Original Article

Factors Affecting Patient Compliance during Orthodontic Treatment with Aligners: Motivational Protocol and Psychological Well-Being

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Main Points
- The psychological profile of individuals did not correlate with their compliance throughout the treatment, but the psychological well-being (PWB) questionnaire showed higher scores after 12 months of CA.
- The motivational protocol used in a group of adult patients already willing to improve their smile with clear and removable aligners did not show significant differences in treatment progress.
- The clinical progress evaluated both on gypsum casts and on digital clin-check demonstrated the efficacy of CA in patients with good adherence to treatment.

ABSTRACT

Objective: Compliance is critical for successful outcomes in orthodontics, and personality traits may play a role in determining patient adherence. This study aimed to monitor compliance during treatment with removable clear aligners (CA) [Align Technology Inc, San José, Calif], and evaluate the influence of motivational techniques and the patient's profiles assessed through the psychological well-being (PWB) questionnaire on clinical outcomes.

Methods: Thirty-nine consecutive patients in permanent dentition seeking treatment with CA were recruited from two universities. Casts were obtained before treatment and after 3, 6, and 12 months and the corresponding digital Clincheck©.STL files were used to calculate the discrepancy index to check for differences between virtual and real treatment stages. Patients were divided into two groups: the Case group, which received motivational techniques at each appointment, and the control group which received instructions only at the beginning. Psychological profiles were evaluated before treatment (T0) and after 3 (T1), 6 (T2), and 12 (T3) months.

Results: There were no differences between the Case and Control groups regarding the use of motivational reminders. The analysis of the PWB showed that almost all values increased, and there was a strong correlation between dental casts and correspondent. STL files at every time point. The PWB showed increased values from T0 to T3 in the sample.

Conclusion: Motivational techniques did not affect patient compliance, and treatment outcomes were achieved as planned. The PWB of all patients improved throughout the treatment with CA.

Keywords: Clear aligners, compliance, patient adherence, psychological well-being, motivational techniques, quality of life

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INTRODUCTION

Nowadays, malocclusion has a negative impact on people's quality of life, social interactions, and self-esteem[1,2] as well as on oral biological conditions and functions.[3,4] The increasing demand for orthodontic treatment in young adults, particularly women, is mainly due to their greater concern for aesthetics over dental health.[5-7] Orthodontic appliance designs also influence the judgments of adolescents, and comfort with the appliances seems to be one of the major factors in increasing treatment acceptance.[8,9] Patients treated with fixed orthodontic appliances report a more intense decrease in functional and psycho-social aspects of their daily lives, so they are more likely to accept removable clear aligners (CA) to avoid tooth soreness, mucosal irritation, esthetic and speech disturbances, as well as possible plaque accumulation and gingivitis that can be induced by fixed labial or lingual multibracket appliances.[10-12] The virtual diagnostic setup, provided before starting treatment, represents a useful consultation device to verify compliance and to show both improvements and the limits of the treatment to each patient. However, there may be some discrepancies between the digital setup and the effective clinical predictability.[10-13] Nevertheless, high compliance throughout the treatment remains the main critical benchmark for successful outcomes.[11-14]

In previous studies, it has been hypothesized that personality traits might partly determine the patient's adherence during orthodontic treatment.[15-18] Thus, understanding a subject's well-being before starting orthodontic treatment with CA may be clinically relevant.[19,20] Over the past few decades, researchers have developed a questionnaire to evaluate orthodontic treatment needs and outcomes in terms of oral health-related quality of life (OHRQoL). The Oral Impact on Daily Performance is one of the most widely used indicators to measure oral impacts. It assesses the impact of oral conditions on basic activities and behaviors that covers the physical, psychological, and social dimension of daily life.[21] However, only a few researchers have focused on the oral impacts of CA on daily performance in adults.[22,23] Nowadays, people of all ages search for information on CA treatment through web and social media, which have become the most commonly used marketing tools.[10,24,25] To improve patient compliance, the integration of new technologies can be considered as an effective solution due to their wider use among the whole population. The use of an app-based approach has shown positive effects in a sample of adolescents.[26]

