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The effect of chewing gum on the impact, pain and breakages associated with fixed orthodontic appliances: a randomized clinical trial

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Structured Abstract

Objectives – To determine whether the use of chewing gum reduced the impact and pain of fixed orthodontic appliances.

Setting and Sample Population – The Orthodontic Department of the Charles Clifford Dental Hospital, Sheffield, UK. Fifty-seven patients aged 18 years or younger and who were about to start fixed orthodontic appliance treatment.

Subjects and Methods – A randomized clinical trial with two parallel groups either allocated to receive chewing gum after placement of their appliance or who were asked not to chew gum. The patients completed a previously validated Impact of Fixed Appliances questionnaire at 24 h and 1 week following each visit up until the placement of the working archwire. A visual analogue scale (VAS) was used to assess the intensity of pain. Appliance breakages were recorded to the end of treatment.

Results – The difference between the median Total Impact Score of the two groups at 24 h was 16, which was significant ($p = 0.031$; Mann–Whitney U -test). The difference between the median VAS between the two groups at 24 h was 25 mm, which was significant ($p = 0.038$; Mann–Whitney U -test). There were no differences at 1 week. None of the risk ratios for appliance breakages were significant.

Conclusion – Chewing gum significantly decreased both the impact and pain from the fixed appliances. There was no evidence that chewing gum increased the incidence of appliance breakages.

Key words: chewing gum; fixed appliance; impacts; orthodontics; randomized controlled trial

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Introduction

It has been shown that fixed orthodontic appliances lead to a deterioration in both adolescent (1, 2) and adult (3) oral health-related quality of life (OHRQoL), particularly in the first month after placement. This is related to the functional and social discomfort associated with wearing a fixed appliance (4), as well as the physical discomfort and pain (5, 6). This impact on OHRQoL may affect compliance and may lead to patients failing to complete treatment.

The commonest method of controlling the pain and discomfort from orthodontic appliances investigated has been the use of systemic analgesics (7, 8). The use of local pharmaceutical agents has also been investigated (9). Nonpharmacological methods include transcutaneous electrical nerve stimulation (10) and lasers (11).

It has been shown that the act of chewing leads to increased pulpal sensory thresholds to electrical stimulation (12). Chewing has been recommended as a means of increasing the blood flow into and around the periodontal membrane, restoring lymphatic circulation and preventing, or relieving, the inflammation and oedema (13). It also stimulates salivary flow, increasing the bicarbonate concentration and consequently the pH and buffering capacity of saliva, as well as increasing the rate of clearance of oral sugar and plaque acid, hence reducing the incidence of demineralization and caries (14).

There are few studies examining the effect of chewing on reducing the impact of fixed orthodontic appliances. Otasevic et al. (15) undertook a randomized clinical trial to compare the effects of using a masticatory bite wafer compared with avoidance of hard food to reduce pain and discomfort associated with initial orthodontic tooth movement. They reported significantly higher median pain scores in the bite wafer group for the first 4 days.

The aim of this study was to determine the effect of chewing gum on the impact and pain caused by fixed orthodontic appliances. The following were the specific research questions:

- Does the use of chewing gum reduce the impact of a fixed appliance?

- Does the use of chewing gum reduce the pain following placement and adjustment of a fixed orthodontic appliance?
- Does the use of chewing gum increase the number of appliance breakages?

Subjects and materials

Ethical approval for this study was obtained from South Sheffield Research Ethics Committee (reference number 07/H1309/96; November 2007). Either the participants or their parents gave written informed consent to take part in the trial.

The design was a randomized clinical trial with two parallel groups. The setting was the Orthodontic Department of a dental teaching hospital, the Charles Clifford Dental Hospital, Sheffield, UK.

Participants were recruited who fulfilled the following inclusion criteria:

- 11–18 years of age;
- About to start treatment with a fixed orthodontic appliance in at least one dental arch.

The following exclusion criteria were applied:

- Patients with a cleft of the lip or palate;
- Patients with phenylketonuria (those patients have to avoid products containing aspartame or artificial sweeteners that contain phenylalanine);
- Significant medical history;

Patients were screened at an initial records appointment, and if deemed suitable for inclusion, the study was explained verbally to the patient and their parent(s) and written information provided. They were allowed at least 1 week to consider whether or not to take part. If they agreed then written consent was subsequently obtained from patients and their parents.

