ORIGINAL ARTICLE

A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment

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Introduction: The aim of this study was to evaluate the differences in quality of life impacts between subjects treated with Invisalign aligners (Align Technology, Santa Clara, Calif) and those with fixed appliances during the first week of orthodontic treatment. **Methods:** A prospective, longitudinal cohort study involving 60 adult orthodontic patients (33 with Invisalign aligners, 27 with fixed appliances) was completed by using a daily diary to measure treatment impacts including functional, psychosocial, and pain-related outcomes. A baseline survey was completed before the start of treatment; diary entries were made for 7 consecutive days to measure various impacts of the subjects' orthodontic treatment over time. The data were then analyzed for differences between treatment modalities in terms of the subjects' reported impacts from their orthodontic treatment. **Results:** The baseline mean values did not differ between groups for pain reports ($P = .22$) or overall quality of life impact ($P = .51$). During the first week of treatment, the subjects in the Invisalign group reported fewer negative impacts on overall quality of life ($P < .0001$). The Invisalign group also recorded less impact in each quality of life subscale evaluated (functional, psychosocial, and pain-related, all $P < .003$). The visual analog scale pain reports showed that subjects in the Invisalign group experienced less pain during the first week of treatment ($P < .0001$). The subjects in the fixed appliance group took more pain medications than those in the Invisalign group at days 2 and 3 (both $P < .007$). **Conclusions:** Adults treated with Invisalign aligners experienced less pain and fewer negative impacts on their lives during the first week of orthodontic treatment than did those treated with fixed appliances. (Am J Orthod Dentofacial Orthop 2007;131:302.e1-302.e9)

The body of literature addressing orthodontic patients' experiences during treatment is relatively small. Most studies in this area focused on the pain experiences of orthodontic patients throughout treatment. Pain resulting from orthodontic treatment was shown to be significant. Jones and Chan[1] found that the pain experienced after initial archwire placement is much greater than pain after extractions. The pain progression after initial archwire placement is well established in the literature. The pain increases 4 hours after placement of the initial archwire, peaks at 24 hours, and decreases to almost baseline levels at 7 days.[1-4] Stewart et al[5] found that the first 4 to 7 days after initial wire placement are the most critical for the patient in terms of general discomfort. Sergl et al[6] found that patients adapt to new appliances within 7 days after appliance placement. From these studies, it can be concluded that the first 7 days after archwire placement are the crucial times for the patient's adaptation to appliances and when most orthodontic pain is experienced.

Past studies examined the differences in the pain response between different modalities of treatment. Stewart et al[5] observed that subjects with fixed appliances had more problems with comfort, tension, pressure, tightness, pain, and sensitivity than did subjects with removable appliances. They found that functional appliances disturbed speech and swallowing more than fixed appliances. Sergl and Zentner[7] and Sergl et al[8] corroborated these results and found that subjects treated with fixed appliances reported more pain and discomfort than did subjects wearing removable plates,

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whereas subjects treated with functional or removable appliances reported more problems with speech, swallowing, and oral constraint than subjects treated with fixed appliances. These studies suggest that fixed appliances have more impact on patients' pain responses during the initial stages of treatment than do removable appliances, whereas removable appliances have more effect on functional response variables such as speech and swallowing.

Over the past decade, Invisalign aligners (Align Technology, Santa Clara, Calif) have emerged as a popular new treatment modality. The technology and fabrication process have been described elsewhere.[9] No studies have evaluated the effect of treatment with Invisalign aligners on patients. Patients who elect to be treated with Invisalign aligners seek appliances that are less obtrusive in their everyday lives. These patients often incur greater treatment expenses in hopes that the appliances will have fewer negative impacts on their quality of life. For the patient and the clinician to make more informed decisions regarding treatment modality, studies are needed to evaluate the differences between Invisalign aligners and fixed appliance therapy in their impacts on patients' quality of life.

To that end, the objective of this study was to evaluate the relationship between modality of treatment—Invisalign aligners or fixed appliances—and quality of life experienced during the first 7 days of orthodontic treatment.