Some researchers have reported that the use of motivation protocols during an orthodontic treatment can have a positive influence on patients' compliance and feelings.[27] For example, Noll et al.[28] analyzed users who liked to show great smile through selfies along with expressing high gratitude for the clinicians. A recent paper showed a consensus between clinicians and patient son the type of outcomes, that are important to be measured in orthodontic studies. Among the final core outcome sets identified, three were involved in this research strengthening the study rationale: the impact of self-perceived aesthetics,

alignment, and patient-related adherence.[29] Currently, the treatment with aligners is the most affected by the patient's compliance and motivation.

Thus, the primary research questions were:

1) Does the use of motivational protocol influence patient adherence in CA treatment?

2) Does the patient's psychological profile, assessed through the psychological well-being (PWB) questionnaire, affect patient compliance?

A secondary objective was to evaluate whether the treatment outcomes measured on digital casts corresponded to the digital planning at different time points. The null hypotheses are represented by the improvement in patient compliance during CA treatment due to the use of motivational techniques and by a positive relationship between the patient's psychological profile and the related compliance during treatment evaluated by the outcomes on dental casts compared with the planned movements with the software.

METHODS

For this prospective study, consecutive patients seeking orthodontic treatment at the Orthodontic Program of the University of Campania Luigi Vanvitelli, and at the Orthodontic Division of the University of Turin, Italy, were selected from July 2017 to October 2019 using the following inclusion criteria:

- Full permanent dentition except for the third molars;

- Mild-to-moderate dental crowding with American Board of Orthodontics (ABO) Discrepancy index (DI) <30;

- Initial dental casts, panoramic and lateral skull radiographs of good quality;

- The ability to communicate in Italian based at least on primary education;

- Patient's approval for orthodontic treatment with CA without extractions.

Subjects with syndromes and/or craniofacial malformations, periodontal diseases, temporomandibular joint disorders,[30] history of previous orthodontic treatment, certified mental disorders, and chronic use of psycho-drugs, were excluded.

Approval for this study was granted from the Institutional Ethics Committee of the University of Campania Luigi Vanvitelli, Italy (approval number: 437, date: 24.07.2017). Informed consent was obtained from each adult patient or minor patient's parents before being involved in the study, after a detailed explanation of the research protocol.

Treatment and Study Protocols
Before beginning the treatment, the investigators measured the ABO DI using the initial printed dental casts, panoramic

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radiograph, and lateral skull radiograph of each patient.[31] The investigators were trained and calibrated beforehand to ensure the accuracy on the measurements. The ABO DI was used to grade only the pre-treatment digital casts with a numeric value correlated with the severity of both dental and skeletal craniofacial problems of each subject. Cephalometric analysis was performed using digital software (Viewbox 3.0. Dhal Software, Kifissia, Greece). Ten variables, 7 angular and 3 linear, were generated for each tracing. The enlargement factor was standardized to 0% (life size). All patients included in the study were treated with Invisalign (Align Technology, San José, CA, USA). Two trained orthodontists used the ClinCheck© software (Align Technology, San José, CA, USA) to design treatment plans. Every virtual setup was then revised by a third specialist to ensure a similar treatment approach was applied in the selected cases.

The patients were randomly assigned to two groups using online software to arrange the items of a list in a randomized order (www.randomizer.org). The first group, called Case, was composed of 20 subjects (10 females and 10 males, mean age 25±14 years) who received appropriate instructions on the use of aligners at each appointment (wear the aligners 22 hours per day, 7 days per week), and motivational and reminder text messages were sent twice a week by the doctor. The content of the text message included, for example, "Please, remember your aligners!", "Are you wearing your aligners right now?", "Let's enjoy your Invisalign!", "Keep smiling with your Invisalign!", "Cheer up and smile with clear aligners!".

The second group, called Control, was composed of 19 patients (10 females and 9 males, mean age 21±9 years) who were provided with verbal instructions about CA use only during the appointment in which the appliance was delivered.

