Aligner treatment: patient experience and influencing factors

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Objectives: To investigate patient experience of aligner treatment and associated influencing factors.

Methods: A total of 102 patients wearing Invisalign clear aligners (Align Technology, California, USA) were recruited in an initial treatment group ($N = 62$) and a refinement group ($N = 40$). Clinical diagnoses and treatment designs were collected. Data from a Visual Analogue Scale (VAS), a Self-Rating Anxiety Scale (SAS), and an Oral Health Impact Profile-14 (OHIP-14) were recorded at the commencement (Day 0, before wearing the first set of aligners) and during the first 7 days (Days 1–7) after wearing the first set of aligners.

Results: The patient experience of aligner treatment (i.e., pain, anxiety and quality of life) was poorest during the first two days ($P < 0.05$), and returned to a normal level within a week. The level of patient experience during the initial phase was greater than that during the later refinement phase ($P < 0.01$). During the initial treatment, the studied factors did not significantly influence the level of pain (VAS) ($P > 0.05$ for all) nor anxiety (SAS) ($P > 0.10$ for all); the number of teeth with optimised attachments significantly ($R = 0.28$, $P = 0.03$) influenced the quality of life (OHIP-14). During the refinement phase, the studied factors did not significantly influence the level of pain (VAS) ($P > 0.09$ for all); the number of aligner sets significantly influenced the level of anxiety (SAS) ($R = 0.41$, $P < 0.01$); the Index of Treatment Complexity Outcome and Need (ICON) ($R = 0.44$, $P < 0.01$) and whether elastics were required significantly influenced the quality of life (OHIP-14) ($R = 0.349$, $P = 0.03$).

Conclusions: Patient experience of aligner treatment was poorest during the first two days and improved over a week. Patient experience during the initial phase was generally worse than that during refinement. Four clinical factors were found to have an influence, including the number of teeth with optimised attachments, the number of aligner sets, the ICON, and the need for elastics.

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Introduction

Clear aligner treatment has become increasingly popular due to its advantages of aesthetics, periodontal health,[1] and chair time efficiency.[2] It has been reported that the major reason for patients who chose aligners over traditional fixed appliances was for aesthetics.[3]

Patient experience of aligner treatment and influencing factors are still poorly understood and controversial. For example, patients treated with clear aligners have reported a relatively lower level of pain and oral symptoms, compared with those treated using fixed appliances;[4–6] however, studies have found that patients treated with aligners had a level of oral dysfunction with relatively high levels of pain during the first days of treatment.[7] Adult patients have reported that clear aligners have been associated with significant discomfort including oral dysfunction, major irritation and even temporomandibular joint symptoms.[4,7,8] A recent systematic review determined that patients treated with aligners experienced less pain than those treated using fixed appliances, but with a high level of

heterogeneity in the design of the included studies.[9] The limitations of the published literature mainly related to a small sample size, ambiguous randomised selection and variable inclusion criteria, e.g., a different complexity of malocclusions, the use of analgesics, and the design of aligners.

A comfortable experience is important for patient-centred healthcare.[10] A poor experience can diminish a patients' compliance, compromise the treatment result and discourage patients from wearing their appliances.[11] Treatment experience and response to fixed appliances has been found to be complex,[12] involving a variety of factors such as age, gender and type of appliance.[13–15] Current patient experience of aligner treatment and its influencing factors, however, are still poorly understood.[4,16,17]

The aims of the present study were therefore to investigate patient experience (i.e., pain, anxiety and quality of life) during aligner treatment, and to explore possible influencing factors (e.g., patients' characteristics, type of malocclusion and treatment design).

Material and methods

Participants

Ethical approval was obtained from the Ethics Committee of West China Hospital of Stomatology, Sichuan University (number: WCHSIRB-D-2019-073). Written informed consent was obtained from each participant. The research was designed as a prospective cohort study. Patients wearing Invisalign aligners (Align Technology, California, USA) were consecutively recruited between May 2017 and Mar 2020, from the Department of Orthodontics, West China Hospital of Stomatology, Sichuan University, China. The determination of the sample size was based on previous estimates of comfort variability in patients wearing clear aligners,[5,18] with an α set at 5%, β at 20% and an effect size of 0.8. This indicated that a total of 85 patients would be required.