MATERIAL AND METHODS

A prospective, longitudinal cohort study involving 60 adult orthodontic patients was completed by using daily diaries to measure treatment impacts. Subjects accepted into the study were required to be at least 18 years of age and in good general health, and to have received treatment in both dental arches. The fixed appliance group was treated with wires and brackets only. Patients with premolar and incisor extractions were acceptable. The Institutional Review Board of the University of Florida approved the study, and participants completed written informed consent forms.

The study sample largely represented adult patients seen in private orthodontic offices and consisted of 33 subjects with Invisalign aligners and 27 subjects treated with preadjusted, fixed appliances. Sixty-four percent of the subjects were drawn from private practices in Florida, Arizona, Kentucky, and Texas. The remaining subjects were drawn from the University of Florida Orthodontic Clinics. A daily diary form (Fig 1) was used to measure the effect of appliance type on the subjects' quality of life. The diary had 3 sections: 13 items measuring functional, psychosocial, and pain-related treatment impacts with a 5-point Likert scale, 1 pain item with a visual analog scale (VAS), and 1 item asking what (if any) pain medications were taken. Socio-demographic information was also collected.

The first diary section was adapted from the well-validated Geriatric Oral Health Assessment Index that was originally designed to measure patient-reported oral function problems involving physical function, psychosocial function, pain, and discomfort.[10] The questions were modified to address impacts relevant to orthodontic treatment. The responses to the first 13 questions were combined to give an overall impact score for each subject at each time point. The impact score is a reflection of the subject's overall reported quality of life. A high score signifies fewer reported impacts; a low score means negative impacts. The questions (Fig 1) were grouped to form 3 subscales: functional impacts (questions a, b, c, d), pain-related impacts (questions e, h, l, m), and psychosocial impacts (questions f, g, i, j, k). The VAS was used as a measure of pain experience, with a higher score corresponding to more pain. The VAS was shown to be a valid instrument for measuring orthodontic pain.[3] Pain medication use was also recorded.

Subjects completed a baseline pretreatment diary form immediately before the initial fixed appliances were placed or the aligners were delivered. Pretreatment study models and demographic data were collected at this appointment. Each subject was then sent home with a study packet that included instructions to complete identical diary forms for 7 consecutive days. After the 7-day period, the study packet was mailed back to the study investigators in a prepaid, preaddressed envelope.

Statistical analysis

Subject characteristics were compared for the 2 treatment groups by using chi-square or Fisher exact tests for categorical variables and Wilcoxon rank sum tests or 2-sample *t* tests for ordinal or continuous variables. Repeated-measure linear mixed models were used to evaluate differences in treatment outcomes due to treatment group, day in treatment, baseline outcome measure, and treatment group by day interaction.[11] The outcome variables of interest were overall impact scores and subscales, and pain scores. After fitting the a priori model specified above, the following variables were added, 1 at a time, to assess their effect on the models: sex, age, previous treatment, income, education, use of pain medication, and reason for treatment (improved appearance vs other reasons). Additional models were considered, based

Instructions: Please complete the following survey about how your teeth or orthodontic appliances (braces or aligners) have affected your life since you started treatment. 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 anything 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

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.

_____

_____

Fig 1. Daily diary survey.

on the impact of added variables. Significance level was set at $P < .05$.

Pretreatment study models were scored by the same investigator (K.B.M.) using the PAR index.[12,13] Pretreatment models were collected to compare the initial severity of the malocclusions between the subjects in the Invisalign aligners and the fixed appliance groups. One investigator (K.B.M.) was calibrated to a gold standard for the PAR index using stone models and digital Orthocad (Cadent, Calif) and Invisalign aligners Clincheck models.