After 3, 6, and 12 months, new dental casts were collected for each patient. The corresponding .STL files for each stage of treatment were extracted from the virtual setup and the list of patients and corresponding ClinCheck© stages were asked to Align Technology technicians who were randomly and anonymously assigned to this research project. The .STL files were emailed to the university responsible for the treatments. The patients, the investigators who calculated the ABO DI at different time points, and the data analysts were blinded to the group to which each subject was allocated. To evaluate treatment efficacy at the three-time points, only the dental DI was calculated on the conventional and printed models to avoid the need for further X-rays.[32] After 15 days, 30% of casts were remeasured to confirm measurement reproducibility.

PWB Questionnaire

The evaluations of the psychological profiles were collected before treatment (T0) and after 3 (T1), 6 (T2), and 12 (T3) months of CA treatment. The evaluations were based on a questionnaire that utilized the Italian version of Carol Ryff's PWB scales, which were used to analyze the psychometric characteristics.[33,34] The PWB is an 84-item self-rating inventory, consisting of six scales

that represent the six dimensions of PWB: self-acceptance, autonomy, environmental mastery, personal growth, purpose in life, and positive relations. Participants were asked to rate their adherence to each item on a six-point Likert scale, with 1 indicating "strongly disagree" and 6 indicating "strongly agree".

The questionnaire was delivered in the university centers by the same two operators who explained the easy instructions to the patients and facilitated its completion on the same appointment. The total score for each dimension represented in the PWB questionnaire is calculated by adding together the degrees of agreement of each item, resulting in a score that potentially varies from 14 to 84. The overall values of the six scales could range from a minimum score of 84 to a maximum of 504. The effect of the PWB questionnaire on patients' compliance was evaluated indirectly through the evaluation of the treatment outcomes at different time points.

Statistical Analysis

Statistical analyses were conducted using the R statistical package (version 3.5.3, R Core Team, Foundation for Statistical Computing, Vienna, Austria). The normality assumption of the data was evaluated with the Shapiro-Wilk test. Multiple regression analysis was performed to estimate the differences at follow-up in the total sample, as well as in the Case and Control group. Three outcomes were considered for the statistical analyses: the cast models, the .STL files of dental models derived from Align Technology ClinCheck© software, and the PWB questionnaire responses at T0, T1, T2 and T3. The estimate of the regression model explains the mean difference (MD) i) between follow-up in all sample analyzes, and ii) between groups for the case-control comparisons. Tukey's multiple comparisons of means with a 95% family-wise confidence level and adjusted P value were considered, with a level of significance set at 0.05. Descriptive tables show the distribution of data. Spearman's correlation was used to evaluate the relationship between the three outcomes. Multiple regression analysis was also performed to estimate the differences at follow-up between the Case and Control groups to check for differences due to the motivational protocol.

The sample size was calculated a priori to obtain a statistical power of the study greater than 0.80 with an alpha of 0.05. The sample size calculation indicated that 16 participants were needed to reach an 80% power for considering differences between the group and during the follow-up, with T statistic and non-centrality parameters with the aim to detect an effect size ≥0.03 considering an average variation of the thickness related to the expected value and a standard deviation of 0.03.

RESULTS

The mean age in all samples was 22.6±2.7 years of age, and no statistical differences in age and gender were detected between the Case and Control groups. The results for intra-rater reliability, assessed with the Spearman rho correlation coefficient, showed

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an excellent agreement (r>0.8) for all performed measurements. Data before treatment showed no differences between the dental cast and the .STL digital models in all samples (Tables 1 and 2). Statistical significance was found on the DI measured at different time points compared to the baseline T0 and to T1 (after 3 months), with a decreased value as expected during CA treatment, in the whole sample (Tables 1 and 2).

Questionnaire scores increased from T0 to T3, and differences in the samples were similar at all time points analyzed (Table 3).

No significant statistical differences were found between the Case and Control groups in the evaluations of the collected records after 3, 6, and 12 months of CA treatment (Figures 1-3).

