

LONG-TERM COMPARISON OF TREATMENT IMPACTS BETWEEN INVISALIGN AND
FIXED APPLIANCE THERAPY

By

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Abstract of Thesis Presented to the Graduate School
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A recent study found subjects treated with Invisalign® appliances reported significantly less pain and negative impact on daily life during the first week of treatment than did subjects treated with fixed orthodontic appliances. The aim of this study was to determine if these differences persist throughout treatment. Eighteen of twenty-five subjects, twelve to fifteen months into treatment at the University of Florida College of Dentistry and at a private orthodontic practice, completed one week surveys to measure the psychosocial and pain related impact of orthodontic treatment with either Invisalign® or fixed appliances. There were no significant differences found between groups with respect to age, race, education, income or severity of initial malocclusion. Also, no significant differences in pain levels or impact on daily life between the two groups were reported. Based on a limited number of subjects the results of this study suggest that the higher pain levels and greater impact on daily life experienced during the first week of treatment by patients treated with fixed appliances compared to those treated with Invisalign® may not persist throughout the duration of treatment.

CHAPTER 1 INTRODUCTION

Much of the orthodontic literature regarding orthodontic treatment with Invisalign® is limited to case reports, and descriptions of technique and mechanics. Few studies have compared treatment with Invisalign® to more traditional fixed appliances. Djeu ¹ reported Invisalign® treatment to be less effective in occlusal and antero-posterior corrections in a retrospective study based on a comparison of finished cases using the American Board of Orthodontics (ABO) scoring methods. It was found that aligners were particularly effective in correcting rotations and marginal ridge discrepancies, however. Plaque scores have been shown to be better in patients treated with Invisalign®. ² This was attributed to improved access for oral hygiene. Due to the weak evidence in the literature and lack of randomized clinical trials, no strong conclusions can be made regarding comparative treatment efficiency. ³

The orthodontic literature addressing the treatment experiences of orthodontic patients is relatively limited. ⁴ Other than length of treatment, pain is the most frequent complaint during orthodontic treatment. ^{5,6} This pain has been described as being more severe than the pain experienced following dental extractions. ⁷ The pain experience following initial appliance placement or activation has been shown to follow a certain pattern, peaking at approximately 24 hours, then returning to baseline levels in five to six days. ^{5,7-12} A diurnal rhythm has also been shown to exist, with pain levels decreasing during the day and then peaking each night, although to a lower level than the previous night. ⁷ Although different force levels are discernable by patients for the first few days, increased force levels ^{10,13} have been shown not to affect pain levels. Increased severity of malocclusion has been shown not to be a significant factor either. ¹⁴ Besides pain and discomfort, orthodontic appliances have additional impacts on the daily lives of patients. Difficulties in eating, swallowing, speech and socializing have been reported with both

fixed and removable appliances.^{9,15-18} Patient anxiety, acceptance of and attitudes towards treatment are the most significant factors contributing to these sequelae.^{18,19}

With the continuing growth in demand for more esthetic appliance systems such as Invisalign®, it is important for orthodontists and patients to have sufficient information regarding the impacts these new appliances will have on patients in order to support informed decisions and realistic expectations of treatment.²⁰ Miller¹¹ reported that patients treated with Invisalign® experience less pain and discomfort and fewer psychosocial and functional impacts than do patients treated with fixed appliances. This study specifically examined the first week of treatment, generally agreed upon in the literature to be the time period in which these impacts are the greatest. Long-term studies however are lacking. Nedwed²¹ reported patients adapt well to Invisalign® over the first three to six months. Functional and psychosocial aspects over this time period diminished significantly although mild pain recurred with each new aligner in approximately half of the patients, and severe discomfort in a few. Long-term adaptation has been reported in fixed appliance treatment as well. Sergl¹⁷ reported good adaptation to both fixed and removable appliances. A greater number of long-term complaints were reported in patients treated with removable appliances. The better adaptation to fixed appliances was not attributed to the appliances themselves but rather to the patients' attitudes towards them.

The aim of this study was to determine whether or not the benefits of Invisalign® treatment over fixed appliance treatment with regards to pain, psychosocial and functional impacts persist throughout the treatment period.

