The effects of fixed versus removable orthodontic retainers on stability and periodontal health: 4-year follow-up of a randomized controlled trial

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Author contribution

PSF, DA, AJ, ND, CMG designed the study. DA and NO'R undertook the data collection. NP undertook the statistical analysis. All authors were involved in interpretation of the results. DA and PSF wrote the manuscript. All authors approved the submitted version.

Introduction

Prolonged and indeed indefinite retention is routinely prescribed following orthodontic treatment to mitigate against post-treatment change related to unstable positioning of teeth, physiological recovery and age-related changes.[1,2] Notwithstanding this, there is a lack of high-quality evidence concerning the relative effectiveness of fixed and removable variants.[3] Moreover, the long-term impact of fixed or removable retention on the periodontium has been the subject of little prospective analysis and compliance levels with prolonged removable retention is unclear.[4]

Relatively few randomized controlled studies have involved comparison of the effectiveness of fixed and vacuum-formed retainers (VFRs).[5,6] Neither of these studies involved follow-up in excess of 2 years. As such, these have reported little difference in terms of stability with mean lower anterior irregularity scores being below 2.0mm in both trials indicating acceptable levels of stability in the short-term. It is intuitive to expect that irregularity would increase over time with important differences between these interventions, therefore, conceivably only emerging over a more prolonged period. In particular, compliance with removable retainer wear may wane leading to the development of post-treatment change primarily due to unchecked maturational changes in the medium-term. Similarly, failure of fixed retainers may also promote deterioration of the post-treatment outcome.[4] Notwithstanding this, in view of the dearth of prolonged, prospective evaluation, the relative impact of these eventualities can only be speculated upon.

In terms of periodontal health, fixed retainers may hinder scrupulous oral hygiene measures; however, it is not known whether this necessarily leads to worsening of periodontal outcomes, particularly in the long-term.[7] A number of observational studies have involved assessment of periodontal integrity during the retention phase.[7-10] The retrospective nature of these studies risks selection bias, in particular, whereby those exhibiting poorer hygiene may not be considered suitable for fixed retainers. Consequently, prospective analysis with random allocation to retainer types is preferable. It is important therefore that a more holistic assessment of benefits and harms with prolonged use of orthodontic retainers is undertaken.

Aims

The primary aim of this study was to compare the stability of orthodontic outcomes with fixed and removable retainers over a period of at least 4 years. The secondary aim was to investigate periodontal outcomes with fixed versus removable retainers over this period.

Materials and methods

Follow-up was undertaken on a randomized controlled trial conducted at ###, which had involved assessment of stability at up to 18 months post-treatment.[6] Ethical approval was obtained (10/H0713/57, Bloomsbury Research Ethics Committee) and all participants who took part in the previous clinical trial were contacted for possible inclusion at least 48 months following withdrawal of active appliances with an appointment arranged at their convenience. In the previous randomized controlled trial (RCT) eighty-two participants were randomly allocated by computer-generated random allocation with allocation concealed from the treating clinician using an opaque, sealed envelope system.[6] Participants received either a mandibular vacuum-formed retainer (VFR) (Essix Ace Plastic 120mm in diameter, (DENTSPLY)) or fixed retainer (0.0175" coaxial archwire; Ortho-Care, Shipley, UK) bonded with Transbond™ LR composite material (3M Unitek, UK). Those in the removable retainer group were instructed to wear the mandibular vacuum-formed retainer on a full-time basis for the first 6 months, nights only for the second 6 months, and alternate nights from 12 to 18 months following removal of active appliances. Thereafter, intermittent nights only wear (1 to 2 nights weekly) was recommended. Of the 82 participants included in the previous RCT, data were obtained from 48 at 18-month follow up.[6]

An information sheet was provided to those participants willing to participate at a minimum of 48-month follow-up following removal of active appliances, and oral and written consent was obtained. Participants were advised not to visit their dentist for scaling for 1 month prior to their appointment with those taking medications known to have an effect on gingival health excluded from the periodontal assessment.