DISCUSSION

This study focused on adults due to the higher impact of their smile display on their social and professional life.[8,9] A recent scoping review evaluated the impact of poor dental appearance on employability and the potential enhancement in employment outcomes after dental treatment in adults.[35] This study assessed a "hot topic", and the responses to the different research questions provided high-impact outcomes for daily clinical orthodontic practices.

Our results indicated that the individual's psychological profile did not have a significant correlation with their compliance throughout the treatment. This is consistent with the findings of Bos et al.[15], who suggested that patients' personality characteristics could not be used to predict their compliance.

Thus, the previous studies that hypothesized that personality traits analyzed through different psychological scales could affect a patient's adherence to the prescribed orthodontic treatment were not confirmed in our study.[36,37] However, the PWB questionnaire showed higher scores after 12 months of CA in most cases, emphasizing the importance of facial and smile

Table 1. Regression model: differences of DI measured on gypsum casts at different time points in all sample

	MD	95% CI	Adjusted p value
T1-T0	-5.03	-8.86 | -1.19	0.004*
T2-T0	-8.25	-12.08 | -4.41	0.008*
T3-T0	-10.31	-14.14 | -6.47	0.000*
T2-T1	-3.21	-7.05 | 0.61	0.132
T3-T1	-5.28	-9.11 | -1.44	0.002*
T3-T2	-2.06	-5.89 | 1.77	0.500

*p<0.05
MD, Mean differences; T0, Baseline; T1, After 3 months; T2, After 6 months; T3, After 12 months; CI, Confidence interval; DI, Discrepancy index

Table 2. Regression model: differences of DI measured on printed casts at different time points in all sample

	MD	95% CI	Adjusted p value
T1-T0	-1.37	-5.41 | 2.66	0.812
T2-T0	-2.96	-7.01 | 1.07	0.228
T3-T0	-5.40	-9.45 | -1.36	0.003
T2-T1	-1.59	-5.63 | 2.45	0.734
T3-T1	-4.03	-8.07 | 0.01	0.051
T3-T2	-2.43	-6.48 | 1.60	0.399

*p<0.05
MD, Mean differences; T0, Baseline; T1, After 3 months; T2, After 6 months; T3, After 12 months; CI, Confidence interval; DI, Discrepancy index

Table 3. Regression model: Differences of PWB Questionnaire values at different time points in all sample

|	MD	95% CI	Adjusted p value
T1-T0	4.62	-22.70 | 31.95	0.971
T2-T0	7.00	-20.32 | 34.32	0.909
T3-T0	13.15	-14.17 | 40.48	0.593
T2-T1	2.37	-24.95 | 29.70	0.995
T3-T1	8.53	-18.79 | 35.85	0.848
T3-T2	6.15	-21.17 | 33.48	0.935

