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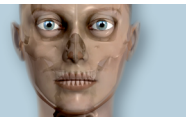

ORIGINAL ARTICLE

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A prospective longitudinal controlled assessment of pain experience and oral health-related quality of life in adolescents undergoing fixed appliance treatment

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Structured Abstract

Objective – To compare subjective pain experience and oral health-related quality of life (OH-QoL) in treated and untreated subjects over the first 3 months of fixed appliance therapy.

Setting and Sample Population – The Department of Orthodontics, School of Medicine and Dentistry. One hundred and twenty-four subjects aged between 11 and 14 years either commencing or awaiting fixed appliance treatment.

Material & Methods – A prospective controlled longitudinal study design was applied to subjects, over a 3-month observation period, following the placement of fixed appliances. Socio-economic status, OH-QoL, pain experience and analgesic consumption were recorded on questionnaires at baseline (T0), 6 weeks (T1) and 3 months (T2).

Results – Oral symptoms and functional limitation domains of OH-QoL were found to worsen, during the follow-up period, in the test group ($p = 0.001$ and $p = 0.002$, respectively). In the treated group, pain intensity declined significantly on days 3 and 2 at T1 and T2, respectively ($p < 0.001$). Analgesia was required during both periods in a total of 13 participants (24.5%) undergoing orthodontic treatment.

Conclusion – Based on this prospective controlled study, the initial stages of fixed appliance treatment results in subjective pain experience, with subsequent reduction, and a significant impact on oral symptoms and functional limitation domains of OH-QoL.

Key words: orthodontic; pain; quality of life

Introduction

The benefit of orthodontics in terms of occlusal and aesthetic improvement and lasting enhancement of oral health-related quality of life (OH-QoL) is established (1). However, as with any intervention, certain drawbacks are associated with treatment. In particular, pain during orthodontics is severe, possibly leading to sleepless nights (2), and commonplace, with over 90% reporting pain during the first 24 h after appliance placement (3). Analgesic consumption to address orthodontic pain is common, with up to 60% of adolescents relying on analgesia over the first days of treatment; however, pain is believed to subside over 7 days after appliance placement (4). Pain experience is believed to have a knock-on effect on compliance with the potential for ensuing compromise on the outcome of treatment (5), with reported pain during the initial 6 months of therapy being key to success. Furthermore, discontinuation of treatment related to pain experience has been estimated at 8% (6).

It is accepted that fixed appliances may be associated with restriction of daily activities; however, it is uncertain to what level this limitation is related to pain experience or other generic factors. The impact of fixed orthodontic treatment on OH-QoL has received limited attention (7–11). These studies have shown that patients may experience negative physical, psychological and social impacts during the course of orthodontic treatment. Zhang et al. (9) reported a negative impact on OH-QoL during the first 6 months of fixed appliance treatment using the Child Perception Questionnaire (CPQ11-14), with the greatest impact arising in the first month of treatment. Similar findings, applying CPQ11-14, were also found in another group of adolescents undergoing fixed orthodontic treatment (12).

Longitudinal assessment of pain experience during orthodontic treatment has rarely been undertaken, with most studies focusing on the first week after placement of appliances. Consequently, although most studies suggest pain intensity is highest during the first week after placement of the appliances before declining, the time required for adaptation to pain is unclear (13). Brown and Moerenhout (2) reported that patients needed up to 14 days to adapt to discomfort and pain experiences, while Sergl et al. (5) alluded to discomfort throughout treatment, although the intensity of pain after 3 months was believed to be lower than during the first week of treatment. Previous research has also lacked untreated control groups; it is therefore difficult to unravel the relative influence of orthodontic treatment from external influences arising over a period of treatment. Use of age-matched patients on treatment waiting lists is considered to be an appropriate way of enrolling subjects with similar severity of malocclusion and socio-economic status without unduly depriving subjects of the benefits of treatment (14). Similarly, longitudinal comparison of the impact of fixed appliance treatment on oral health-related quality of life with untreated controls has not been reported. Moreover, the relative influence of pain experience during treatment and OH-QoL during orthodontics has not been elucidated. Thus, the aims of this prospective controlled longitudinal study were to assess subjective pain experience and OH-QoL in subjects over a 3-month period, following placement of their fixed appliances.

Materials and methods

A prospective controlled longitudinal study design was used to compare adolescent children undergoing orthodontic treatment (test group) with subjects awaiting treatment (control group). The research was undertaken in a hospital setting over a 6-month period (December 2009 to May 2010), with full ethical approval granted and informed consent obtained from both participants and their parent/guardian(s).