CHAPTER 2 MATERIAL AND METHODS

A prospective, longitudinal cohort study was completed using daily diaries (Figure 2-1) to measure the psychosocial and functional impacts of orthodontic appliances over a seven day period, twelve to fifteen months into treatment with Invisalign® or straightwire fixed appliances. Subjects were recruited from the private practice of an orthodontist in Arizona and from the University of Florida Orthodontic clinics. The Institutional Review Board of the University of Florida approved the study, and participants provided written informed consent.

Subjects for the study were selected by asking all patients meeting the inclusion criteria over a one year period if they would like to participate at the beginning of their regularly scheduled appointments. The inclusion criteria were (1) Upper and lower dental arches must be treated; (2) The fixed appliances group must be treated with wires and brackets only (no quad helix, Rapid Palatal Expander (RPE), etc); (3) Must be 12 to 15 months into treatment; (4) Must be 18 years of age or older; (5) Must be willing to sign and give written informed consent in accordance with institutional and federal guidelines; (6) Must be in good general health; and (7) Premolar and incisor extraction cases were acceptable.

Twenty-five adult subjects agreed to participate in the study and complete the one week daily diary. The diary measured impacts such as teeth soreness, soft tissue irritation, eating problems and speech impairment. Baseline data was taken the day of the appointment just prior to appliance adjustment or new aligner delivery. Informed consent was obtained and demographic and socioeconomic data were collected at the appointment as well. Subjects were asked to begin the diary on the day after their appointment and fill it out each day at the same time and then return it in the envelope provided. Subjects were mailed a movie rental gift card once their diary was received. Nineteen subjects returned completed diaries, seven male and

twelve female. Eight subjects were being treated with Invisalign®, ten were being treated with fixed appliances, and one subject was being treated with Invisalign® in one arch and fixed appliances in the other. This patient was excluded from the analyses.

The diary questionnaire form (Appendix A) was adapted from the well-validated Geriatric Oral Health Assessment Index,²² which was developed to measure the psychosocial impacts of oral conditions. The daily diary questionnaire form consisted of 13 questions with ordinal responses on a Likert scale, and one pain-related question using a visual analog scale (VAS). The responses from the first 13 questions were summed to give a total ‘impact score’ for each subject. The pain responses from the visual analog scale were used to give a more exact measure of pain experienced during these seven days of therapy. The design of this study is similar to one previously reported¹¹ which examined these factors and variables during the first week of treatment. Some but not all of the subjects in the present study were participants in the prior study. Because of the anonymity of the study design, direct long-term comparisons for these subjects were not possible.

The response variable measured was the impact of therapy as assessed with the daily diary. Factors of interest were: treatment type (Invisalign® or Fixed Appliances), time (days one through seven after fixed appliance adjustment or new aligner delivery), and initial malocclusion as assessed with the Peer Assessment Rating (PAR) index²³ by the same calibrated investigator (A.W.C.). Subjects were not randomly assigned to treatment groups and the examiner could not be blinded as to the treatment group because PAR scores were assessed on electronic casts. Casts for patients in the Invisalign® treatment group were ClinCheck files whereas the casts from the fixed appliance group were OrthoCAD files.

CHAPTER 3 STATISTICAL ANALYSIS

The data was input and analyzed to determine relevancy and significance. Data from the subject treated with both fixed appliances and Invisalign® was omitted from the analyses. For the purposes of group characteristic comparisons, non-Caucasian subject data was combined and subjects with at least some college education were analyzed together. Initial power analysis indicated an optimum sample size of one-hundred subjects, fifty per treatment group. Due to the relatively small sample size attained, variables were analyzed and groups compared by Fisher exact and Wilcoxon rank sum tests.

CHAPTER 4
RESULTS

Preliminary analysis (Tables 4-1, 4-2) showed that the Invisalign® and fixed appliance treatment groups were balanced with regard to age (Wilcoxon rank sum $p=0.90$), sex (Fisher exact $p=0.37$), ethnicity (FE $p=0.66$) and level of education (FE $p=0.64$). Subjects treated with Invisalign® did report higher incomes than those treated with fixed appliances, however these differences did not reach statistical significance (WRS $p=0.13$). PAR scoring of pretreatment casts revealed no significant group differences in severity of initial malocclusion (WRS $p=0.20$).