The inclusion criteria were: (1) adult patients; (2) permanent dentition; (3) patients who were intending to wear Invisalign aligners; and (4) no history of major dental surgery. The exclusion criteria were: (1) any systemic diseases; (2) mental or psychological disorders, such as anxiety, depression or sleep disorders; (3) taking analgesics or medication that can cause/treat anxiety or depression; and (4) a history of periodontal disease, temporomandibular joint disorders, toothache, or untreated dental caries within the previous three months. If a patient needed tooth extraction or the placement of temporary anchorage devices, it was arranged at least one week before or after the investigation.

A total of 102 patients were included in the study and divided into two groups based on the stage of aligner treatment. The initial group (N = 62) referred to patients who had yet to commence treatment; the refinement group (N = 40) referred to patients who had completed the first series of aligners and would need mid-course corrections. All patients were asked to wear each pair of clear aligners 22 hr/day for at least 10 days.

Data collection

The general information of participants included: (1) age and gender; (2) clinical diagnoses, including Angle's classification, skeletal classification (Class I 0° ≤ ANB ≤ 4°; Class II ANB > 4°; Class III ANB < 0°), the level of crowding (I° 0mm ≤ crowding < 4mm; II° 4 mm ≤ crowding < 8 mm; III° crowding ≥ 8 mm) and Index of Complexity, Outcome and Need (ICON) which was to evaluate treatment difficulty.[19,20]

Data from the ClinCheck process (Align Technology, California, USA) were collected, comprising: (1) Invisalign treatment design, including the number of aligners, the number of extracted teeth, and the amount of interproximal reduction; (2) Attachment design, including the number of teeth with attachments, the number of teeth with optimised attachments, the ratio of teeth with optimised attachments (the number of teeth with optimised attachments in relation to all teeth with attachments), and the number of upper incisors with attachments; and (3) the use of elastics, including the number of attached button hooks.

Intra-operator reliability was tested by intra-class correlation coefficients for the assessment of ICON. Twenty-five patients were randomly selected and measured by one investigator, and repeated after two weeks. The intra-rater reliability was excellent (correlation coefficient = 0.96).

The investigators as well as the statistician were blinded to the study design. The investigators directly retrieved the patient's medical records from the hospital database to obtain relevant general information without knowing the treatment stage. Animation schemes were exported from the ClinCheck data (the patients' personal information was hidden) and the information was collected by one investigator.

Patient experience (pain, anxiety, and quality of life)

Data generated from a Visual Analogue Scale (VAS) of pain, Self-rating Anxiety Scale (SAS) and Oral Health Impact Profile-14 (OHIP-14) were collected to assess patient experience.

The level of pain was assessed by using a VAS, consisting of a graduated 10-cm straight line, ranging from 0 (no pain at all) to 10 (worst pain possible).[21] The VAS has been commonly used as a clinical pain evaluation tool because of its intuitive, rapid and sensitive characteristics.[22] A mark is placed on the line to correspond with the level of pain. A higher score indicates greater pain intensity.

The SAS was a 20-item self-report assessment device used in population surveys to assess anxiety levels.[23,24] Validity has been demonstrated for the Chinese version of SAS. Each question is scored on a Likert-type scale of 1 to 4, ranging from "a little of the time," "some of the time", "good part of the time", and to "most of the time". A generated SAS score is multiplied by 1.25 times; whereby, standard scores above 50 suggest clinically significant levels of anxiety.[25]

The OHIP-14 survey containing 14 items was used to assess OHRQoL.[26] The Chinese version of OHIP-14 has shown good validity and reliability and been widely used for assessing the impact of oral disorders.[27] Each item begins with the phrase "in the last 24 hours". The response options are "never", "hardly", "occasionally", "fairly often" and "very often", which are given values of 1, 2, 3, 4, and 5, respectively. The scores are totalled, producing an overall range of 14 to 56. Lower scores represent a higher OHRQoL.

The patients were asked to complete the online questionnaire daily at the commencement (Day 0, one day before wearing the first set of aligners) and each of the 7 days after wearing the first set of aligners (Day 1–7). All questions were mandatory and repeated daily. One investigator was responsible for the daily oversight, the check of questionnaire completeness and the sending of reminders.