Subjects were selected on the basis of being aged between 11 and 14 years and requiring fixed orthodontic treatment only, in one or both jaws. All subjects were treated using the same pre-adjusted edgewise appliance system. Subjects in both groups had similar severity of

malocclusion (grades 4 and 5), determined from the dental health component of the Index of Treatment Need (15) and verified by a calibrated operator.

To detect a 14-mm difference in reported pain levels in the test group applying a standard deviation of 28.3 mm (16), at an alpha value of 5 and 80% power, required 51 subjects in each group (test and control). To allow for loss to follow-up, recruitment was inflated to 62 subjects in each group. Therefore, the total required sample for the proposed study was estimated to be 124 subjects.

Socio-economic status was determined by assessing the following indicators: which adult the patient was living with, parental employment, household crowding, car ownership, house ownership and access to Internet (17). Ethnicity was categorized into five groups: White, Asian, Black, Mixed and Others. Subjects in both test and control groups were asked to complete the Child Perception Questionnaire (CPQ11-14) (18) at the outset. Each item of the CPQ11-14 was scored on a 5-point Likert scale to rate the impact of oral health status on the particular aspect of QoL, with responses ranging from 'never' (score = 0) to 'every day or almost every day' (score = 4). Possible score ranges for oral symptoms, functional limitations, emotional well-being and social well-being may total up to 24, 36, 36 and 52, respectively.

Following their first appointment, each subject was given a pain diary to record perceived pain intensity related to their dentition and provoked by chewing and biting over 7 days and at one time point at the end of every subsequent week until their next scheduled follow-up visit. A 100-mm unmarked visual analogue scale (VAS) was used to record pain scores, anchored at both extremities by the descriptive terminology 'my teeth don't hurt me at all' on the left and 'my teeth hurt me very badly' on the right. Subjects were asked to place a mark on the line that best corresponded to the level of pain experienced and, in addition, were asked to record the use of analgesics. For the control group, the word 'braces' was removed from the questions in the pain diary. From the start of the study (T0), follow-up was undertaken at two further time intervals, after 4–6 weeks (T1) and at 3 months (T2), with subjects in both groups being asked to complete a CPQ11-14 and pain VAS.

Statistical methods

The test–retest reliability of responses to the CPQ11-14 and pain questionnaires was assessed using intra-class correlation coefficients (ICC). Internal consistency for CPQ11-14 was 0.84 and intra-class reliability coefficient was 0.96. Similarly, intra-class reliability coefficient for VAS scores was excellent (1.00). Paired *t*-tests also showed no evidence of systematic error. Assessment for baseline similarity was undertaken using descriptive statistics using frequency distribution, although inferential testing of baseline equivalence was also undertaken with chi-squared tests and independent *t*-tests as indicated.

Changes in pain experience and OH-QoL were assessed throughout the study period from T0 to T1, T0 to T2 and T1 to T2, using analysis of covariance (ANCOVA). Baseline recordings were treated as covariates in the analyses. The effects of variables including age, gender and group (treatment vs. control and extraction vs. non-extraction) on changes in OH-QoL and pain experience were assessed initially in a univariate analysis; simple linear regression, independent *t*-test (or Mann–Whitney *U* test if data were not normally distributed) and ANOVA test (or Kruskal–Wallis test if data were not normally distributed) were conducted as appropriate. Only variables that were significantly different at the 0.05 level between both groups were tested. Finally, significant differences in OH-QoL and pain scores were assessed in a multiple regression model by entering the independent variables found to be statistically significant at the 0.2 level in the univariate analysis.

Results

Of 128 patients invited to participate, only four refused to take part, giving a 96.8% response

rate, despite no financial or other incentive being offered. One hundred and twenty-four patients were therefore recruited to the study. However, a further 15 patients (12.1%) were subsequently excluded from further analysis, nine from the test group and six from the control group. The reasons for failure to complete the study were as follows: incomplete records during the study period or appointment failure (n = 11), patients who were given appointments beyond the study's follow-up periods (n = 3) and unknown reasons (n = 1). The final sample therefore included 109 patients (53 in the test group and 56 in the control group), maintaining the statistical power of the study. The majority of the patients were female (65, 59.6%), with the mean age of subjects being 13.1 (SD 0.91) years (Table 1). Asians (40.4%) and White Caucasians (39.4%) were the predominant ethnic backgrounds followed by Afro-Caribbeans (14.7%). Almost 82% of patients lived with both parents, 20% lived with unemployed parents, and 83% lived in non-crowded houses. Eighty percentage of patients' parents owned one car or more, 60% of patients lived in owned houses, and all patients had access to Internet. There were no significant differences detected with respect to OH-QoL at baseline (T0), indicating that both groups were homogeneous.