No significant group differences were present in baseline pain as measured on a visual analog scale (VAS) or quality of life as measured by diary questionnaire Geriatric Oral Health Assessment Index impact scores. During the week after new aligner delivery or appliance adjustment, mean pain levels in both groups increased, peaking on day 1 or day 2 (Figure 4-1). Pain levels in both groups returned to baseline levels by day 6 or day 7. No statistically significant differences in pain levels were reported between treatment groups on any particular day during the seven day period. Two subjects (20%) in the fixed appliances group and one subject (13%) in the Invisalign® group reported using an analgesic at some point during this week. Impact scores quantifying the functional and psychosocial impacts of orthodontic appliances in both groups dropped slightly on day 1, the day following the subjects' appointments (Figure 4-2). Impact scores quickly returned to baseline levels by day 3. There were no statistically significant group differences in mean impacts scores found on any day of the survey.

Table 4-1. Group demographics data as reported on the Demographics Questionnaire

Treatment Group	Age		Sex		Race			
	Mean	SE	Male	Female	African American	Caucasian	Hispanic	Asian
Invisalign®	30.225	3.442	2	6	1	5	1	1
Braces	30.920	3.620	5	5	2	5	2	1
P value	$p=0.90$		$p=0.37$		$p=0.66$ (Caucasian vs. non-Caucasian)			

Table 4-2. Group socioeconomic data and mean PAR scores

Treatment Group	Education			Income*		Initial Malocclusion	
	High school	Some College	College Graduate	Mean	SD	PAR score	SD
Invisalign®	0	5	3	3.75	1.753	20.00	7.792
Braces	1	3	6	2.50	1.958	24.90	9.550
P value	p=0.64 (H.S. vs. College)			p=0.13		p=0.20	

*Income groups: 2=\$10,000-24,999; 3=\$25,000-49,999; 4=\$50,000-74,999

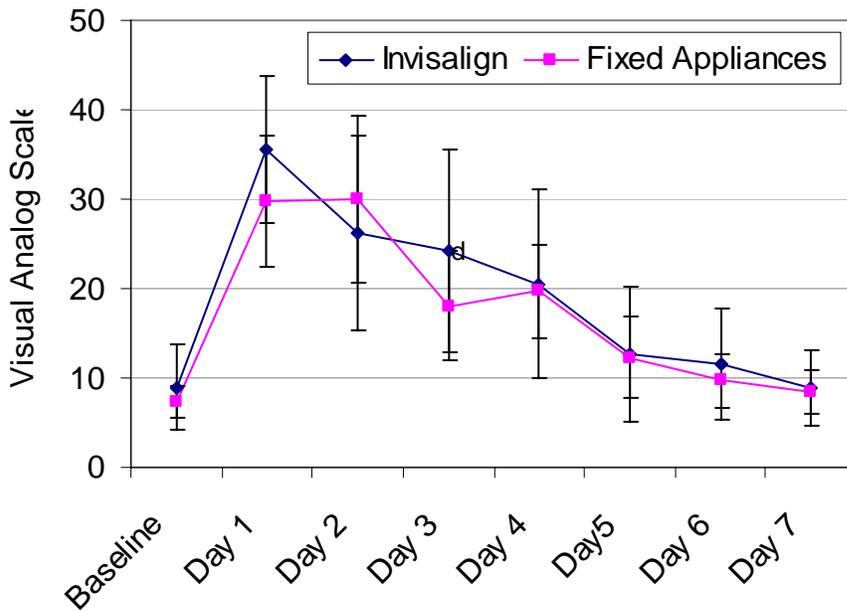


Figure 4-1. Mean pain levels. Mean (\pm standard error) pain intensity scores for week following appliance adjustment / new aligner delivery appointment, twelve to fifteen months into treatment. Data was taken from question 2 on subject daily diary questionnaires (Appendix A).