Orthodontic stability was based chiefly on the irregularity of the mandibular incisors using Little's Irregularity Index to assign a cumulative score for the contact point displacement in

the mandibular inter-canine region.[11] Allied measurements including inter-canine and inter-molar widths, arch length and extraction space opening were also recorded.[6] Five clinical measures of periodontal health were scored: gingival inflammation,[12] calculus and plaque levels,[13,14] clinical attachment level (CAL) and bleeding on probing (Appendix).

An impression of the mandibular arch was taken for all participants using hydrophilic vinyl polysiloxane (Virtual®, Ivoclar Vivadent AG, Schaan, Liechtenstein). The impression was then cast in hard (Type III gypsum) stone. Orthodontic stability was measured from the study models, adopting the same technique used in the previous study.[6] The lingual surfaces of mandibular labial segment were obscured on the study models using prosthetic dental wax (Ribbon Wax, Metrodent, Huddersfield, UK) to ensure assessor blindness. Measurements were performed by one researcher (##) using a digital caliper (150mm DIN 862, ABSOLUTE Digimatic caliper, model 500-191U; Mitutoyo, Andover, Hampshire, UK) with a resolution of ±0.01mm. Periodontal measurements were recorded for the labial and lingual surfaces of mandibular canines, central and lateral incisors. Each tooth surface was divided into thirds using vertical lines based on the morphology and position of the dental papilla to demarcate mesial, mid and distal surfaces. The periodontal measures were scored clinically by one researcher (##) (Appendix).

All participants were asked about frequency, duration, type of tooth-brushing and the time elapsed since the last visit to the dentist. Patients wearing mandibular vacuum-formed retainers were also asked to complete a retainer wear chart. The self-reported compliance levels were categorized as follows:

- Compliant: reported wear of retainers was as advised,
- Partially-compliant: retainer wear instructions were not followed precisely
- Non-compliant: not wearing retainers.

The status of the fixed retainer in addition to history of retainer repair and previous breakage was recorded in the fixed retainer group.

Inter- and intra-examiner reliability of clinical and of study model measurements were tested by assessing agreement between repeat measurements.[15] For stability outcomes, intra-examiner reliability was performed on 10 randomly selected study models 4 weeks after the

initial measurement. Inter-examiner reliability (##, ##) was performed on 10 randomly selected study models with excellent agreement for intra-examiner (0.97) and inter-examiner (0.92) reliability. As the examiner (##) was an orthodontist, familiarization with measurement of periodontal outcomes was required; and therefore facilitated by completion of an online course with oversight from a specialist in Periodontology (##) prior to recruitment. Intra-examiner reliability for scoring of modified gingival index and plaque scoring was assessed by repeating measurements on 10 intra-oral photographs at a 4-week interval.[12,14] Repeated measurement was performed on 10 healthy volunteers 30 minutes apart to assess repeatability of measurement of calculus scores and CAL. Excellent agreement was observed (0.94 to 0.97) for inter-examiner reliability.

Sample size calculation

The initial sample size was calculated based on previous research,[16] although a higher level of attrition was to be expected after more prolonged follow-up. A total of 72 participants (36 in each group) was required with a power of 90% to detect a difference of 0.5 mm in at the 0.05 level of statistical significance. To compensate for a dropout rate of at least 15%, the final number enrolled in the trial was 82 participants at the outset.[6]

Statistical analysis

As the data was not normally distributed, median regression was used to compare the effectiveness of the two types of retainers on orthodontic stability accounting for baseline differences between the groups. Similarly, the median difference between fixed and removable retainers in terms of gingival inflammation, calculus and plaque levels, CAL and bleeding on probing was assessed using Mann-Whitney U test. A subgroup analysis was performed to compare the median difference in periodontal outcomes between fixed and removable groups on the labial and lingual surfaces independently. If significant differences were identified in relation to gingival inflammation plaque or calculus scores, probing depth or bleeding on probing, median regression analysis was to be used to assess the influence of age, gender, brushing frequency and duration, and type of retainer on the outcome. A similar model was to be used to evaluate the effect of retainer type on clinical attachment level. The level of statistical significance in all analyses was set to 0.05 with all analyses undertaken using

the Stata statistical software package (version 14.1; StataCorp, College Station, Tex).