Oral health-related quality of life

Significant changes in OH-QoL in both groups were observed both between T0 and T1 ($p = 0.012$) and between T0 and T2 ($p = 0.015$). Total OH-QoL scores in the control group decreased significantly at T1 and T2, while no significant changes in the test group were observed (Table 2), reflecting improvement in OH-QoL in the control group during the study period. There was no significant difference in the emotional well-being (EWB) domain between the groups at T1 and T2; however, EWB scores increased significantly from T0 in the respective groups ($p = 0.001$). A significant decrease in social well-being (SWB) was identified in the control group, resulting in a significant between-groups difference between T0 and T2 ($p = 0.035$). Oral symptoms (OS) and functional limitation (FL) domains deteriorated significantly in the test group during the first month of treatment. FL scores in the control group in particular decreased significantly (−1.26, $p = 0.002$) during the first month, indicating improvement in this domain during this period.

Pain level

Pain was only evaluated in relation to the test group as no reported pain was found in the control group, with respect to pain level or pain experience during biting and chewing. Median pain intensity from the teeth and on biting and chewing declined significantly on days 3 and 2 at T1 and T2, respectively, from the first day in the treated group ($p < 0.001$, Table 3). The decline in pain scores continued over the 2 weeks after appliance placement (T1) or manipulation (T2), indicating that there was an adaptation to pain with time. When comparing between the same time points, that is, day 1–7 and weeks 2–4, at T1 and T2, overall pain levels at T2 were found to be lower, although this decrease was not of statistical significance ($p = 0.06$–0.204).

Analgesic consumption

In the treated group, the total number of patients who consumed analgesics at any point at T1 and T2 was 33 and 15, respectively. At T1, the number of patients who reported consuming analgesics on the first day was 28 (52.8%). However, this level decreased in the following days, declining to just three patients in the second week. At T2, the number of patients who reported taking analgesics during the first day was considerably lower (n = 14, 26.4%), with a further decrease over the following days. Analgesia was required during both periods in a total of 13 participants (24.5%) undergoing orthodontic treatment. The hierarchical statistical model did not identify analgesic consumption as a confounder in pain experience within the test group, and this is supported by the change in pattern of analgesic use during the follow-up period.

Table 1. **Socio-demographic characteristics of the sample (n = 109)**

	Test group (n = 53)	Control group (n = 56)	Overall (n = 109)	*p* Value
Age, Mean (SD)	13.14 (0.78)	12.91 (0.94)	13.10 (0.91)	0.29
Male, n (%)	25 (47.2)	19 (33.9)	44 (40.4)	0.225
Female, n (%)	28 (52.8)	37 (66.1)	65 (59.6)	
White, n (%)	17 (32.1)	26 (46.4)	43 (39.4)	0.225
Asian, n (%)	21 (39.6)	23 (41.1)	44 (40.4)	
Black, n (%)	11 (20.8)	5 (8.9)	16 (14.7)	
Mixed, n (%)	3 (5.7)	2 (3.6)	5 (4.6)	
Other, n (%)	1 (1.9)	0 (0)	1 (0.9)	
Family composition				
Which adult they live with				
Living with both parents n (%)	39 (73.6)	50 (89.3)	89 (81.7)	0.16
Only father, n (%)	1 (1.9)	1 (1.8)	22 (1.8)	
Only mother, n (%)	12 (22.6)	5 (8.9)	17 (15.6)	
Neither, n (%)	1 (1.9)	0 (0)	1 (0.9)	
Parental employment				
Both employed, n (%)	23 (43)	30 (53.6)	53 (48.6)	0.763
Only father, n (%)	12 (22.6)	11 (19.6)	23 (21.1)	
Only mother, n (%)	6 (11.3)	5 (8.9)	11 (10.1)	
Both not employed, n (%)	12 (22.6)	10 (17.9)	22 (20.2)	
Crowding				
Yes, n (%)	8 (15.1)	11 (19.6)	19 (17.4)	0.532
No, n (%)	45 (84.9)	45 (80.4)	90 (82.6)	
Car ownership				
Own more than two cars, n (%)	17 (32.1)	24 (42.9)	41 (37.6)	0.507
One car only, n (%)	24 (45.3)	21 (37.5)	45 (41.3)	
No cars, n (%)	12 (22.6)	11 (19.6)	23 (21.1)	
Home ownership				
Own home, n (%)	25 (47.2)	40 (71.4)	65 (59.6)	0.03
Rent home, n (%)	22 (41.5)	14 (25)	36 (33)	
Don't know, n (%)	6 (11.3)	2 (3.6)	8 (7.3)	
Access to Internet				
Yes, n (%)	53 (100)	56 (100)	109 (100)	0.999
No, n (%)	0 (0)	0 (0)	0 (0)	
Total	53	56	109	