Statistical analysis

Data were presented in mean ± standard deviation and *N* (%), and analysed using SPSS Statistics 21 (Statistical Package for the Social Sciences, SPSS Inc., Chicago, IL, USA). The Student's *t* test and chi-squared test were used to compare the baseline characteristics of the two groups. The analysis of variance for repeated measurement was used to compare patient experience between and within the initial and refinement groups. When the data of the VAS, SAS and OHIP-14 were not satisfied with a 'football' symmetry test, a Greenhouse-Geisser coefficient was used to correct the degree of freedom. The score changes were defined as the difference between the highest scores and baseline scores. The Spearman correlation analysis and rank-sum test were applied to explore the correlation between patient experience (VAS, SAS and OHIP-14) and continuous/discrete influencing factors (e.g., age, gender, clinical diagnosis, treatment design, attachment design and elastics design). A P-value of less than 0.05 was considered to be statistically significant.

Results

Patients' characteristics

Baseline characteristics of the initial and refinement groups were similar ($P > 0.05$ for all) (Table I). The treatment difficulty and complexity of the initial group

Table I. Baseline characteristics of the initial and refinement groups.

Characteristics	Initial group	Refinement group	*P*-value
Age (years)	29.23 ± 8.07	27.93 ± 5.73	0.38
Gender (male; female)	8; 54	7; 33	0.57
VAS (Visual Analogue Scale)	1.48 ± 1.21	1.10 ± 0.87	0.09
SAS (Self-Rating Anxiety Scale)	38.17 ± 6.94	37.97 ± 6.02	0.88
OHIP-14 (oral health impact profile-14)	12.73 ± 9.51	12.80 ± 9.74	0.97
ICON (Index of Complexity Outcome and Need)	39.27 ± 21.60	20.80 ± 13.97	<0.01

Note: Data were presented as mean ± standard deviation or number only. The Student's *t* test and χ^2 test were used.

(ICON = 39.27 ± 21.60) were greater than those of the refinement group (ICON = 20.80 ± 13.97) ($P < 0.001$).

The effective recovery was 94%. Of the patients who dropped out of the study, five patients were from the initial group (three were due to the extraction of premolars or third molars; two were due to the placement of temporary anchorage devices within a week of starting aligner wear), and one patient from the refinement group declined to continue for personal reasons.

Patient experience of aligner treatment

Patient experience (VAS, SAS and OHIP-14) of aligner treatment was poorest during the first two days (Fig. 1). The VAS and OHIP-14 in both groups and SAS in the initial group reached a peak at day 1, and SAS in the refinement group reached a peak at day 2 ($P < 0.05$). All scores returned to the baseline level within 7 days but the level and fluctuation of patient experience in the initial group was generally greater than that of patients in the refinement group ($P < 0.01$).

Factors influencing patient experience

Table II presents the descriptive statistics and correlation analysis of patient experience and influencing factors. During the initial phase, the studied factors did not significantly influence the level of pain (VAS) ($P > 0.05$ for all), nor anxiety (SAS) ($P > 0.10$ for all). The number of teeth with optimised attachments significantly ($R = 0.28$, $P = 0.03$) influenced the quality of life (OHIP-14).

During the refinement treatment, the studied factors also did not significantly influence the level of pain (VAS) ($P > 0.09$ for all). The number of aligner sets significantly influenced the level of anxiety (SAS) ($R = 0.41$, $P < 0.01$). The ICON ($R = 0.44$, $P < 0.01$) and with/without elastics ($R = 0.35$, $P = 0.03$) significantly influenced the patient's quality of life (OHIP-14).