RESULTS

Sample characteristics

The 2 treatment groups were comparable with regard to sex, education level, health status, and prior orthodontic treatment (Table I). Although not reaching statistical significance, more Invisalign aligners subjects were white (73%) than in the fixed appliance group (48% white). More Invisalign aligners subjects reported seeking treatment "to improve my appearance," (85% vs 67% for fixed appliances), whereas more fixed appliance subjects reported seeking treatment "because my dentist referred me" (26% vs 3% for Invisalign aligners subjects). The Invisalign aligners subjects were significantly older and had higher incomes than the fixed appliance subjects. The Invisalign aligners and the fixed appliance groups had similar severities of malocclusions as rated by the PAR Index.

Table I. Subject characteristics by treatment group

	Invisalign aligners n (%)	*Fixed appliances n (%)*	P *value*
Sex			.34
Male	11 (33%)	6 (22%)	
Female	22 (67%)	21 (78%)	
Race			White vs nonwhite
White	24 (73%)	13 (48%)	.05
Black	1 (3%)	5 (18%)	
Asian	2 (6%)	1 (4%)	
Hispanic	5 (15%)	7 (26%)	
Other	1 (3%)	1 (4%)	
Education			.16
<High school graduate	0 (0%)	1 (4%)	
High school graduate	2 (6%)	2 (7%)	
Some college	8 (24%)	10 (37%)	
College graduate	23 (70%)	14 (52%)	
Income			.015
< $10,000	2 (6%)	5 (19%)	
$10,000-25,000	3 (9%)	4 (15%)	
$25,000-50,000	5 (15%)	6 (22%)	
$50,000-75,000	7 (21%)	6 (22%)	
$75,000-100,000	3 (9%)	3 (11%)	
>$100,000	13 (40%)	3 (11%)	
Health status			.32
Excellent	21 (64%)	13 (48%)	
Very good	11 (33%)	11 (41%)	
Good	1 (3%)	3 (11%)	
Fair	0 (0%)	0 (0%)	
Poor	0 (0%)	0 (0%)	
Reason for treatment			.040
Improve appearance	28 (85%)	18 (67%)	
Difficulty eating	0 (0%)	0 (0%)	
Dental or facial pain	3 (9%)	2 (7%)	
Dentist referral	1 (3%)	7 (26%)	
Other	1 (3%)	0 (0%)	
Previous treatment			.24
Yes	16 (48%)	9 (33%)	
No	17 (52%)	18 (67%)	
Age			
Mean (SD)	38.0 (12.4)	28.6 (8.7)	.002
PAR index (combination)			
Mean (SD)	20.0 (9.6)	20.5 (7.7)	.86

Overall impact scores

Figure 2, *A*, illustrates the overall impact scores for the 2 treatment groups during the first week of treatment. The groups did not differ at baseline ($P = .51$). During the first week of treatment, significant differences were found between treatment groups and between treatment days (both, $P < .0001$). The treatment group by day interaction components were not significant ($P = .62$), indicating that the pattern of response was similar for the 2 treatment groups. This can be seen in Figure 2, *A*; the 2 treatment group responses were parallel for days 1 through 7. The baseline (pretreatment) impact score was not a significant factor ($P = .12$) in modeling overall treatment impact during the first week. For the Invisalign aligners group, the mean impact score returned to baseline level by day 4; for the fixed appliance group, it remained below baseline level for the entire week.

Subcomponent impact scores

The pattern of response for the functional and pain subscales mimicked the overall impact score response, with the Invisalign aligners group's mean functional and pain scores returning to baseline levels at day 7, and the fixed appliance group's scores remaining below baseline for the week. For both subscales, significant differences were found between treatment groups and between days (all, $P < .0001$), and no interaction between treatment group and day was found (functional, $P = .68$; pain, $P = .55$). The baseline functional score was a significant factor ($P = .047$) in the model for functional impact, whereas baseline pain score was not ($P = .40$) in the model for pain.