Following consent participants were randomly allocated to one of two groups:

- Chewing Gum (CG): received chewing gum (Orbit Complete, Wrigleys, Chicago, Ill, USA) to use when required at the bonding/separator

appointment and subsequent appointments up to the visit after the placement of the working archwire (0.019 × 0.025-inch stainless steel).

- Non-chewing Gum (NG): were specifically asked not to chew gum for the duration of the study.

Randomization was carried out by one of the authors (PEB) using computer-generated random numbers. To ensure an equal number in the two groups, a block design was used with randomly allocated blocks consisting of 4, 6, 8 or 10 participants. Enrolment into the trial was undertaken by two of the authors (RMR and RJA). The allocations were concealed in consecutively numbered opaque sealed envelopes, which were opened only after the patient and parent had agreed to enter the trial and had signed the consent form. Masking of the patient to group allocation was not possible because they were either asked to chew gum or not. Masking of the operator was undertaken where practical; however, this was not always possible. Following an administrative error, the first six patients in the chewing gum group received a diary that did not contain the 24 h questionnaire; therefore, one subsequent random block was weighted to contain more participants to be randomly allocated to the CG group.

The participants were treated by one of three orthodontic postgraduate students in the department using standard treatment mechanics. Upper and lower preadjusted edgewise appliances (0.022-inch slot, MBT prescription, Victory®; 3M, St Paul, MN, USA) were placed using bonds on incisors, canines and premolars. Bands were placed on first molars. The initial aligning archwire was a round nickel-titanium (0.014-inch). Once alignment was achieved, a rectangular nickel-titanium (0.018 × 0.025-inch) was placed followed by a rectangular stainless steel (0.019 × 0.025-inch). After each visit up to and including placement of the rectangular stainless steel, participants were asked to complete a diary that included a previously validated Impact of Fixed Appliances (IFA) questionnaire designed to quantify the impact of a fixed appliance on a patient's daily life (16). IFA consists of one global question and 32 questions in 9 subscales,

including aesthetics, functional limitations, dietary impact and social impact. The response options are on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree). The responses of the 32 questions are summed to give an overall Total Impact Score (TIS).

Patients in the CG group were asked to use the chewing gum whenever they needed it, but in particular, they were asked to chew gum for 10 min before filling in the questions. Patients in the NG group were specifically asked not to chew gum for the duration of the study.

Patients were given the diary to take home and asked to complete it at 24 h and 1 week after placement or adjustment of their appliances (Supporting Information available online). The patients were also asked to indicate on a 100 mm visual analogue scale (VAS) how much their teeth were hurting at that time, where the left side of the scale indicated 'My teeth do not hurt at all' and the right side of the scale indicated that 'My teeth hurt very badly' and whether they had taken any analgesics and had any other problem with the appliance. Patients in the CG group were asked to make a note of how many sticks of gum they used.

Outcomes

The primary outcome was the TIS reported by the participants at 24 h and 1 week after placement of the appliance.

Secondary outcome measures included the following:

- Patients' assessment of pain using the VAS measurements at 24 h and 1 week after placement of the appliance;
- Reported use of oral analgesics;
- Recorded appliance breakages.

Statistical analysis

Data from a study using a similar methodology, but a different questionnaire were used in an *a priori* sample size calculation (17). This determined that a sample size of 60 patients should be sufficient to detect a 20% difference in impact score (SD, 14.4) to a power of 0.85 ($\alpha = 0.05$).

The data from each diary were entered into a spreadsheet (Excel® 2007; Microsoft Corp, USA, Redmond WA). The frequency of the modal responses for each participant to the global question ‘How much does the brace affect your life overall?’ were determined at 24 h and 1 week. The mode was used because examination of the data showed that many participants recorded the same global score over several visits; therefore, this was considered the most appropriate summary measure. The five possible responses were collapsed into three groups (‘Not at all’/‘Very little’; ‘Some’; ‘A lot’/‘Very much’). The difference in frequencies between the NG and CG groups was tested using the chi-squared test for trends.

The median TIS and VAS recorded at 24 h and 1 week for each participant were used as summary measures in the analysis. The distributions of the TIS and VAS were examined and found not to be normal; therefore, differences between the median scores recorded by the two groups at 24 h and 1 week were tested using the nonparametric Mann–Whitney *U*-test.

A frequency table of analgesic use was constructed to compare the participants who reported that they had and had not used analgesics. A chi-squared test was used to detect any difference in analgesic use between the chewing gum and the non-chewing gum groups at 24 h and 1 week.

