24 (13.0) | 38 (11.7) |
| 5 | 3 (13.6) | 3 (2.5) | 12 (6.6) | 18 (5.6) |
| 6 | 1 (4.5) | 2 (1.7) | 3 (1.6) | 6 (1.9) |
| 7 | 1 (4.5) | 0 (0) | 3 (1.6) | 4 (1.2) |
| Total | 22 (100) | 118 (100) | 184 (100) | 324 (100) |

Values are given as n (%).

Figure 1 shows the median number of initial and refinement aligners per patient according to aligner number category. Table 5 shows there was a significant difference in the median number of aligners prescribed in each category.

An increasing number of initial aligners was weakly associated with an increased number of aligners in refinement (r = 0.33; 95% confidence interval [CI] = 0.22–0.42; $P < 0.001$).

No difference was recorded between the number of overall aligners prescribed to those patients aged <18 years and those aged ⩾18 years ($P = 0.053$). In addition, the age of patients and the number of prescribed aligners was weakly correlated (r = −0.15; 95% CI = −0.26 to −0.04).

## Discussion

### Summary

The present study appears to be among the first to assess specifically the number of initial and final DTPs with CAT and the numbers of aligners provided to patients in the initial and refinement phases of treatment. The findings indicated that several plans were often required. They also indicated and that almost as many aligners were required in the refinement phase of CAT as in the initial phase.

### Comparison with other work

The sample size of 324 patients, in this study, was higher than assessed in other CAT studies that have included 20–155 cases (Charalampakis et al., 2018; Hansa et al., 2020, 2021). A total of 30 patients per orthodontist was chosen to optimise the number of patients who satisfied inclusion/exclusion criteria. The 1-year timespan for the commencement of treatment was chosen to limit the possibility of any changes in Align's initial treatment planning protocols. Most (71.9%) of the patients were female, which corresponded with the findings of 68%–73% observed in recent CAT studies (Arqub et al., 2022; Hansa et al., 2021; Pacheco-Pereira et al., 2018). There were no differences between male and female patients in the parameters investigated in this study, which indicated that the findings and conclusions relate to factors other than gender.

The median age of 28.5 years was comparable to that found in similar studies and corresponded to the approximate age with which CAT is generally associated (Arqub et al., 2022; Kravitz et al., 2022). According to a recent survey investigating aligner practices among orthodontists, 65.02% of orthodontists in Australia reported that they made 1–3 changes to the initial DTP before it was finalised and 24.14% made 4–6 changes (Meade and Weir, 2022). Just 0.6% of the patients in the present study did not require a refinement plan, which contrasted with 6.0% observed in a recent U.S. investigation (Kravitz et al., 2022). A median of two refinement plans per patient was recorded, which was greater than the 0.79–1.64 noted in two recent investigations (Hansa et al., 2020, 2021). However, it compared with a mean of 2.5 refinement plans among patients with a range of malocclusions treated with the Invisalign® Full or the Invisalign® Teen appliances in a 2022 study (Kravitz et al., 2022).

The median number of refinement aligners required per patient in the investigation presented here was 21 per dental

**Figure 1.** Median scores for the initial and refinement number of aligners per patient according to aligner number category. Box plots provide information about sample distribution. The boundaries of the rectangle indicate the 25% and 75% quartiles. The line inside the rectangle indicates the median. The distance between the median and the quartile indicates the skew of the data. The two lines (whiskers) and dots extending from the box indicate the outlier values. N, number.