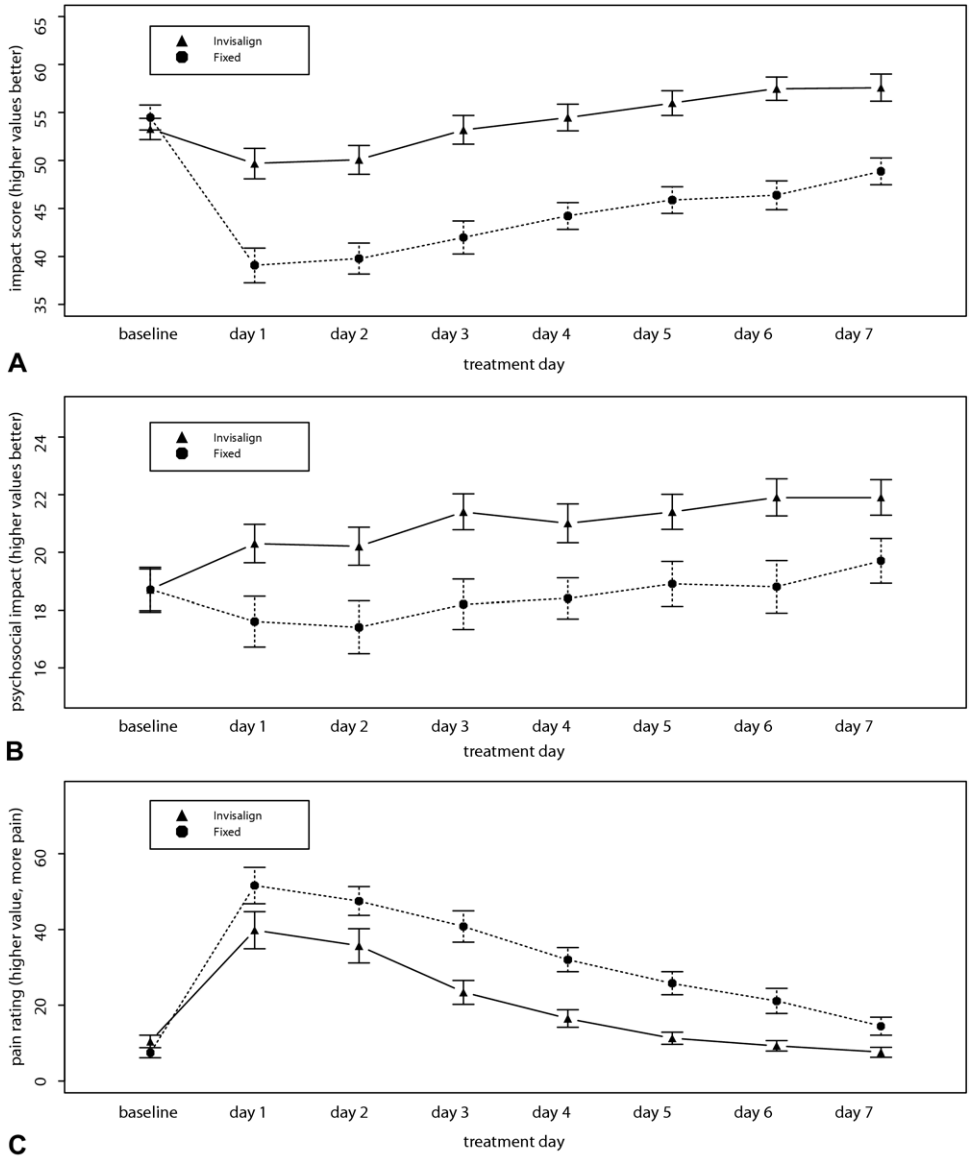

Fig 2. A, Mean (± SE) overall impact scores over treatment days for Invisalign and fixed appliance groups. Higher scores on y-axis indicate more positive quality of life. **B,** Mean (± SE) psychological subcomponent impact scores over treatment days for Invisalign and fixed appliance groups. Higher ratings on y-axis indicate more positive psychological component. **C,** Mean (± SE) pain ratings as recorded on VAS over treatment days for Invisalign and fixed appliance groups. Higher ratings on y-axis indicate more pain.

