An objective system for appraising clear aligner treatment difficulty: clear aligner treatment complexity assessment tool

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Abstract

Background: Recent years has witnessed a remarkable evolution of clear aligner technology and clear aligners are becoming more and more versatile in managing orthodontic patents. The aim of this study was to develop an objective evaluation system for assessing clear-aligner treatment difficulty.

Methods: A total of 100 eligible patients were recruited in this study. Based on clinical data (dental models, radiographs and photographs), difficulty levels were evaluated by two experts and regarded as the gold standard. Difficulty scores were determined through an evaluation system encompassing three domains (dental model analysis, radiographic examinations and clinical examinations). The reliability of the evaluation system was examined through analyzing the agreement between difficulty levels and difficulty scores. Moreover, multivariate linear regression test was used to examine the independent effect of each variable (e.g. overbite and crowding) on difficulty level.

Results: The results revealed that the assessment of treatment complexity by this objective evaluation system matched perfectly with the gold standard (kappa=0.80). The multivariate regression test revealed that difficulty level was significantly associated with difficulty score ($\beta=0.13$, $p<0.001$), age ($\beta=-0.04$, $p=0.015<0.01$), tooth extraction ($\beta=1.14$, $p<0.001$) and number of difficult tooth movement ($\beta=0.09$, $p=0.005<0.05$). This objective evaluation system elaborated in this study is viable and reliable in appraising clear-aligner treatment difficulty in clinical practice.

Conclusions: We suggest practitioners, especially general practitioners, use this evaluation system for appropriate clear-aligner patient selections.

Background

Recent years has witnessed a dramatic evolution of clear aligner technology and numerous innovations have been built into clear aligners (1). Compared with traditional brackets and wires, clear aligner appeals to orthodontic patients for its advantages of invisibility, comfort and esthetics (2–4). This renders more and more practitioners, especially general practitioners, to use clear aligners for orthodontic treatment (5). However, different opinions exist for the ability and versatility of clear aligners in treating different types of malocclusion (6, 7), which is partly attributed to different levels of education and training received by practitioners. It has been reported that practitioners with
different levels of orthodontic education differed in aligner expertise and management of aligner patients (5). Moreover, practitioners with more orthodontic training are better at recognizing case complexity and eliminating potential risks (8). Thus, to guarantee a successful treatment of aligner patients, the expertise of recognizing case complexity of aligner patients is very important.

Although numerous evaluation systems are designed for the assessment of case complexity for traditional appliances (e.g., peer assessment rating and ABO discrepancy index) (9, 10), none of them is for clear aligners. Considering that clear aligner has a distinct biomechanic system and is able to achieve multiple types of tooth movement with varying degrees of predictability (11–14), a new evaluation system of case complexity for clear aligner treatment is urgently needed for both orthodontists and general practitioners.

Therefore, the aim of this study was to develop a new evaluation system for the assessment of case complexity for clear aligner patients.

**Methods**

**Participants**

A total of 100 patients receiving clear aligner treatment were selected from a patient pool in West China Hospital of Stomatology, Sichuan University. The inclusion criteria were patients receiving clear aligner treatment and both genders. The exclusion criteria included orofacial syndromes and unwillingness to participate. Prior to orthodontic treatment, clinical photographs, panoramic photograph, lateral photograph and dental impressions were taken for all the participants. Dental study casts were made from the dental impressions. Furthermore, clear aligner treatment stages and the number of difficult tooth movements were recorded from the clear aligner software (Clincheck, San Jose, USA). This study was approved by the Ethical Committee of West China Hospital of Stomatology, Sichuan University (WCHSIRB-OT-2019-086). Informed consent was obtained from all the patients above 18 yrs old and from both the patients and their parents for patients under 18 yrs old.

**Evaluation of difficulty levels by two experts**

Based on the clinical data (clinical photographs, radiographics and dental casts), difficulty levels of patients receiving clear aligner treatment were assessed by two experts independently. The difficulty
levels assessed by the two experts ranged from one to ten, with one being the easiest and ten being the most difficult. The results of difficulty levels assessed by the experts were regarded as the gold standard.