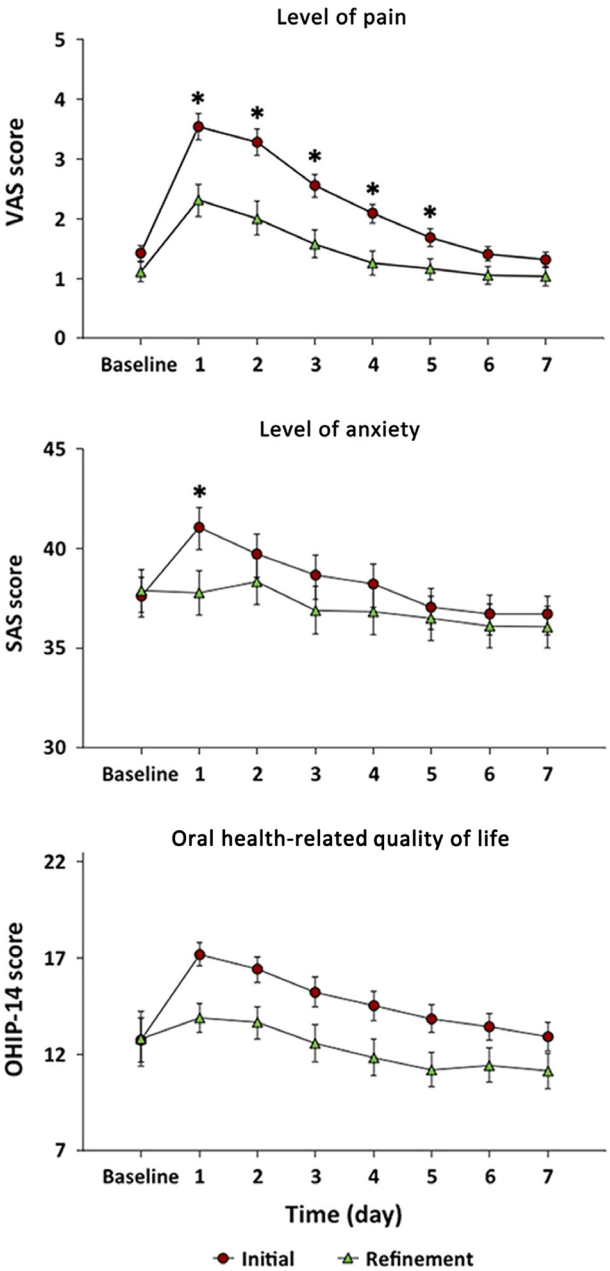

Figure 1. Patient experience during the initial treatment and refinement treatment. *$P < 0.05$.

Discussion

Invisalign treatment is popular but patient experience from their perspective is poorly understood. It has been found that adults usually prefer clear aligners rather than fixed orthodontic appliances mainly for aesthetics and social events;[28,29] however they also complain, to some degree, of discomfort and pain.[30] In the present study, the level of pain increased in both initial and refinement groups, to a peak during the first few days of wearing aligners to a normal level by steady reduction within a week. This is in agreement with previous studies.[4,8] In addition, the change in anxiety level showed a similar pattern with that of pain. This may be because the self-reported pain might be somatisation of the anxiety, the way patients transformed their anxious status into a tangible psychological concern.[10]

Table II. Descriptive statistics and correlation analysis of patient experience and influencing factors.

	Initial group				Refinement group			
Factors	Characteristics	VAS	SAS	OHIP-14	Characteristics	VAS	SAS	OHIP-14
Age (years)	29.23 ± 8.07	0.05	0.69	0.14	27.93 ± 5.73	0.81	0.37	0.44
Gender		0.82	0.20	0.92		0.24	0.90	0.89
Male	8 (13%)				7 (17.5%)			
Female	54 (87%)				33 (82.5%)			
Angle's classification		0.18	0.50	0.38		0.87	0.39	0.28
Class I	11 (17.7%)				13 (32.5%)			
Class II	39 (63%)				18 (45%)			
Class III	12 (19.3%)				9 (22.5%)			
Skeletal classification		0.17	0.12	0.29		0.93	0.09	0.07
Class I	27 (43.5%)				21 (52.5%)			
Class II	29 (46.8%)				11 (27.5%)			
Class III	8 (9.7%)				8 (20%)			
Crowding		0.61	0.56	0.37		N/A	N/A	N/A
None	15 (24.2%)				34 (85%)			
I°	29 (44.6%)				0 (0)			
II°	9 (14.5%)				0 (0)			
III°	4 (6.5%)				0 (0)			
Space	8 (10.2%)				6 (15%)			
ICON scores	39.27 ± 21.60	0.22	0.10	0.47	20.8 ± 13.96	0.58	0.92	**<0.01**
Treatment design								
Number of aligners sets	47.98 ± 11.77	0.82	0.50	0.35	29.7 ± 11.94	0.86	**<0.01**	0.20
Number of extraction teeth	1.92 ± 1.72	0.49	0.58	0.20	0 (0)	N/A	N/A	N/A
Amount of interproximal reduction (mm)	1.56 ± 1.05	0.46	0.59	0.56	1.84 ± 1.71	0.66	0.67	0.75
Attachment design								
Number of teeth with attachment	16.95 ± 1.99	0.15	0.17	0.89	15.85 ± 3.69	0.09	0.36	0.35
Number of teeth with optimised attachments	7.9 ± 4.98	0.92	0.96	**0.03**	6.73 ± 4.01	0.93	0.47	0.15
Ratio of teeth with optimised attachments to all teeth with attachments	0.46 ± 0.29	0.14	0.12	0.89	0.42 ± 0.25	0.68	0.67	0.16
Number of upper incisors with attachments	1.48 ± 1.11	0.96	0.19	0.15	1.75 ± 1.17	0.98	0.54	0.51
Elastics design (the need for elastics)		0.34	0.26	0.24		0.81	0.43	**0.03**
With elastics	46 (74.2%)				24 (60%)			
Without elastics	16 (25.8%)				16 (40%)			
Number of buttons	1.06 ± 1.21	0.17	0.41	0.25	1.1 ± 1.41	0.30	0.95	0.06