The total number of bands and brackets placed and the number of first-time failures during the experimental period (up to and including the visit in which the 0.019 × 0.025-inch SS working archwire was placed) and the whole treatment were recorded contemporaneously on a data collection sheet placed in the patient notes. In addition, the number of wire failures (defined as fracture or total loss of the archwire) was recorded, as well as the frequency and reason for any other problems with the appliance. The percentages of first-time failures and the risk ratios (and 95% confidence intervals) for patients in the CG experiencing at least one failure of their appliance compared with patients in the NC group were calculated for both the experimental period and the whole of treatment.

The statistical tests were performed with PASW statistics (v18.0, SPSS Inc, USA, Armonk, NY), and the statistical significance was set at $p < 0.05$.

Results

Figure 1 shows the flow of patients through the trial (18). Recruitment started in February 2008 and was completed in April 2009 with 68 patients recruited and randomized. The numbers were slightly increased in the CG group because of an administrative error, which led to the first six patients receiving a diary that did not contain the 24 h questionnaire. To compensate, one of the randomization blocks later in the trial was weighted to contain more participants randomly allocated to the CG group. One patient in the CG group dropped out of treatment; one patient in the CG group and three patients in the NG group were excluded from the analysis because they did not return any diaries and six patients from the CG group were excluded because of the administrative error. The final numbers of participants in each group included in the analysis were 28 patients in the NC group and 29 patients in the CG group.

The baseline demographics and treatment characteristics of the two groups are shown in Table 1. Overall, 31 boys and 26 girls took part in the study; however, the randomization led to more boys in the NC group compared with the CG group. The age demographics were similar in both groups, and the youngest participants, who were considered competent to complete the questionnaires independently, were aged 11 years. The median number of returned diaries was 6 (SD; range, 1–13).

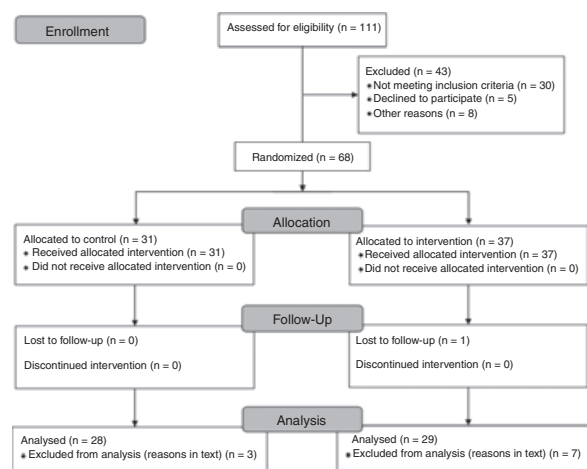


Fig. 1. Flowchart of participants through the trial (18).

Table 1. Baseline, treatment characteristics and mean number of returned diaries of the participants in the two groups

	Non-chewing Gum N = 28	Chewing Gum N = 29
Gender		
Males	19	12
Females	9	17
Mean Age in Yrs (SD) at start of treatment	14.7 (1.5)	13.9 (1.6)
Treatment		
Extraction	17	17
Nonextraction	11	12
Mean length of time (mths) in the study (SD)	12.9 (4.8)	11.4 (6.7)
Mean length of time (mths) in active treatment (SD)	23.3 (5.9)	24.8 (8.2)
Mean number of visits in active treatment (SD)	16.3 (3.6)	16.1 (5.0)

Global rating of Impact

Table 2 shows the frequency of the modal responses for each participant to the global question. The statistical analysis suggests that the frequency of impacts was significantly lower for the CG group at 24 h ($p = 0.044$; chi-squared test for trend), but not at 1 week ($p = 0.291$; chi-squared test for trend).

Table 2. Frequency of responses (mode for each participant) to the global question 'How much has your brace affected your life overall?' for the two groups at 24 h and 1 week (responses collapsed into three groups)

	Non-chewing Gum N = 28				Chewing Gum N = 29			
	24 h		1 week		24 h		1 week	
	N	%	N	%	N	%	N	%
'Not at all' or 'Very little'	13	46.4	18	64.3	22	75.9	22	75.9
Some	9	32.1	6	21.4	4	13.8	5	17.2
'A lot' or 'Very much'	6	21.4	4	14.3	3	10.3	2	6.9