**Difficulty scoring through the evaluation system**

The assessment tool is an objective evaluation system that encompasses three major domains: dental model analysis, radiographic examinations and clinical examinations. The assessment tool is detailed in Table 1. In brief, the domain of dental model analysis mainly included overjet, overbite, crowding, molar relationship, posterior teeth and spacing. The domain of radiographic examinations mainly encompasses ANB angle, U1-SN angle and SN-MP angle. Furthermore, the domain of clinical examinations mainly includes E-line and gummy smile. For the items in each domain, different weights were added onto different items.

For each participant, difficulty scoring was based on the aforementioned assessment tool and the sum of the scores of all the items was the final difficulty score for each participant.

**Table 1. Clear aligner treatment complexity assessment tool (CAT-CAT)**

| Model analysis | 0-1 mm | 1-3 mm | 3-5 mm | 5-7 mm | 7-9 mm | >9 mm | Crossbite |
|----------------|--------|--------|--------|--------|--------|-------|-----------|
| Overjet        | 2      | 0      | 4      | 6      | 8      | 10    | 2/mm      |
| Overbite       | 0-1 mm | 1-3 mm | 3-5 mm | 5-7 mm | >7 mm  | 15    | 3/tooth-mm|
|                | 0      | 0      | 6      | 9      | 15     |       |           |
| Crowding       | 0-3 mm | 3-5 mm | 5-7 mm | >7 mm  |        |       |           |
|                | 0      | 2      | 3      | 4      |        |       |           |
| Molar          | 0      | 2      | 3      | 7      | 12     |       |           |
| relationship   |        |        |        |        |        |       |           |
| Maintenance    | <2 mm  | 2-5 mm | >5 mm  | <2 mm  | 2-5 mm | >5 mm |           |
|                | 0      | 3      | 7      | 3      | 7      | 12    |           |
| Distalization  |        |        |        |        |        |       |           |
| Mesialization  | <2 mm  | 2-5 mm | >5 mm  | <2 mm  | 2-5 mm | >5 mm |           |
|                | 3      | 7      | 12     | 3      | 7      | 12    |           |
| Posterior teeth| Openbite| Crossbite| Scissorsbite|       |       |       |           |
|                | 2/tooth-mm| 4/tooth | 6/tooth |       |       |       |           |
| Spacing (Largest)| ≤2 mm | >2 mm |        | If not to be closed orthodontically |       |       |           |
|                | 0      | 2 for one additional mm | 0 |       |       |       |           |
| Other          | Anomaly| Midline deviation (x mm) | Premolar rotation | Lateral inciso |
|                | 5/tooth| (x-2)^2 | 2/10° | 2/10 |       |       |           |

Radiographic examinations
Reliability of the evaluation system
The reliability of the assessment tool was determined through analyzing the agreement between the gold standard (difficult levels evaluated by the expert) and the difficulty scores obtained through the assessment tool.

Statistical analysis
The agreement on difficulty levels between the two experts was analyzed through intra-class correlation coefficient (ICC). The reliability of the assessment tool was analyzed through Pearson’s correlation test. Moreover, multivariate linear regression test was used to examine the independent effect of each variable (e.g., overbite and crowding) on difficulty level. All the statistical analyses were performed in GraphPad Prism 7.0 and SPSS 21.0. A p value less than 0.05 was considered as statistical significance.

Results
Patients
A total of 100 clear-aligner patients were recruited in this study. Their ages ranged from 10 yrs to 48 yrs, with a female predominance (86%). Among them, 64% were non-extraction patients (n = 64) and the remaining 36% were extraction patients (n = 36). Aligner stages ranged from 12 to 98, with a
mean of 39. Moreover, the number of difficult tooth movement were 7.3 ± 4.5.

Evaluation of difficulty levels
The difficulty levels as assessed by the expert were 6.5 ± 2.3. The ICC was 0.92, indicating that the evaluations of treatment complexity by the two experts were in perfect agreement. The percentage of different difficult levels was displayed in Fig. 1.

Evaluation of difficulty score
The difficulty scores ranged from 6 to 59, with a mean of 30.7 ± 10.9. The reliability test showed that the results assessed by the two evaluators were in perfect agreement (kappa = 0.86). The percentage of different difficult scores was depicted in Fig. 2. Shapiro-Wilk normality test revealed that the difficulty scores of the participants were normally distributed (p = 0.99 > 0.05).