Note: Data were presented as mean ± standard deviation and *N* (%). The Spearman correlation analysis and rank-sum test were used for comparative statistics. VAS: Visual Analogue Scale of pain; SAS: Self-Rating Anxiety Scale; OHIP-14: Oral Health Impact Profile-14. N/A, not applicable.

The current study found that patients with additional aligners experienced less discomfort than those with initial aligners. This may be because the adaptability to additional new aligners was enhanced after the initial treatment, for example, patients became more experienced and familiar with the wear and removal of the aligners, the placement of attachments and buttons to the teeth, and the application of elastics.

In the present study, the pain experienced by patients receiving aligners for the first time did not seem to be directly related to the treatment design. One possible explanation was that patients' attitude towards treatment might have more impact on the perceived discomfort than the design of aligners when receiving clear aligners for the first time.[31] It has been found that an individual's physiological and psychology state were considered a significant factor in the intensity of tissue pain following the placement of orthodontic appliances.[32]

A patient's satisfaction with aligners could be affected by various factors, including a disturbance in oral function, the improvement in appearance, the doctor-patient relationship, and treatment strategy.[33,34] Of note in the present study, the number of teeth with optimised attachments was negatively correlated with the OHRQoL of patients receiving a first series of aligners. This might be because, although their size was reduced and optimised compared with the traditional attachments, the increased number of optimised attachments could still affect aesthetics and increase the practical inconvenience of wearing and removing the aligners. Furthermore, additional aligners sets and higher ICON scores, indicating longer treatment times, were more likely to impact patient experience in those patients who required additional aligners.

For each new aligner, the first few days were considered to be the "troubled period", and clinicians are advised to carefully explain expected discomfort and pain to patients, or structure a follow-up telephone call, if necessary, in order to avoid affecting a patient's compliance during this transition time.[18,34] Given that anxious patients usually tend to choose clear aligners,[35] the management and support of their psychological wellbeing should be considered in the decision-making process. For patients receiving aligners for the first time, a comprehensive explanation of possible discomfort and a follow-up phone contact are recommended.[18]

In addition to patient experience, the treatment outcome is also important in relation to clinical excellence. It has been found that treatment efficacy of a removable functional appliance was negatively affected by poor compliance related to insufficient wear time (less than 9 hours per day).[36] Only 36% of 2644 patients showed self-reported full compliance of aligner wear time of more than 22 hours per day.[37] Compliance with removable orthodontic appliances is suboptimal,[38] and a poor treatment experience could even lead to the discontinuation of clear aligner therapy. This indicates the need for assured patient compliance and experience. Although patients in the present study were generally satisfied with the treatment outcome, the study was focused on the patients' experience and no data of treatment outcome was collected and analysed. A future study could consider investigating the possible relationship between patients' experience and treatment outcome.

There are recognised limitations of the study. The sample size was relatively small; the participants were all of Chinese ethnicity and most were young females from the southwest of China, which might limit its generalisability. The ICON did not consider face shape nor skeletal relationship of patients and a more objective and comprehensive assessment system to evaluate patients' treatment difficulty is still needed. Further research involving a larger and more heterogeneous study sample is required.

Conclusions

Patient experience of aligner treatment (i.e., pain, anxiety and OHRQoL) was poorest during the first two days of treatment and returned to a normal level within a week. The level and fluctuation of patient experience during the initial phase was generally greater than that experienced during a refinement phase. Four factors influenced patient experience, including the number of teeth with optimised attachments, the number of aligner sets, the ICON, and whether elastics were required.

Conflict of Interest

The authors disclosed no conflict of interest.
Lin Xu and Hanshi Li: Both authors contributed equally to this work.

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