Total Impact Scores

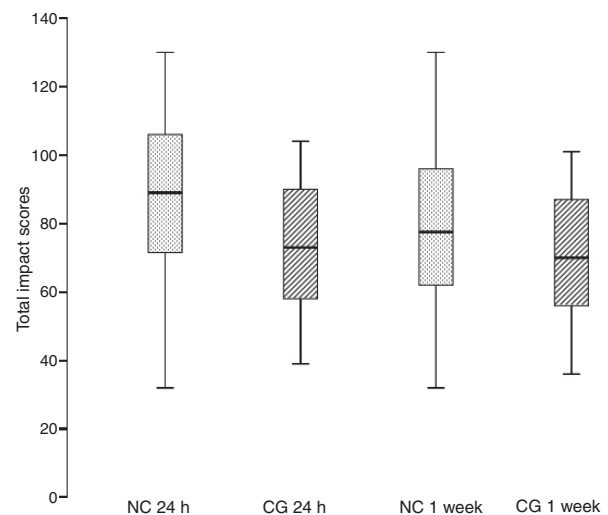
Figure 2 shows boxplots for the TIS. At 24 h the median TIS was 89 (range, 32–130) for the NC group and 73 (range, 39–145) for the CG group, which was significantly different ($p = 0.031$; Mann–Whitney *U*-test). At 1 week the median TIS was 78 (range, 32–130) for the NC group and 70 (range, 36–148) for the CG group, which was not significantly different ($p = 0.185$; Mann–Whitney *U*-test).

Visual Analogue Scores

Figure 3 shows boxplots of the VAS. At 24 h the median VAS was 45 mm (range, 0–84 mm) for the NC group and 20 mm (range, 0–87 mm) for the CG group, which was significantly different ($p = 0.038$; Mann–Whitney *U*-test). At 1 week, the median VAS was 21 mm (0–69 mm) for the NC group and 9 mm (range, 0–91 mm) for the CG group, which was not significantly different ($p = 0.255$; Mann–Whitney *U*-test).

Medication use

Table 3 shows the number of participants in the NC and CG groups who did and did not report taking painkillers during the experimental period. There were no statistically significant differences between the two groups at either 24 h ($p = 0.903$;

**Fig. 2. Boxplots of median Total Impact Scores for the two groups at 24 h and 1 week.**

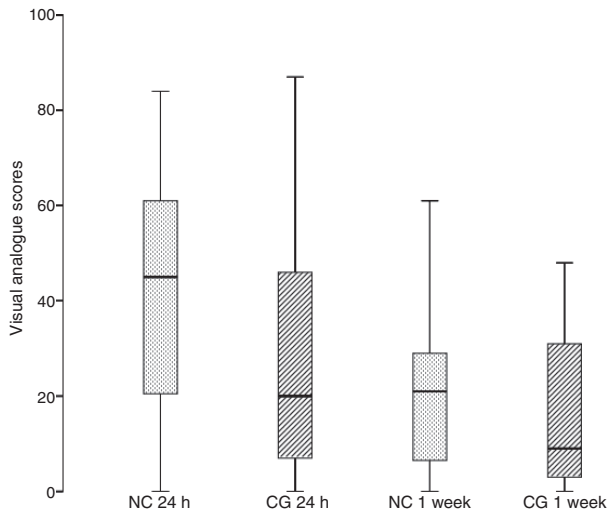


Fig. 3. Boxplots of median visual analogue scales for the two groups at 24 h and 1 week.

Table 3. Number of participants who did and did not respond to the question ‘Have you taken any painkillers or other medications because of your brace today?’ at least once during the experimental period

	Non-chewing Gum N = 28				Chewing Gum N = 29			
	24 h		1 week		24 h		1 week	
	N	%	N	%	N	%	N	%
Did not report using analgesics	13	46.4	22	78.6	13	44.8	17	58.6
Reported the use of analgesics at least once	15	53.6	6	21.4	16	55.2	12	41.4

Pearson chi-squared) or 1 week ($p = 0.104$; Pearson chi-squared).

The median number of sticks of chewing gum used was 5 (range, 2–19) at 24 h and 6 (range, 2–14) at 1 week.

Appliance failures

A total of 252 bands were placed in participants (NC 125; CG 127), and the number of first-time band failures during the experimental period was 11 (NC 4; CG 7; failure rate 4.4%) and 15 (NC 7; CG 8; failure rate 6.3%) throughout treatment. A total of 1009 brackets were placed (NC 498; CG 511),

and the number of first-time failures was 72 during the experimental period (NC 36; CG 36; failure rate 7.1%) and 94 during the whole treatment period (NC 52; CG 42; failure rate 9.3%). The bracket failures occurred equally in all groups of teeth (incisors 36; canines 11; premolars 37; molars 10).