Agreement between difficulty level and difficulty score
As depicted in Fig. 3, Pearson's correlation test revealed that difficulty level and difficulty score were significantly correlated (R² = 0.80).

Multivariate regression test
The results revealed that difficulty level was significantly associated with difficulty score (β = 0.13, 95% CI: 0.11 ~ 0.16; p < 0.001), age (β= -0.04, 95% CI: -0.07 ~ -0.01; p = 0.015 < 0.01), tooth extraction (β = 1.14, 95% CI: 0.61 ~ 1.67; p < 0.001) and number of difficult tooth movement (β = 0.09, 95% CI: 0.03 ~ 0.15; p = 0.005 < 0.05). However, it was not significantly associated with gender (p = 0.22 > 0.05).

We further performed multivariate linear regression test to analyze the association between the difficulty level and different items in the evaluation system. As displayed in Table 2, we found that difficulty level was significantly correlated with overjet (β = 0.18, 95% CI: 0.09 ~ 0.27; p < 0.001), overbite (β = 0.14, 95% CI: 0.08 ~ 0.20; p < 0.001), crowding (β = 0.43, 95% CI: 0.24 ~ 0.61; p < 0.001), molar relationship (β = 0.23, 95% CI: 0.14 ~ 0.33; p < 0.001), posterior teeth (β = 0.17, 95% CI: 0.11 ~ 0.24; p < 0.001), other model analysis (β = 0.15, 95% CI: 0.08 ~ 0.22; p < 0.001), ANB (β = 0.13, 95% CI: 0.04 ~ 0.22; p = 0.006 < 0.05), U1-SN (β = 0.23, 95% CI: 0.14 ~ 0.32; p < 0.001), SN-MP (β = 0.24, 95% CI: 0.03 ~ 0.44; p = 0.02 < 0.05), E-line (β = 0.21, 95% CI: 0.14 ~ 0.29; p < 0.001) and other clinical examinations (β = 0.08, 95% CI: 0.01 ~ 0.16; p = 0.03 < 0.05). Yet, it was not associated
with spacing (p = 0.96 > 0.05), other radiographic analysis (p = 0.23 > 0.05) or gummy smile (p = 0.18 > 0.05).

Table 2
Multivariate regression analysis of the association between multiple indices with difficulty levels

| Other | Chin deviation (if surgery) | Occlusal canting | Periodontitis | TMD | Generalized caries |
|-------|-----------------------------|------------------|---------------|-----|------------------|
| Index | Regression coefficient (β) (95% CI) | p value | | | |
| Dental model analysis | | | | | |
| Overjet* | 0.18 (0.09, 0.27) | < 0.001 | | | |
| Overbite* | 0.14 (0.08, 0.20) | < 0.001 | | | |
| Crowding* | 0.43 (0.24, 0.61) | < 0.001 | | | |
| Molar relationship* | 0.23 (0.14, 0.33) | < 0.001 | | | |
| Spacing (the largest) | -0.01 (-0.17, 0.16) | 0.96 | | | |
| Posterior teeth* | 0.17 (0.11, 0.24) | < 0.001 | | | |
| Other model analysis* | 0.15 (0.08, 0.22) | < 0.001 | | | |
| Radiographic examinations | | | | | |
| ANB* | 0.23 (0.04, 0.22) | 0.006 | | | |
| U1-SN* | 0.23 (0.14, 0.32) | < 0.001 | | | |
| SN-MP* | 0.24 (0.03, 0.44) | 0.02 | | | |
| Other radiographic examinations | 0.06 (-0.04, 0.17) | 0.23 | | | |
| Clinical examinations | | | | | |
| E-line* | 0.21 (0.14, 0.32) | < 0.001 | | | |
| Gummy smile | 0.18 (-0.09, 0.45) | 0.18 | | | |
| Other clinical examinations* | 0.08 (0.01, 0.16) | 0.03 | | | |

*p < 0.05 indicates statistical significance

Discussion

Clear aligners differ from conventional fixed appliances in biomechanics. For clear aligners, tooth movements are achieved through compression force on teeth produced by elastic changes of aligners. In contrast, tooth are moved through both compression and traction forces generated by the interaction between brackets and wires. Moreover, distinct from fixed appliances, the clear aligner system suffers from a significant disadvantage: teeth may “escape” from the aligners (off-tracking) and force applications cannot be fully applied on these teeth (15). This results in varying degrees of predictability for different types of tooth movements, with molar distalization most predictable (88%) and incisor extrusion least predictable (30%) (11–14). The evaluation system of treatment complexity elaborated in this study was designed specifically for the clear aligner system. The results revealed
that the assessment of treatment complexity by this objective evaluation system matched perfectly with that by experts (gold standard) (kappa = 0.80).