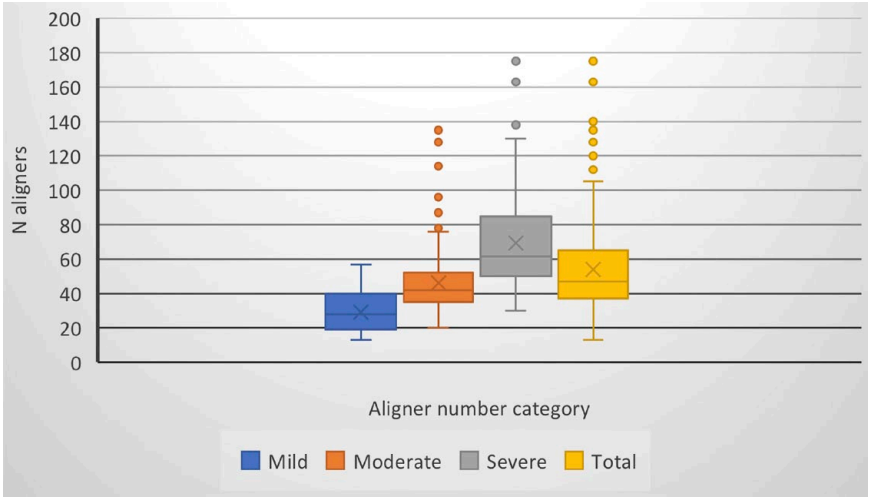


**Table 5.** Frequency of aligners by initial aligner category and per initial and refinement DTPs per dental arch.

| | Initial aligner category | | | | | | | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mild | | | Moderate | | | Severe | | | | | |
| | Median | 25%–75% IQR | Range | Median | 25%–75% IQR | Range | Median | 25%–75% IQR | Range | Median | 25%–75% IQR | Range |
| Initial DTP | 14* | 13–14 | 6–14 | 23* | 20–25 | 15–29 | 35* | 32–45 | 30–78 | 26 | 20–32 | 6–78 |
| All Refinement plans | 13* | 7–14 | 0–15 | 15* | 12–19 | 5–50 | 18* | 13–26.75 | 0–73 | 20.5 | 14–31 | 0–132 |
| Total | 28* | 19–40 | 13–57 | 42* | 35–52 | 20–135 | 61.5* | 35–52 | 30–175 | 47 | 37.25–65 | 13–175 |

*$P < 0.001$ (Kruskal–Wallis test).
DTP, digital treatment plan; IQR, interquartile range.

arch. This is of consequence as it may have doubled the patient's overall treatment time. It was greater than the mean of 19.85–19.91 in a study with 155 patients comparing the effects of Invisalign® with and without telemonitoring on several treatment criteria (Hansa et al., 2020). However, it was less than the mean of 27.16–31.93 reported in a similar study with 90 patients (Hansa et al., 2021).

Frequently reported reasons for refinement plans and provision of additional aligners are poor patient compliance with wear protocols, difficulties encountered with some tooth movements, loss of CR attachments and deficiencies in CAT technology (Arqub et al., 2022). Further research is required to determine the association of factors, such as complex tooth movement, with the requirement for additional aligners. Alternatively, acceptance that refinement is a necessary part of effective treatment may be the appropriate option. Interestingly, however, the findings from Arqub et al. (2022) suggested that going beyond three refinement plans does not necessarily improve the final occlusal outcome.

An overall total of 35,174 aligners were prescribed to patients in this study. This raises the issue of how aligners are managed after their use to ensure that the deleterious environmental impact of the non-biodegradable plastic used in their manufacture is kept to a minimum (Peter et al., 2022).

## Limitations

The present study has some limitations. One limitation of this study was its retrospective nature. Selection bias, however, was minimised by only including consecutive patients who satisfied the tightly defined inclusion/exclusion criteria. The risk of clinician performance bias was also minimised

by the selection of patients from 11 specialist orthodontists experienced in the use of the Invisalign® appliance and working in a wide range of private practice environments.

The patients were categorised as mild, moderate and severe, based on the initial prescribed number of aligners. This was not intended to necessarily represent treatment complexity but provide an easily quantifiable categorisation that may have suggested the degree of difficulty the clinician perceived in successfully managing the patient's malocclusion. Further research, however, is required to determine the relationship of treatment complexity and the required number of aligners to manage the malocclusion.

### *Strengths*

A strength of this study was that completion of the course of treatment for all patients was the end of the 5-year period from the initial treatment plan when additional aligners could no longer be ordered. In addition, even though assessment of a treatment endpoint (and, therefore, calculation of treatment duration) was precluded, it enabled a 'real-world' appraisal of DTP and aligner provision requirements not afforded to many relevant study designs.

### *Implications for clinical practice*

The findings of this study have provided new information regarding DTPs and aligner provision at the beginning and during treatment. It gives clinicians and aligner manufacturers further information regarding the management of CAT protocols. It may also provide patients with information concerning the likelihood of refinements and the duration of treatment in a shared decision-making environment (Meade et al., 2019).

### *Implications for research*

Further research is necessary to determine what aspects of the initial planning processes are responsible for the clinicians requiring the median of three plans per patient in this study. Additional research is also required to determine how making changes to the initial DTP and planning refinement impacts on clinician time and resources.

## Conclusions

In conclusion, a median of three initial DTPs and two refinement plans were required for patients in this study. Virtually all patients required a refinement plan. Patients were prescribed almost double the number of aligners initially predicted to manage their malocclusion.

### Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The third named author is the curator of AARD.

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