Table 4 outlines the proportions of patients experiencing first-time band and bracket failures, as well as wire and other problems with their appliance. All the risk ratios and their 95% confidence intervals were within a value of 1, which denotes that there were no significant differences between the NC and CG groups for any of the appliance failures.

Discussion

This randomized controlled trial with two parallel groups of young people undergoing fixed orthodontic treatment found that chewing gum significantly decreased the impact and pain from the appliance without increasing the incidence of appliance breakages. The results suggest that when placing a fixed appliance, young people can be advised to use a sugar-free chewing gum when required to relieve discomfort without this having a detrimental effect on their treatment.

The results of this study are contrary to the findings of Otasevic et al. (15) who found that participants randomly allocated to chew on a bite wafer reported higher pain levels for the first 4 days after placement of a fixed appliance than those who were asked to avoid chewing hard food. The authors speculate that this might have been because the participants in the bite wafer group were advised to chew to ‘avoid’ pain (the implication being that pain was inevitable), whereas the control participants were advised not to chew hard foods to ‘prevent’ pain (which might suggest that pain is not certain). The instructions to participants in the present trial were different to those of Otasevic et al. Those allocated to the Chewing Gum group were told to use the gum when required to represent the ‘real-world’ situation; however, they were specifically asked to chew for 10 min prior to completing the

Table 4. Numbers and proportions of participants and risk ratios for the various appliance failures between the two groups during the experimental period and throughout treatment

		Non-chewing gum (N = 28)		Chewing Gum (N = 29)		Total (N = 57)		Risk Ratio	95% Confidence Intervals
Type of Appliance Failure	Time period	N	%	N	%	N	%		
1st time band failures	Experimental period	4	14.3	5	17.2	9	15.8	1.21	0.36, 4.04
	Treatment period	5	17.9	5	17.2	10	17.5	0.97	0.31, 2.98
1st time bond failures	Experimental period	16	57.1	18	62.1	34	59.6	1.09	0.71, 1.67
	Treatment period	18	64.3	20	69.0	38	66.7	1.07	0.74, 1.55
Wire failures	Experimental period	5	17.9	4	13.8	9	15.8	0.77	0.23, 2.58
	Treatment period	5	17.9	6	20.7	11	19.3	1.16	0.40, 3.37
Other problems	Experimental period	13	46.4	15	51.7	28	49.1	1.11	0.66, 1.89
	Treatment period	16	57.1	17	58.6	33	72.7	1.03	0.66, 1.60

questionnaire. This was requested in order to capture the immediate effect of chewing on impact and pain, rather than relying on the recall of previous experience; however, it is possible that this introduced some participant bias. The gum itself was low tack to prevent it sticking to the appliance and was relatively soft and pliable compared with a bite wafer. It also presents a small surface area that could be swiftly moved around the dentition, unlike a bite wafer, which would potentially affect the whole dentition when chewing.

This was the first study to use the impact questionnaire developed by Mandall et al. (16) as a primary outcome in a randomized controlled trial. It is increasingly being recognized that the aim of health care is to improve an individual's health and that the patient is in the best position to judge this. It is hoped that researchers will increasingly consider using patient-based measures, rather than the more traditional cephalometric and occlusal outcomes when designing clinical trials in the future (19).

Miller et al. (17) used an impact questionnaire with two cohorts of adult patients undergoing fixed appliances and clear aligners, although the development and testing of the questionnaire for validity and test-retest properties are not described. The authors did find that the patients receiving aligners suffered fewer impacts; however, no randomization was undertaken and there

were significant differences in the age, income and reason for treatment between the two groups at the start of treatment. In addition, it is not clear from the report whether the severity of the patient malocclusions was similar between the two groups. By randomizing to the intervention and nonintervention, we hope to have addressed these confounders in our study.

One limitation of the study is that it was difficult to assess compliance with the instructions provided. It is possible that some participants in the non-chewing gum group were actually chewing gum, even though they were specifically asked not to and some in the chewing gum group did not chew as asked. If this were the case, it would be difficult to explain the significant differences in the impact and pain found between the two groups, because, apart from the gender proportions, the randomization ensured that the participants in the two groups had similar baseline and treatment characteristics.