*p<0.05
MD, Mean differences; T0, Baseline; T1, After 3 months; T2, After 6 months; T3, After 12 months; CI, Confidence interval; PWB, Psychological well-being
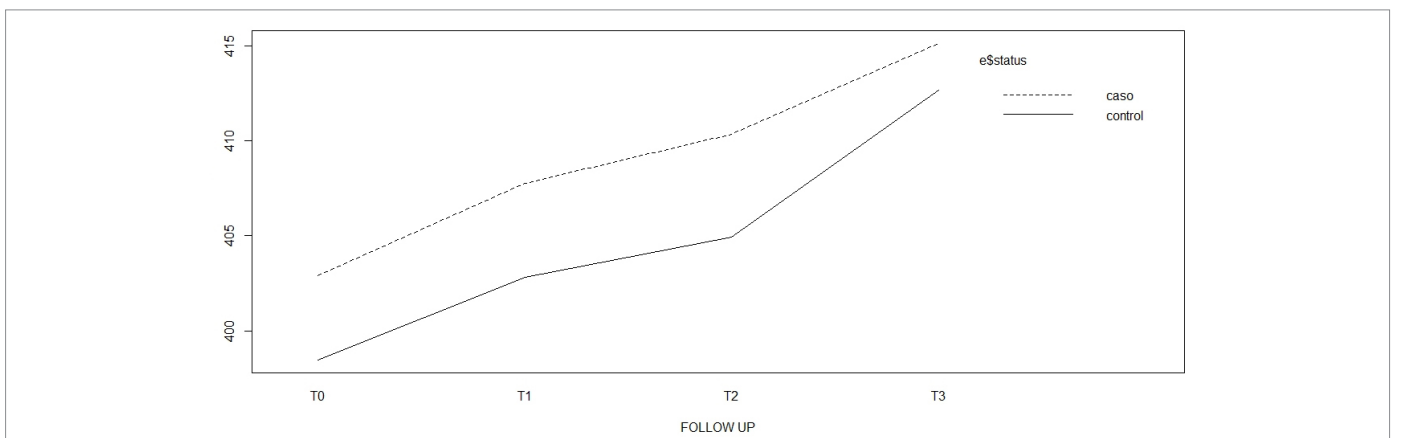
Figure 1. Psychological Well-being questionnaire scores between the Case (dashed line), and Control (continuous line) groups at T1, T2, and T3 (after 3, 6, and 12 months, respectively)
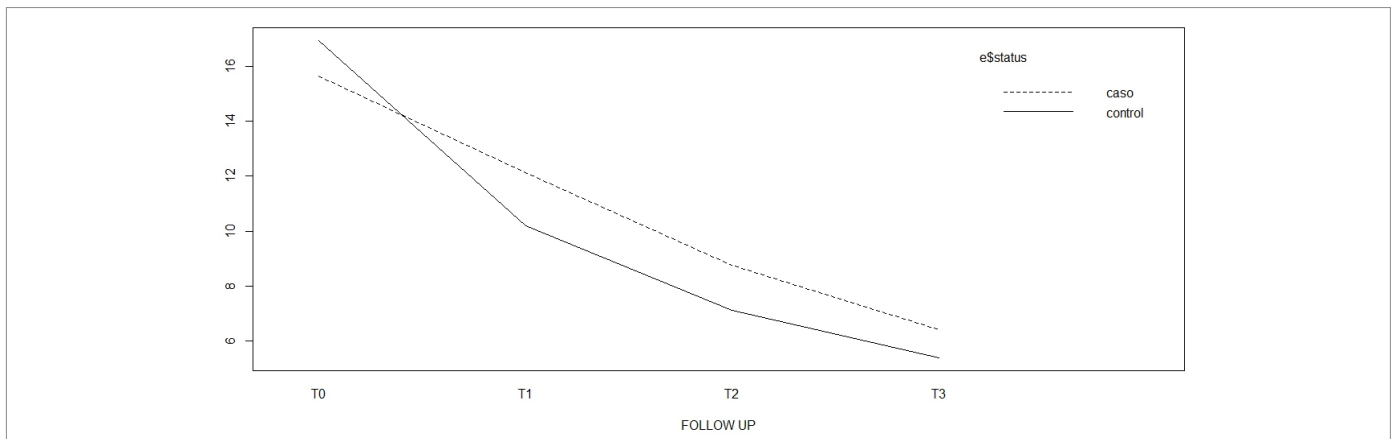
Figure 2. Gypsum cast Discrepancy Index between the Case (dashed line), and Control groups (continuous line) at T1, T2, and T3 (after 3, 6, and 12 months, respectively)
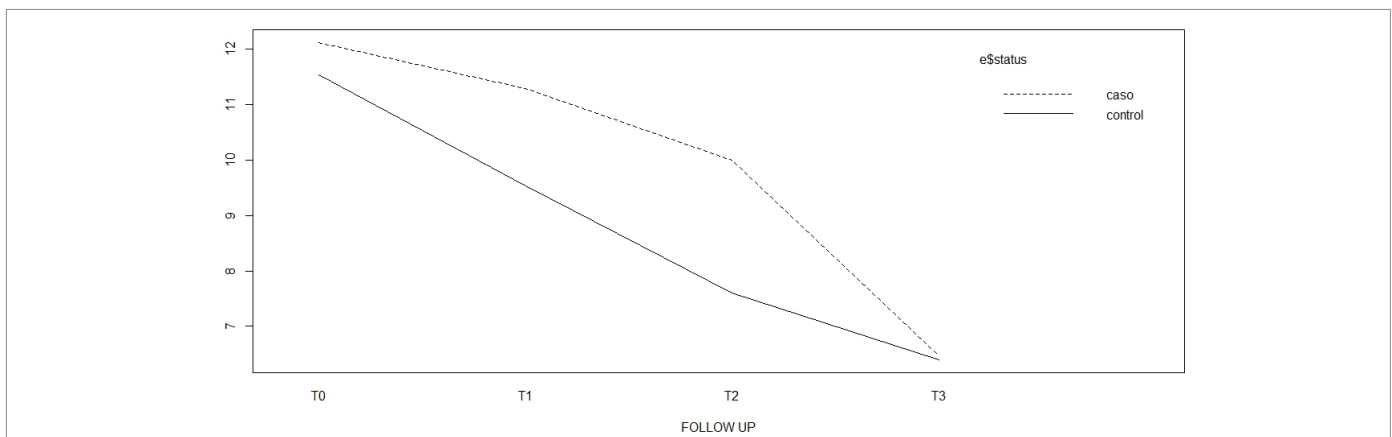
Figure 3. Printed cast Discrepancy Index between the Case (dashed line), and Control (continuous line) groups at T1, T2, and T3 (after 3, 6, and 12 months, respectively)