Discussion

While fixed appliance therapy is relied upon for optimal correction of malocclusion, there is a shortage of patient-centred research to permit understanding of functional and social impacts of such treatment. Previous research in this area is lacking and compromised by recruitment of ill-defined samples, cross-sectional analysis (7) and lack of contemporaneous controls (12). Further knowledge is instrumental to the process of informed consent, providing patients with a realistic insight into likely experiences during the initial stages of treatment and permitting the

Table 2. **Changes in total QoL and subdomain scores in both groups during the study periods (test group n = 53 and control group n = 56)**

	T0–T1				T0–T2				T1–T2			
Change	Mean	95% CI	*p* value	Effect size	Mean	95% CI	*p* value	Effect size	Mean	95% CI	*p* value	Effect size
Overall score												
Test group	0.4	1–9.1	0.012	0.06	0.2	1–9.5	0.015	0.055	−0.2	−2.8 to 3.36	0.588	0.003
Control group	−4.6*				−5.2*				−0.67			
EWB												
Test group	−1.54*	−1.3–1.8	0.855	0.00	−1.77*	−1.4 to 1.8	0.795	0.001	−0.23	−1.18 to 1.12	0.766	0.001
Control group	−1.78*				−1.98*				−0.2			
SWB												
Test group	0.3	1.1–0.86	0.204	0.01	0.02	0.13–3.4	0.035	0.041	−0.28	−1 to 1.9	0.304	0.01
Control group	−0.82				−1.57*				−0.75			
OS												
Test group	0.83*	0.52–2.6	0.001	0.125	0.88	0.05–2.3	0.005	0.072	0.05	−1.2 to 0.56	0.718	0.001
Control group	−0.73*				−0.32				0.41			
FL												
Test group	0.81	0.5–3.6	0.002	0.086	1.1	0.86–4.1	0.001	0.107	0.3	0.65–1.4	0.128	0.022
Control group	−1.26*				−1.37*				−0.11			

p value obtained from ANCOVA test to assess differences between groups adjusted for baseline measurements; EWB, emotional well-being; SWB, social well-being; OS, oral symptoms; FL, functional limitation.
*Paired *t* statistics were significant, indicating within-group changes over time.

development of coping methods to limit the impact of these issues. Consequently, it is realistic to expect that patient compliance with treatment may improve paving the way for more positive objective and subjective treatment outcomes (5, 11). While a randomised design would have been preferable to achieve these objectives, it was considered unethical to knowingly deny subjects treatment, by assigning them to an untreated control group (14). Thus, control subjects were chosen from the existing waiting list and were destined to commence treatment within 6–9 months. Consequently, subjects were consecutively assigned to the test group from those reaching the top of the treatment waiting list, while those concurrently allocated to the waiting list acted as the control group. This is the first example of deploying an age- and malocclusion-matched untreated sample in a prospective investigation of orthodontic treatment on pain and OH-QoL. The hierarchical statistical model did not identify ethnicity, gender or treatment mechanics with extraction or non-extraction therapy.

Table 3. **Median pain intensities from teeth in the test group (n = 53) during the study periods at all time points compared with day 1**

Time points	T0–T1 (between baseline and 4–6 weeks) Median	T1–T2 (between 4–6 weeks and 3 months) Median	*p* value
Day 1	54	51	0.204
Day 2	48	42*	0.184
Day 3	34*	30*	0.156
Day 4	25*	24*	0.108
Day 5	15*	14*	0.125
Day 6	9*	7*	0.132
Day 7	7*	3*	0.100
Week 2	4*	0	0.060
Week 3	0	0	–
Week 4	0	0	–

*($p < 0.001$) obtained from Wilcoxon's test between each individual time point in each period and day 1.