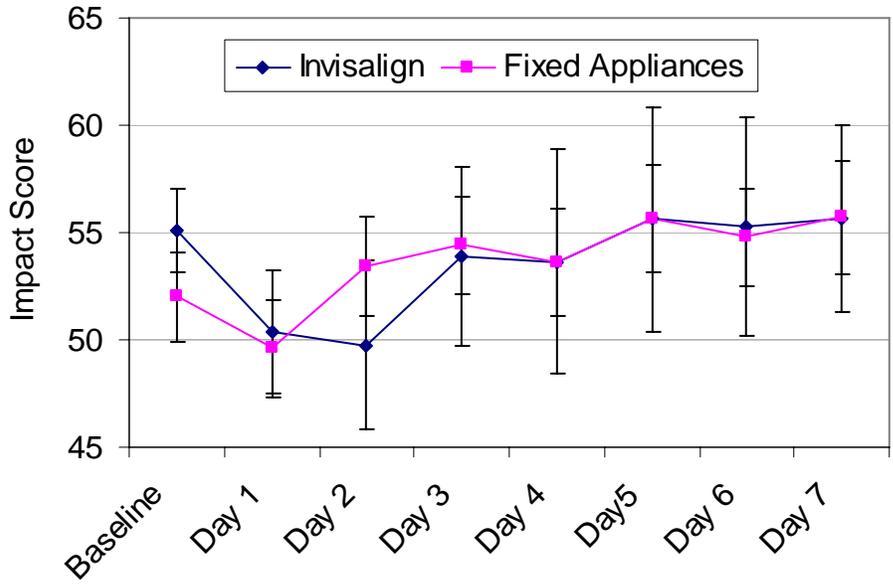


Figure 4-2. Quality of life. Group means (\pm standard error) measured by impact scores for the week following appliance adjustment / new aligner delivery appointment. Scores indicate the group means from the summed component totals of question 1 on the daily diary questionnaires (Appendix A).

CHAPTER 5 DISCUSSION

People seeking orthodontic treatment need to know and often inquire about what to expect during treatment. Orthodontists need information at their disposal in order to help patients make informed decisions when deciding to undergo treatment and when choosing between various treatment options. Few studies have examined the functional and psychosocial impacts new orthodontic appliances such as Invisalign® have on patients. In a similar study¹¹ conducted during the first week of treatment, subjects in the Invisalign® group reported a significantly lower negative impact on daily life from day one through day seven with all p-values ≤ 0.0001 . Nedwed²¹ reported patients adapt well to Invisalign® over the duration of treatment. Although Invisalign® appliances were not studied, Sergl¹⁷ reported good adaptation to both fixed and removable appliances.

This study investigated whether or not the differences in negative impacts on patients' daily lives found in a prior study persist in the long-term, throughout the duration of treatment. In order to attain the desired sample size of one-hundred subjects, the study design included the recruitment of twenty subjects, ten in each treatment group, from each of five locations around the United States. Due to lack of interest by patients in three of the four private orthodontic practices, subjects were enrolled in this study from only the two locations. Only six patients agreed to participate in the study from the remaining private practice. As a result of missed appointments and discontinuation for or modification with fixed appliances of the limited number of Invisalign® cases at the university extending at least twelve months, only thirty of these patients were asked to participate in the study. Despite little interest by patients in the study, nineteen patients from the University agreed to participate. Twelve of these nineteen subjects, and five of the six subjects from the private practice returned completed surveys.

When comparing impact scores after one year of treatment, impact scores in both treatment groups dropped slightly the day after their braces were adjusted or new aligners were delivered. Impact scores returned to baseline levels in a few days just as were the patterns during the first week of treatment as previously reported.¹¹ However, in this study the Invisalign® group did not report significantly less negative impact than did the fixed appliance group, indicating that long-term adaptation to appliances has eliminated any significant differences in quality of life between the two treatment modalities.