Results

Eighty-two participants were enrolled in the original RCT.[6] Of these, 48 attended at 18-month follow-up (T3). At the 4-year follow-up (T4), 42 participants returned- 21 per group (Figure 1). Groups were well-matched in terms of age, gender and treatment protocol with the majority being females and 43% and 48% having extraction-based treatment in the fixed and removable groups, respectively (Table 1). In terms of fixed retainer integrity, all (100%) were in place at recall although three (14%) were partially detached and two (10%) had history of repair. In the removable retainer group, reported non-compliance levels increased from 0% over the initially 6 months to 19% from 6-12 months, 52% in the second year and 67% thereafter.

Orthodontic stability with fixed versus removable retention

In terms of the irregularity of the mandibular anterior segment, data from 42 participants were analyzed (Table 2). Some degree of relapse occurred in both treatment groups at 4-year follow-up with median increases in the degree of irregularity of 0.85mm and 1.47mm in fixed and removable retainer groups, respectively. After adjusting for confounders, the median between-groups difference was 1.64mm higher in those wearing vacuum-formed retainers (P= 0.02; 95% CI: 0.30, 2.98mm). No statistical difference was found between the treatment groups in terms of inter-canine (P= 0.52; 95% CI: -1.07, 0.55) and inter-molar widths (P= 0.55; 95% CI: -1.72, 0.93), arch length (P= 0.99; 95% CI: -1.15, 1.14) and extraction space opening (P= 0.84; 95% CI: -1.54, 1.86).

Periodontal outcomes

For modified gingival index, score 3 was the most frequent in both fixed (55.4%) and removable (52.6%) retainer groups at 4-year follow-up. In relation to plaque index, score 4 was most frequently observed in both fixed (31.3%) and removable retainer groups (27.7%). When calculus was present, score 2 was the most common score in both groups (18.9% in fixed, 17.6% in removable). However, around two thirds of tooth surfaces were free of calculus in both fixed and removable retainer groups.

No statistical difference in relation to periodontal parameters was found between fixed and removable retainer groups (Table 3). In particular, median scores for modified gingival index was slightly lower in the fixed retainer group (*P*= 0.76). However, median plaque levels (*P*= 0.27) and CAL (*P*= 0.23) was slightly higher in the fixed group, although this was not of statistical significance. When periodontal outcomes for the lingual surfaces of the mandibular anterior segment in the fixed and removable groups were compared, no significant difference was found (*P*> 0.05). Similar findings were found in relation to the buccal surfaces.

Discussion

Based on the findings of this 4-year follow-up study, fixed retainers appear to be more effective in preserving mandibular anterior segment alignment in comparison to vacuum-formed retainers with in excess of 1.6mm less irregularity observed in the previous, although some deterioration was observed in both groups. Given that subjects were randomly allocated to retainer type, irrespective of baseline oral hygiene levels and previous periodontal condition, it appears that fixed retention offers the potential benefit of improved preservation of alignment in the long-term without significantly increasing the risk of periodontal deterioration relative to removable retainers. It is important to note, however, that periodontal conditions cannot be considered healthy in either group, with significant gingival inflammation and elevated plaque levels a common finding which highlights the premium on periodontal maintenance following orthodontics.