The randomization did lead to a higher proportion of boys in the NC group and a higher proportion of girls in the CG group. Amongst those approached to take part in the study, the proportions were similar to those undergoing treatment (56% girls to 44% boys). This was almost exactly reversed when patients were recruited to the study (46% girls vs. 54% boys). We can only speculate about the reasons for this, because ethical considerations meant that those

approached did not have to give a reason why they did not want to take part, but perhaps chewing gum is more popular with boys compared with girls.

There are conflicting reports about whether there are differences in the reporting of pain between boys and girls. Some studies have found that gender has no significant effect on the impact of fixed appliances (16, 20). Miller et al. (17) found that girls reported higher impacts than boys, although gender was not a significant predictor of VAS values. We found no significant differences between boys and girls for the median TIS at 24 h ($p = 0.911$; Mann–Whitney *U*-test) and 1 week ($p = 0.779$; Mann–Whitney *U*-test) or the median VAS scores at 24 h ($p = 0.785$; Mann–Whitney *U*-test) and 1 week ($p = 0.372$; Mann–Whitney *U*-test). Our study was not designed to determine differences between genders, but if girls were to score higher than boys (21–23), then the increased proportion of girls in the chewing gum group would have reduced the difference between the NC and CG groups and decreased the possibility of finding a significant difference; therefore, the true difference between the NC and CG groups might actually be greater.

The prevalence of impacts on the adolescents' life because of a fixed appliance was quite high according to the global question. Over one half of participants in the non-chewing gum group (54%) reported that the appliance affected their life overall 'Some', 'A lot' or 'Very much' at 24 h, which reduced to 36% at 1 week. In contrast, the equivalent proportions for the chewing gum group were 24 and 25%, which concurs with the results of Bernabe et al (20).

We chose to use a single summary measure of impact and pain (the median score) at 24 h and 1 week even though we collected serial data over a number of visits. We were interested in the differences between the NC and CG groups, rather than changes with time. Generally, 24 h after fixed appliance placement/adjustment is considered the peak time for pain, which then reduces over the next week (22, 24). One common statistical approach is to use linear regression to detect differences at different time points. On examination of the data, we believe that a simplified

approach was appropriate as interpretation of multiple *p*-values at different time points would have been difficult (25). There was no simple linear relationship between the data at different time points and the participants returned different numbers of diaries owing to the speed with which they progressed to the working archwire, as well as sometimes forgetting to return the diaries.

The overall bond failure rate (9.3%) was slightly higher than is reported in other studies. This might have been due to the treatments being carried out by three postgraduate students with limited experience of bonding appliances before starting the course. An appropriate statistical analysis was used that took into account clustering of teeth within the mouth (26). Breakages were assessed both during the experimental period and throughout the treatment. This was undertaken because it is possible that chewing gum led to weakening of a bond, which subsequently failed outside the experimental period; however, we found no evidence for this. Most bracket and band failures occurred in the initial stages of treatment.

One interesting aspect of the diary was the comments placed in a box after the impact questions. Most of the comments made by the chewing gum group indicated that chewing gum helped with the pain and discomfort, for example: 'At first they were painful but now I am use (*sic*) to them, they do not hurt and chewing the gum helped heal the pain.' Some mentioned that chewing gum distracts their attention from the discomfort: 'I feel the gum helps because you're occupied and you do not fiddle about with the brace, it also helps you to forget about the brace and it releases the pain slightly.' Others found that chewing gum did not help when the teeth were very sore:

'I used the chewing gum as it hurt a lot; however, this made it worse. I have found that if the pain is extreme the chewing gum hurts more; however, if the pain is slight then chewing the gum helps to loosen the jaw.' A few noticed that it helped to keep the appliance clean: 'I think sometimes the chewing gum does help release food that gets stuck in the brace.'

The additional potential benefit of chewing gum increasing salivary flow and helping to clean the

appliance and possibly reduce demineralization would be an interesting avenue for future studies.

Conclusions

Chewing gum reduced the impact and pain from fixed orthodontic appliances. There was no evidence that chewing gum increased the incidence of appliance breakages.

Clinical relevance

Orthodontic appliances cause discomfort and can affect eating, speaking, smiling and other activi-

ties. Some patients give up treatment early because of the impact on their everyday life. We should therefore do all we can to minimize this impact. One simple intervention is to advise patients to chew gum when it suits them. However, there are few clinical studies examining either the positive or negative effects in patients with fixed orthodontic appliances, which hopefully are addressed with this study. This study found that chewing gum reduced the impact and discomfort of fixed appliances without the negative effects of causing more breakages.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Chewing Gum Group.

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