The pattern for the psychosocial subscale is shown in Figure 2, *B*. The results are similar to the previously discussed scales, with significant treatment group and day differences ($P = .0021$ and .0026, respectively). The baseline psychosocial value and treatment day by treatment group interactions did not contribute significantly to the model ($P = .19$ and .62, respectively). The mean values for the Invisalign aligners group were above the baseline value for the entire week. The fixed appliance group means were below the baseline level at days 1 and 2 but at baseline or higher for days 3 through 7.

VAS pain reports

Figure 2, *C*, illustrates the pain reports of the 2 groups during the first week of treatment as recorded on

Table II. Subjects reporting taking pain medications on specified treatment days

Treatment day	*Invisalign aligners (n = 33)*	*Fixed appliance (n = 27)*	P *value**
Baseline	9%	4%	.62
Day 1	42%	67%	.06
Day 2	27%	67%	.0023
Day 3	21%	56%	.0060
Day 4	15%	26%	.30
Day 5	15%	26%	.30
Day 6	9%	19%	.45
Day 7	3%	11%	.32

*Chi-square or Fisher exact test.

a VAS. The same pattern for the overall impact score was again observed (but reversed because a high score represents more pain). At baseline, there was no difference in pain reports between the groups ($P = .22$). From days 1 through 7, the fixed appliance subjects reported more pain than the Invisalign aligners subjects. The overall pain progression is an initial increase in pain at day 1 followed by a gradual return to near baseline levels over days 2 through 7. The Invisalign aligners group's mean pain level returned to baseline at day 5 and decreased slightly below baseline levels at days 6 and 7. The fixed appliance group's mean pain reports did not return to baseline levels by day 7, indicating an overall negative pain experience during the first week of treatment. Modeling results indicate significant treatment group and treatment day effects (both, $P < .0001$); baseline pain level and treatment day by treatment group interaction were not significant ($P = .10$ and .26, respectively).

Pain medication

Table II shows pain medication intake during the study period. Subjects reported using only over-the-counter pain medications, such as Advil, Tylenol, ibuprofen, Motrin, and Aleve. At baseline, there was no difference between the groups in pain medications reports. At day 1, the difference between groups approached significance ($P = .06$), with the fixed appliance group taking more pain medication. On days 2 and 3, the fixed appliance group took more pain medication ($P < .007$). From days 4 through 7, there was no significant difference between the groups.

Influence of covariates

As an exploratory analysis, we considered the impact of the following factors on overall impact score and VAS pain scale: sex, age, previous orthodontic treatment, income, education level, use of pain medication, and reason for treatment. Both the impact of each factor and the possible interactions with treatment group and day were considered. Sex might play a role in the overall impact score ($P = .0073$); model estimates indicate that women have lower scores (more negative impact) than men. This is illustrated in Figure 3. Sex was not statistically significant in the VAS pain scale model ($P = .14$). Age was a significant factor when added to both models (overall impact, $P = .0411$; VAS pain, $P = .0479$), with more negative impact and pain associated with younger ages. Previous orthodontic treatment was not a significant factor in either model. The roles of income and education in treatment response were inconsistent and difficult to interpret, perhaps due to the imbalances in these factors between the 2 treatment groups. Pain medication use was a significant factor in the overall impact score ($P = .0002$) and might play a role in VAS pain ($P = .09$). In both cases, the use of pain medication was associated with more negative impact and more pain. The reason for seeking treatment was not a significant factor when added to the overall impact score or the VAS pain models.

DISCUSSION

A daily diary was used to record the impact of the appliance on each subject as it was being experienced. Diary assessment is seen as a more valid and reliable measure than retrospective response data that rely on patient recall.[14] Because Invisalign aligners are a new appliance type, no studies have evaluated their impact on patients. Previous studies looked at the impact of fixed appliances compared with removable plates. Sergl et al[6] and Stewart et al[5] found that fixed appliances caused more discomfort for patients than removable appliances. Sergl and Zentner[7] also found that appliances that take up minimal space in the mouth are the most readily accepted by patients. Our study results are consistent with the findings of these studies. Because an Invisalign aligner is removable most likely adds substantially to the patient's quality of the life. The patient can remove the appliance for eating and hygiene. The small size of the Invisalign aligner and its lack of sharp edges also add substantially to the patient's quality of life compared with fixed appliances.