Few previous randomized controlled studies have involved a comparison of the effectiveness of fixed and vacuum-formed retainers.[5,6,17] One of these involved a comparison between lingual fixed retainer combined with a nights-only Hawley retainer and vacuum-formed retainers prescribed for full-time wear. Similar stability of the mandibular incisors alignment was noted at 1-year follow-up.[5] However, this study risked attrition bias due to high levels of drop-out with a small sample size. Similarly, in the earlier report of the present study, O'Rourke *et al*. (2016) alluded to a lack of significant between-groups difference in relation to mandibular anterior segment stability after 18 months. A recently published RCT involved a involving comparison of fixed retainers and vacuum-formed retainers prescribed for nights only wear also reported comparable levels of relapse in the maxillary arch with marginally greater change (LII: 0.92mm) in the mandibular arch at 12-month follow-up.[17] The findings from the present study imply that the benefit of fixed retention may well become more apparent following more prolonged periods of retention mitigating against both unstable tooth positioning and also against maturational change, while declining levels of compliance with removable retention may predispose to change. It would therefore be intuitive to expect that further changes might take place in the removable retainer group in the long-term, amplifying this between-groups difference in the longer term.

The observation of waning compliance over time with removable retention is unsurprising; moreover, it is likely that the suboptimal levels of wear claimed in the present sample, with

67% non-compliant more than 2 years into the retention phase, represents an overestimate of co-operation. It is accepted that compliance with removable orthodontic components during active treatment is limited with patients routinely failing to reach stipulated levels of wear.[18] The expectation that patients might wear removable retainers many years subsequent to treatment may therefore be somewhat optimistic, particularly when much of this period is often not routinely monitored by the treating clinician.[19] It therefore appears that novel means of enhancing compliance with retention regimes, including approaches not directly reliant on patient-clinician contact, require further refinement. These may include web-based or electronic methods such as providing accessible and high-quality online information, promoting positive behaviours on social media platforms, or the use of electronic reminders in the form of e-mails or mobile applications. Although VFRs are commonly prescribed as orthodontic retainers, only one randomized controlled trial has involved periodontal assessment of patients wearing VFRs.[5] In a 12-month follow-up, higher calculus index scores were associated with fixed retainers compared to VFRs,[5] although periodontal assessment in the latter was confined to calculus scores, in isolation. Furthermore, patients in the fixed retainer group were instructed to wear an additional removable retainer at night, making it difficult to distinguish between the effects of different types of retainers. In the present study, participants with bonded wires were not prescribed supplementary wear of removable retainers ensuring that the impact of retainer type both on stability and periodontal outcomes could be clearly elucidated.

Participants in the present study were previously randomized into different retainer groups, ensuring that all groups were likely to be similar with respect to potential confounders including oral hygiene levels, although levels of hygiene were suboptimal overall. This continued to be borne out in the present follow-up. In particular, randomization is likely to minimize selection bias, particularly as fixed retainers are more likely to be reserved for those patients exhibiting good oral hygiene. Observer bias was minimized in the assessment of stability by obscuring the lingual surfaces of the teeth; however, blinding was not feasible in the assessment of periodontal outcomes, as this was measured clinically. Stability was assessed in the mandibular arch as instability tends to be more salient in the mandibular anterior region both due to treatment-induced and physiological changes.[20] As such, more significant between-groups differences may be apparent in the lower arch; nevertheless,

maxillary fixed retainers are similarly likely to be associated with optimal stability. Notwithstanding this, the failure rate for maxillary retainers tends to be slightly higher in view of occlusal and masticatory forces,[21] potentially diluting any associated advantage. Stability was assessed directly from study models using Little's irregularity index;[11] this is the most accepted approach to assessing stability. However, it fails to account for vertical displacements, reciprocal rotations, angulation and inclination changes. Based on lay and professional opinion, however, horizontal displacements are consistently scored as the most salient feature[22] and this is reflected in Little's scores. In addition, we were also mindful of inadvertent complications such as localized change in torque, which are particularly prone to arise with fixed retainers in the long-term.[23,24] However, these complications were not apparent in the present sample, although this may reflect the relatively small sample size.