The most frequently reported complaint and apprehension of orthodontic treatment reported in the literature is pain and discomfort.^{5,6} Subjects in both treatment groups in this study experienced the typical pattern of pain and discomfort over the seven day study period as has been reported elsewhere pattern.^{5,7-12} However, the subjects being treated with fixed appliances did not experience significantly greater pain than did those treated with Invisalign® as was found during the initial week of treatment previously reported.¹¹ The results of this study suggest that, as was found with other types of removable appliances,¹⁷ patients adapt to fixed appliances to the extent that the benefits of Invisalign® over fixed appliances with regards to pain and discomfort do not persist throughout the duration of treatment.

CHAPTER 6 CONCLUSION

Based on a limited number of subjects (N=18), the results of this study suggest that while patients treated with Invisalign® experience lower pain levels, psychosocial and functional impacts initially, these benefits may be limited to the beginning of treatment and do not persist throughout the duration of treatment. Further studies are necessary to confirm these results. Orthodontists can utilize the results of this and prior studies to inform patients contemplating a decision between Invisalign® and braces. Patients can be told that while their apprehensions towards braces of higher pain levels, greater psychosocial and functional impacts are well founded, the long-term benefits of Invisalign® in these respects are not long-term as they will in all likelihood adapt well to the appliances. Patients can also expect mild transient increases in pain and other negative impacts with both appliances following each adjustment or new aligner.

APPENDIX A
DAILY DIARY QUESTIONNAIRE

SUBJECT ID # _____

DATE ___ - ___ - ___

Day: _____

Instructions: Please complete the following survey about how your teeth or orthodontic appliances (braces or aligners) have affected your life since your last visit. Answer only what you feel and have experienced, not what you think is the right answer. There are no right or wrong answers to these questions.

1. Please circle one response for each of the following questions.

In the past 24 hours, how often:	Always	Often	Some- times	Seldom	Never
a. did you limit the kinds or amounts of food you eat because of problems with your mouth, teeth, or orthodontic appliances?	1	2	3	4	5
b. did you have trouble biting or chewing any kinds of food, such as firm meat or apples?	1	2	3	4	5
c. were you able to swallow comfortably?	1	2	3	4	5
d. did your teeth or orthodontic appliances prevent you from speaking the way you wanted?	1	2	3	4	5
e. were you able to eat without feeling discomfort?	1	2	3	4	5
f. did you limit contact with people because of the condition of your teeth or orthodontic appliances?	1	2	3	4	5
g. were you pleased or happy with the looks of your teeth or orthodontic appliances?	1	2	3	4	5
h. did you use medication to relieve pain or discomfort from around your mouth?	1	2	3	4	5
i. were you worried or concerned about the problems with your teeth or orthodontic appliances?	1	2	3	4	5
j. did you feel nervous or self-conscious because of problems with your teeth or orthodontic appliances?	1	2	3	4	5
k. did you feel uncomfortable eating in front of people because of problems with your teeth or orthodontic appliances?	1	2	3	4	5
l. were your teeth sensitive to hot, cold or sweets?	1	2	3	4	5
m. did your orthodontic appliances cause discomfort to your cheeks, lips, or tongue	1	2	3	4	5

Daily Diary Questionnaire. Answers from question 1 are summed to give the impact score.

2. Please mark an "X" on the line below to indicate how severe your discomfort has been within the last 24 hours:

No pain Severe Pain

3. Please indicate what time of the day you are filling out this survey: _____:_____AM/PM
hh mm

4. A) Have you taken any medications today? Y / N (please circle)

B) If so, please write in which medications you took today:

5. Are you having any other problems or concerns about your teeth or orthodontic appliances since your last orthodontic visit? If so, please describe.

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BIOGRAPHICAL SKETCH

Aaron William Carroll was born on November 10, 1974 in Tallahassee, Florida. With a younger sister, he grew up in a rural area outside of Tallahassee, Florida, graduating from James S. Rickards High School in 1992. He earned his B.S. from the Florida State University (FSU) in 1997. During college and after graduation, Aaron was employed as an Information Technology Specialist by the Florida Supreme Court until 2000. Aaron entered dental school at the University of Florida College of Dentistry in 2000 and graduated *magna cum laude* in 2004, after which he began his residency in orthodontics at the University of Florida.

Upon completion of his residency and master's program, Aaron will enter private practice in Sarasota, Florida. Aaron was recently married to Tiffany, and they are expecting their first child in September.