In this study, we also found a significant time effect on the outcome measures. Subjects in both groups reported peaks in impact/pain at day 1 followed by decreases to near baseline levels at day 7 (Fig 2). This pain progression after the start of treatment is well validated in the literature for fixed appliances.[1,2,4,15] The impact/pain progression of Invisalign aligners treatment is similar to that already demonstrated for

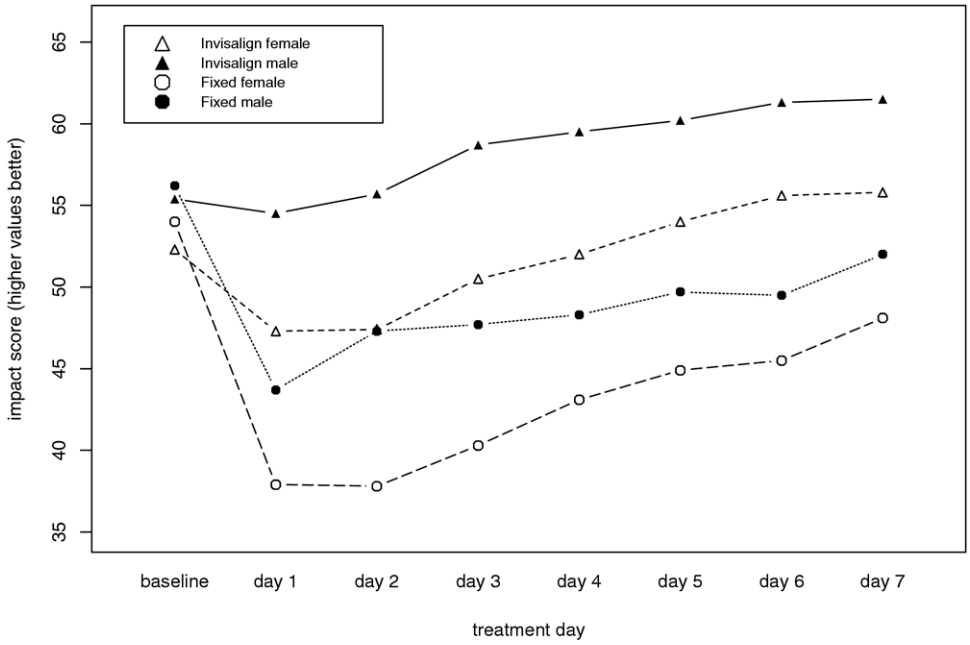

Fig 3. Mean (± SE) overall impact scores over treatment days for Invisalign and fixed appliance groups for men and women. Higher scores on y-axis indicate more positive quality of life.

fixed appliances. The key difference is that the initial impact/pain for those in fixed appliances is more extreme, with recovery parallel for later time points. In support of these findings, both groups' pain medication intakes peaked at day 1 and decreased to near baseline levels by day 7. As would be expected, pain medication intake correlated with pain levels throughout the week. These findings agree with those of Erdinc and Dincer,[16] who also found a correlation between pain intensity scores and consumption of pain medication during orthodontic treatment.

Quality of life functional, psychosocial, and pain-related impact subscales were also compared. For each subscale, from days 1 through 7, the fixed appliance group reported more negative impacts than did the Invisalign aligners group. These findings agree with prior studies. Scheurer et al[4] found that, for fixed appliance patients, eating is the greatest challenge to quality of daily life. Oliver and Knapman[17] found that patients reported pain caused by, and the appearance of, fixed appliances to be the major discouraging factors during treatment. The esthetics, removability, and small size of the Invisalign aligners probably accounted for the functional and psychosocial differences between the appliances. The pain-related subscale impact scores agreed with the pain scores recorded on the VAS.