esthetic improvement related to a better quality of life for these patients. It was reported that for each of the six dimensions of the PWB representing the quality of life, an increasingly positive impact was reported at different times. In particular, the dimensions of self-acceptance and environmental controls were strongly associated with life-satisfaction measurements.

Agou et al.[19] demonstrated that better PWB in children was associated with better OHRQoL regardless of their orthodontic status. However, our data did not support this finding, possibly due to our sample including adolescents and adults, with a mean age of 22 years, who were seeking a specific esthetic treatment with CA.

The motivational protocol used in our Case group did not show significant differences in the treatment progress. The explanation may be the inclusion of adult subjects, who were already motivated to improve their smile with clear and removable appliances. Thus, the desire to straighten teeth and improve the esthetic smile seems to be a primary motivating factor for adults seeking orthodontic treatment, especially with the frequent use of digital social media. This may be a limitation of the study as it did not consider the importance of motivation and encouragement throughout the treatment, which is often

highly crucial in younger patients. Communication between orthodontists and their patients should be considered a vital part of achieving patient adherence and satisfaction with treatment.[6] Finally, the satisfactory agreement between the clinical progress evaluated on gypsum casts, and the digitally prescribed models, demonstrated the efficacy of CA when there is good patient adherence to treatment.

Moreover, looking at a recent literature review,[38] deeper knowledge of the orofacial pain felt with CA versus fixed orthodontic treatment would be clinically interesting. Future research may include a larger sample and further evaluation at the end of treatment to obtain more information on the long-term impact of orthodontic treatment with CA.

CONCLUSION

The clinical progress evaluated on gypsum dental casts was comparable to those digitally prescribed before treatment, demonstrating the good adherence of all patients in wearing CA. The patients' compliance seeking orthodontic treatment with CA seems to be unaffected by motivational techniques delivered twice a week during treatment. The well-being questionnaire from all patients already showed high values at baseline that

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further improved throughout the treatment. However, no correlation between well-being values and compliance was found, as no differences were revealed in the treatment efficacy.

Ethics

Ethics Committee Approval: Approval for this study was granted from the Institutional Ethics Committee of the University of Campania Luigi Vanvitelli, Italy (approval number: 437, date: 24.07.2017).

Informed Consent: Informed consent was signed by each adult patient or minor patient's parents before being involved in the study after a detailed explanation of the research protocol.

Peer-review: Externally peer-reviewed.

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