The present study investigated prospectively the intensity and duration of pain following the insertion of orthodontic appliances over a period of up to 3 months. The description of increased pain experience in conjunction with eating and chewing corroborates previous reports particularly related to consumption of foods with firm or hard consistency (19–21). Patients adapted to pain and discomfort after insertion of the initial aligning archwires within 2–3 days. This finding is in keeping with previous randomized controlled trials, which have shown pain to peak within 24 h of appliance placement (4, 22, 23). Similar results have also been identified in other prospective studies (3, 19, 24). The VAS pain scores in the present study were analogous to those demonstrated in other samples with a score of 54 mm at 24 h; Scott et al. (22) and Fleming et al. (4) reported levels of 58 and 61 mm at this time point. By the third day, pain scores had subsided to 34 again in keeping with both Scott et al. (22) and Fleming et al. (4) who reported mean scores of 42 mm. A slight reduction in pain scores was found later in treatment although these differences were not of statistical significance. Nevertheless, this does suggest that orthodontic pain may lessen in intensity during treatment or may reflect a certain degree of acclimatization to discomfort during treatment. This pattern confirms those of Tecco et al. (3) who noted a diminution in pain scores at the first and second reactivation of the appliance.

This is the first longitudinal study to assess the OH-QoL of adolescent patients undergoing fixed orthodontic treatment compared to an untreated control group with similar malocclusion severity. QoL is a multidimensional concept with many aspects of life having the potential to influence QoL to a significant level. Therefore, a control group was essential to isolate the treatment effect from extraneous factors that might influence the perceived OH-QoL in the test sample. The present study revealed a significant between-groups difference in changes in overall OH-QoL scores both between baseline and 4–6 weeks and between baseline and 3 months. However, within-group changes revealed that the overall OH-QoL in the test group deteriorated during the initial weeks of treatment, although not significantly, before recovering to basal levels after 3 months of treatment. Surprisingly, the between-groups difference was related to an improvement in overall OH-QoL in the control group during the observation period; this change may reflect reassurance due to the expectation of imminent treatment. In addition, subjects under investigation tend to fare or perform artificially well possibly due to increased attention and investigation, a phenomenon known as the Hawthorne effect (25). This effect tends to be more marked for subjective or psychological outcomes and in studies with repeated follow-up (26), as in the case of the present research. While it has been argued that the influence of the Hawthorne effect on research outcomes may be overstated (27), in view of the inclusion of an untreated but assessed control group, it was not possible to circumvent the possibility of confounding in the present study. A significant between-groups difference in both oral symptoms and functional limitation domains was observed at both 4–6 weeks and 3 months. This finding is likely to relate to both pain experience and oral health

problems including gingivitis, ulceration (13) and speech problems. Similarly, Zhang et al. (9) reported deterioration in these domains after 1 month of fixed appliances treatment.

Total OH-QoL scores and all subdomain scores improved significantly in the control group; the main difference between groups relates to significant improvement in the control group rather than to deterioration in the test group. This pattern was unexpected as this group did not receive any intervention, and reproducibility of CPQ11-14 is high (1, 18). Adolescents, however, may not recall their baseline status, leading to changes in their responses on a later occasion (28). This explanation was upheld by Kok et al. (29) who suggested that children provide more favourable responses for OH-QoL when a questionnaire is re-administered. Finally, the improved OH-QoL observed in the control group may stem from the clinical attention given to patients during the preparatory period before fixed appliance placement. Similar effects have previously been reported with *placebo* interventions known to have a therapeutic impact with particular potential to influence patient-reported outcomes such as OH-QoL (30).

Conclusions

Based on this prospective controlled study, the initial stages of fixed appliance treatment result in subjective pain experience, with subsequent reduction, and a significant impact on oral symptoms and functional limitation domains of OH-QoL.

Clinical relevance

Impairment of daily activities has been attributed to fixed orthodontic appliances; however, the influence of fixed orthodontic treatment on OH-QoL and pain experience has had insufficient investigation. This longitudinal study confirms that orthodontic treatment is accompanied by pain after placement and manipulation of appliances. However, while pain experience is common, reassuringly patients do not appear to experience impairment in OH-QoL during the initial phase of orthodontic treatment. This information will facilitate accurate counselling on the implications and experience of orthodontic treatment as part of the informed consent process.

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