Statistical modeling indicated that a subject's baseline report in the functional subscale is related to future functional reports. In this study, there was no statistical difference between the groups' baseline functional impact reports; therefore, any baseline effect should be equally distributed between the groups.

Our treatment groups were not balanced for all demographic components. The subjects in the Invisalign aligners group were older and had higher incomes than those in the fixed appliance group (Table I). In addition, the statistical models indicated that female subjects and younger subjects tend to report poorer quality of life during treatment. The age effect should be interpreted with caution, because there were age differences between the 2 treatment groups. For the Invisalign and fixed appliance groups, the median ages (interquartile range) were 40 (26-50) and 26 (21-34) years, respectively. Separate models were fit; for the Invisalign subjects, age was not a significant covariate for overall impact score ($P = .27$) or VAS pain scale ($P = .15$). Age was also not statistically significant in the fixed appliance group when modeling VAS pain ($P = .33$). For the overall impact score in this group, a significant age by day interaction was found ($P = .0012$), and, along with age ($P = .09$), this suggests that younger fixed appliance subjects are more negatively impacted, particularly on the first 3 treatment days. Brown and Moerenhout[18] found that adolescents, preadolescents, and adults varied in their pain reports during orthodontic treatment, with adolescents report-

ing the most pain. Because our subjects were 18 years of age and older, impacts in adult groups should be studied further. A larger study designed to examine sex, age, income, and other covariate effects is needed to better evaluate these factors. Although a randomized study would be ideal, it might be unrealistic to expect subjects to agree to be randomized to either treatment.

The difficulty in balancing for income is exacerbated because Invisalign treatment is often more expensive for patients because of the substantial laboratory fee incurred by the doctor. This higher treatment fee might explain why the Invisalign aligners subjects had higher incomes and were older than those in the fixed appliance group. In addition, 78% of the Invisalign aligners subjects were drawn from a private practices, whereas only 44% of the fixed appliance subjects came from private practices. The rest of the subjects were drawn from a university clinic. The larger proportion of private-practice subjects in the Invisalign aligners group could account for the income differential between the groups.

The groups also differed in their stated reasons for seeking treatment. More Invisalign aligners subjects reported seeking treatment to "improve my appearance," whereas more of the fixed appliance subjects reported seeking treatment "because my dentist referred me." Different motivations for treatment between the groups could influence perceived pain during treatment, although this was not detected in our study. The mean psychosocial subscale scores where higher than the baseline level for all treatment days for the Invisalign aligners subjects, and even the fixed appliance group had a higher mean at day 7, relative to baseline. Sergl et al[6] found that patients with higher internal loci of control and concern about their malocclusions perceived lower levels of pain during orthodontic treatment.

CONCLUSIONS

The results of this study demonstrate significant differences between Invisalign aligner and fixed appliance therapies in how they impact subjects during the first week of treatment. The Invisalign aligners subjects' overall quality of life was better than that of the fixed appliance subjects during this time period. Many factors influence the selection of an appropriate orthodontic appliance for each patient. The results of this study give the practitioner and the patient additional information that can be used when choosing appliance type. This information could also be helpful in educating patients about what to expect during the first week of treatment.

The following conclusions can be made:

1. Both the Invisalign aligners and the fixed appliance groups reported decreases in quality of life after the start of treatment. This decrease peaked at day 1 and returned to near baseline levels by day 7.
2. The fixed appliance group reported a more intense decrease in overall quality of life and a more intense increase in pain beginning at day 1 and extending through day 7.
3. The fixed appliance group reported more intense decreases in functional, psychosocial, and pain-related aspects of their daily lives.
4. The fixed appliance subjects took more pain medication during days 2 and 3 of treatment.

Further study is warranted to better understand the roles of age, sex, reason for seeking treatment, and other covariates on the perceptions of pain and quality of life during orthodontic treatment.

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