Several evaluation systems for assessing treatment complexity are available for conventional fixed appliances, e.g., peer assessment rating (PAR) and ABO discrepancy index (DI) (9, 10). PAR system appraises treatment complexity based on model analysis only and DI system evaluates treatment difficulty through analysing dental models and radiographs. However, neither include soft tissue analysis for the assessment of treatment complexity. The evaluation system described in this study is complete for taking all the three tissues (dental, skeletal and soft tissues) into considerations. All the evaluation system, including the one elaborated in this study, assess treatment difficulty through adding difficulty points for each independent item, e.g., overjet, overjet and molar relationship. PAR and DI systems fail to evaluate treatment difficulty dynamically. For example, a full Class II molar relationship is considered to be more difficult than Class I relationship. In effect, in clinical scenarios, full Class II molar relationship is sometimes acceptable and does not require molar movement. Thus, for the item of molar relationship, the treatment difficulty is the same for a Class I relationship and a full Class II relationship. The only difference between the two clinical conditions is different overjets: patients with full Class II are more difficult due to a larger overjet that should be corrected rather than due to molar relationship. No point is added for patients whose molar relationship will be maintained. Therefore, the dynamic movement of molars are considered in our evaluation system, rather than a simple classification of molar relationship.

The multivariate regression test revealed that difficulty level was positively correlated with difficulty score (β = 0.13, 95% CI: 0.11 ~ 0.16; p < 0.001), indicating that difficulty level will be increased by 0.13 if difficulty score is increased by one. Moreover, we found that difficulty level was positively associated with tooth extraction and number of difficult tooth movement. Although clear aligners are able to manage extraction patients with good treatment outcomes (16, 17), premolar extractions followed by anterior teeth retraction requires meticulous design of aligner biomechanics and will definitely increase treatment complexity. Difficult tooth movement is defined by the clear aligner software based on predicted distances of tooth movement for each tooth, e.g., molar intrusion greater
than 5 mm. Conceivably, a higher difficulty level is anticipated with a larger number of difficult tooth movement. Ironically, we found that difficulty level was negatively associated with patient age ($\beta=-0.04$, $p = 0.015 < 0.01$). This may be attributed to a selection bias that adults patients with high treatment complexity were not included in this study given that patients with greater age had smaller number of difficult tooth movement ($p = 0.01 < 0.05$).

For the domain of model analysis, the multivariate regression test revealed that difficulty level was positively associated with all items except for spacing (Table 2). A large overjet requires premolar extractions and subsequent upper anterior retraction while large overbite requires large amounts of lower incisor intrusions. All of these types of tooth movement are considered to be difficult in clear aligner treatment. Therefore, we put more weights on these two items (e.g., 10 points will be added for patients with an overbite greater than 9 mm and 9 points will be added for patients with an overbite of 6 mm). Treatment complexity is increased among patients with more crowding ($p < 0.001$). However, we did not put much weight on this item since severe crowding could be easily resolved through premolar extraction and subsequent minimal incisor retraction (most of the extraction space is used for resolving crowding rather than incisor retraction). As mentioned above, we evaluated molar relationship dynamically. Zero point is added for patients needing molar relationship maintenance (Class I, full Class II or III). For clear aligner treatment, considering molar mesialization is more difficult than molar distalization (18), we put more weights on molar mesialization. For posterior teeth, all the three types of malocclusion (openbite, crossbite and scissorbite) are difficult to correct and thus we add much weight on this item, e.g., 10 points will be added for patients with a posterior tooth with a 5-mm openbite (2 pts/tooth-mm). For the item of spacing, we only analyzed the largest space since patients with one space of 5 mm will be more difficult to treat than those with several small spaces totaling 5 mm (if the spaces are to be closed orthodontically). Moreover, if a space will not be closed orthodontically (e.g., closure through implants), no point will be added. The reason why spacing was not correlated with difficulty level in this study is that all patients received low marks for spacing and the marks of spacing were similar among patients. For other model analysis, it encompasses tooth anomaly, midline deviation, premolar
rotation and incisor rotation. As is well documented, tooth movement is achieved through elastic changes of aligners and adequate aligner wrapping is critical for the predicted tooth movement. Any tooth anomaly will reduce the adequacy of aligner wrapping and make tooth movement less predictable. Five points will be added for each abnormal tooth. It has been reported that a midline deviation less than 2 mm was acceptable by general population (19). Thus, only the amount of midline deviation greater than 2 mm counts in our evaluation system. Rotations of premolar and lateral incisors are difficult to correct in clear aligner system, since premolars are round or oval in shape and lateral incisors are short from the occlusal view (clear aligners are not able to exert adequate tangent forces that are crucial for derotation).