In relation to the periodontal assessment, both an overall evaluation and analysis of buccal and lingual surfaces, in isolation, were included. The latter ensured that the effect of plaque accumulation adjacent to bonded wires on the lingual surfaces would not be diluted. In keeping with previous research focusing on Hawley retainers at up to 6-month follow-up[25] whereby gingival index scores were increased on the buccal surfaces of maxillary and mandibular anterior teeth, minor changes were also observed with VFRs in the present study. The plaque scores present in both groups were relatively high with median plaque index scores of 3 to 3.5, being approximately 0.5 units higher than the mean plaque scores found on the lingual surfaces of the mandibular incisors with fixed and Hawley retainers over a 6-month period.[25] A recently published RCT, involved a comparison between fixed and vacuum-formed retainers in the mandibular labial segment with no significant difference found in gingival and plaque indices; however, fixed retainers were associated with significantly higher plaque scores.[26] A number of periodontal outcomes were assessed in the present study potentially risking false positive outcomes in view of the high number of statistical tests; however, these were all pre-specified and statistically significant findings were not observed. This multitude of outcomes suggests that refinement of outcomes within periodontology and general dental research would be timely.[27]

The present study was limited by a relatively small sample size potentially reducing the statistical power and risking false negative results; however, significant findings were

observed for the main outcome. Moreover, drop-out was significant over the 4-year period, although the final sample of 42 was just 6 less than that obtained 2.5 years previously.[6] However, drop-out was balanced between the groups and the main reason for failure to attend was logistical ensuring that missing data occurred at random and therefore the risk of attrition bias was minimized. Notwithstanding this, the challenge of recruiting and retaining a sufficiently large sample to an orthodontic retention study is clear. Future research evaluating the effectiveness of long-term approaches to orthodontic retention should therefore be mindful of this issue. Furthermore, as this study was conducted at a single, university-based centre, the findings are applicable to patients with similar characteristics and may not be generalizable to other settings and patient groups. Baseline periodontal assessment would have facilitated a clearer understanding of adverse changes occurring over the retention period; however, patients with a history of periodontal disease were excluded at baseline.[6] Finally, an untreated control group would have helped to ascertain whether periodontal change beyond that characteristic of maturation was associated with the 4-year retention period. However, recruitment of an age-matched, untreated control with similar occlusal characteristics over a prolonged period could not be justified from an ethical standpoint. Moreover, the magnitude of attachment loss observed was small indicating that minimal effect could be attributed to either retention regime.

Conclusions

Fixed retainers may be more effective in retaining mandibular anterior segment alignment compared to vacuum-formed retainers at 4-year follow-up, although some change arose in both groups. Both fixed and removable retainers were associated with similar levels of gingival inflammation and poor oral hygiene. On the basis of the present study, it therefore appears that fixed retainers may be the approach of choice to maintain alignment of the lower anterior teeth in the long-term but there is a clear need for optimal oral hygiene before, during and after orthodontics to avoid increased levels of gingival inflammation.

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Not applicable

Conflict of interest

The authors report no commercial, proprietary, or financial interest in the products or companies described in this article.

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Figure Caption

Figure 1. Study flow diagram.

RCT: Randomized controlled trial

Table legends

Table 1. Baseline characteristics overall and in both groups.

Table 2. Stability outcomes in fixed and removable retainer groups.

Table 3. Periodontal outcomes in fixed and removable retainer groups.

Table 1. Baseline characteristics overall and in both groups.