The domain of radiographic examinations encompasses ANB, U1-SN, SN-MP and other radiographic examinations. ANB is a radiographic index for assessing relative positions between upper and lower jaws and SN-MP is an index for evaluating mandibular plane angle. Deviations of these two indices from normal range will increase clear-aligner treatment complexity. U1-SN denotes upper incisor proclination and proclined upper incisors require gaining space and subsequent retraction of incisors. Thus, treatment complexity is increased among patients with abnormal U1-SN values. Moreover, tooth impaction, supernumerary teeth, missing teeth, tooth transposition, root resorption and severe skeletal problems needing orthognathic surgery all increase clear-aligner treatment difficulty. We put different weights on these items according to their influence on treatment complexity. The multivariate regression test showed that difficulty level were associated with all items in the domain of radiographic examinations except for other radiographic examinations. This could be attributed to the fact that small number of patients had these other radiographic problems (e.g., impaction), making this index (other radiographic examinations) similar among patients with different difficulty levels. Thus, further study with a larger sample size is warranted.

The domain of clinical examinations had three indices: E-line, gummy smile and other clinical examinations. The multivariate regression test found that difficult level was correlated with E-line and other radiographic examinations, while not with gummy smile. Likewise, this may be due to that small number of patients required gummy smile correction. An abnormal E-line (e.g., 4 mm denoting lips
are protrusive by 4 mm in reference to E-line) requires space gaining and anterior teeth retraction, thereby increasing aligner case difficulty. Moreover, all of the indices (chin deviation, occlusal canting, periodontitis, TMD and generalized caries) in the other clinical examinations increase clear aligner treatment complexity. Thus, we put different weights on these indices.

Conclusion
The objective evaluation system elaborated in this study is viable and reliable in appraising clear-aligner treatment difficulty in clinical practice. We suggest practitioners, especially general practitioners, use this evaluation system for appropriate clear-aligner patient selections.

List Of Abbreviations
ICC: intra-class correlation coefficient
PAR: peer assessment rating
DI: discrepancy index
CAT-CAT: Clear aligner treatment complexity assessment tool

Declarations
Ethics approval and consent to participate
This study was approved by the Ethical Committee of West China Hospital of Stomatology, Sichuan University (WCHSIRB-OT-2019-086). Informed consent was obtained from all the patients above 18 yrs old and from both the patients and their parents for patients under 18 yrs old.

Consent for publication
Not applicable

Availability of data and material
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
HL and WL realized the research and conducted evaluation of difficulty levels. ZW, QW YW, FJ, LL and XL performed difficulty scoring through the evaluation system. ZW and QW conducted statistical analysis. ZW drafted manuscript. LL corrected the writing. All authors read and approved the final manuscript.

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Figures

Figure 1

The percentage distribution of difficulty levels as assessed by orthodontic experts.
Figure 2

The percentage distribution of difficulty scores as evaluated through clear aligner treatment complexity assessment tool (CAT-CAT).
Figure 3

Correlation between difficulty level and difficult score. Pearson's correlation test revealed that the two items were significantly correlated ($R^2=0.80$).