		Overall sample n= 42	Fixed retainer group n= 21	Vacuum-formed retainer group n= 21
Mean age in years (SD)		21.15 (2.41)	21.54 years (3.06)	20.77 years (1.49)
Gender	**Males**	n= 10	n= 3	n= 7
	Females	n= 32	n= 18	n= 14
Mean years in retention (SD)		4.16 (0.35)	4.09 (0.25)	4.23 (0.42)
Treatment protocol	**Extraction**	n= 19	n= 9	n= 10
	Non-extraction	n= 23	n= 12	n= 11
Type of tooth-brush	**Manual**	n= 37	n= 18	n= 19
	Electric	n= 5	n= 3	n= 2
Daily tooth-brushing frequency	**1X**	n= 7	n= 6	n= 1
	2X	n= 35	n= 15	n= 20
Time spent in tooth-brushing	**<1 minute**	n= 1	n= 0	n= 1
	1-2 minutes	n= 29	n= 14	n= 15
	>2 minutes	n= 12	n= 7	n= 5
Use of other oral hygiene measures	**None**	n= 23	n=13	n=10
	Dental floss	n= 10	n= 4	n= 6
	Interdental brush	n= 3	n= 2	n= 1
	Toothpick	n= 9	n= 4	n= 5
Last visit to the dentist	< 6 months	n= 10	n= 5	n= 5
	6 months – <1 year	n= 5	n= 3	n= 2
	1 – 2 years	n= 12	n= 9	n= 3
	> 2 years	n= 15	n= 4	n= 11
Smokers		n= 4	n= 3	n= 1
Gingival biotype	**Thick**	n= 17	n= 7	n= 10
	Thin	n= 24	n= 14	n= 10
Fraenal attachment	**Low**	n= 41	n= 21	n= 20
	High	n= 1	n= 0	n= 1

SD: standard deviation

Table 2. Stability outcomes in fixed and removable retainer groups.

Outcome measures	Number of participants	Time point	Statistical measures	Fixed retainer group	Vacuum-formed retainer group	Coefficient	95 Confidence Interval	P-value
Irregularity index	FR group: n= 21 VFR: n= 21	T0	Median	0.25	0.42	1.64	0.30, 2.98	0.02*
			IQR	0.47	0.84			
		T4	Median	1.23	3.16			
			IQR	1.27	2.74			
		T4-T0	Median	0.85	2.37			
			IQR	0.91	2.26			
Intercanine-width	FR group: n= 21 VFR group: n= 21	T0	Median	26.9	26.77	-0.26	-1.07, 0.55	0.52
			IQR	1.89	2.29			
		T4	Median	26.74	25.62			
			IQR	1.84	2.51			
		T4-T0	Median	-0.28	-0.52			
			IQR	0.88	1.6			
Intermolar-width	FR group: n= 21 VFR group: n= 19	T0	Median	42.8	41.77	-0.40	-1.72, 0.93	0.55
			IQR	3.96	4.03			
		T4	Median	42.23	42.66			
			IQR	5.82	4.93			
		T4-T0	Median	0.15	-0.42			
			IQR	2.08	2.09			
Arch length	FR group: n= 21 VFR group: n= 19	T0	Median	24.45	25.84	-0.01	-1.15, 1.14	0.99
			IQR	3.83	7.04			
		T4	Median	22.15	20.81			
			IQR	2.96	8.33			
		T4-T0	Median	-3.63	-3.78			
			IQR	0.59	2.1			
Extraction site opening	FR group: n= 9 VFR group: n= 10	T0	Median	0	0	0.16	-1.54, 1.86	0.84
			IQR	0.19	0			
		T4	Median	1.37	1.65			
			IQR	0.72	1.57			
		T4-T0	Median	1.23	1.65			
			IQR	1.14	2.13			

FR: fixed retainer, VFR: vacuum-formed retainer

Table 3. Periodontal outcomes in fixed and removable retainer groups.

Outcome measures	Statistical measures	Fixed retainer group (n= 21)	Vacuum-formed retainer group (n= 21)	P-value
Modified gingival index	Median	2.5	3	0.76
	IQR	3	3	
Plaque index	Median	3.5	3	0.27
	IQR	1	2	
Calculus index	Median	0	0	0.19
	IQR	1	1	
Clinical attachment level	Median	2	1.5	0.23
	IQR	1	1	
Bleeding on probing	Median	1	1	0.87
	IQR	2	2	

Figure 1. Study flow diagram.

RCT: Randomized controlled trial