ORIGINAL ARTICLE

The effectiveness of Hawley and vacuum-formed retainers: A single-center randomized controlled trial

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Introduction: Vacuum-formed retainers (VFRs) are often prescribed by orthodontists in the British National Health Service (NHS). There is no good evidence that VFRs are more effective than Hawley retainers. The aim of this study was to compare the clinical effectiveness of Hawley and VFRs over a 6-month period of retention. The study design was a randomized clinical trial, performed in a single orthodontic practice. **Methods:** Eligible patients treated by a specialist orthodontist were randomly allocated to either Hawley retainers (n = 196) or VFRs (n = 201). Two technicians fabricated the retainers to standardized designs. A blinded, dentally qualified examiner analyzed the records. Maxillary and mandibular dental casts at debond and 6 months into retention were assessed for tooth rotations mesial to the first permanent molars, intercanine and intermolar widths, and Little's index of irregularity. **Results:** The results showed significantly greater changes in irregularity of the incisors in the Hawley group than in the VFR group at 6 months. There were otherwise no statistically significant differences. **Conclusions:** VFRs are more effective than Hawley retainers at holding the correction of the maxillary and mandibular labial segments. The median differences were 0.56 mm in the mandibular arch and 0.25 mm in the maxillary arch. Although this difference is unlikely to be clinically significant in the maxillary arch, it could be considered clinically significant in the mandibular arch if located to a single tooth displacement. (Am J Orthod Dentofacial Orthop 2007;132:730-7)

After fixed appliance orthodontic treatment, retainers are routinely fitted by the orthodontist and are worn by the patient for 6 to 12 months while the soft and hard tissues remodel around the teeth.[1] In the long term, retention might be necessary until growth is complete or indefinitely if teeth are in unstable positions. Hawley retainers and vacuum-formed retainers (VFRs) are the 2 most commonly prescribed removable retainers in the United Kingdom's National Health Service (NHS). Data from the Dental Practice Board[2] in the United Kingdom demonstrate the increasing use and popularity of VFRs. This is probably due to their improved esthetics, ease of fabrication, and lower costs. There is, however, no good clinical evidence to support the use of VFRs over conventional Hawley retainers. To date, only 1 published study has compared the clinical effectiveness of Hawley and VFRs. Lindauer and Shoff[3] carried out a prospective nonrandomized clinical trial to compare Essix retainers with Hawley retainers during the first 6 months of active retention. Essex retainers are vacuum-formed and cover the canines and the incisors. Their single-center study was done in a dental teaching hospital. A significant proportion (29%) of the sample was lost during the study period, so that the final sample size was small (40 total; 19 Essix, 21 Hawley) and therefore had limited statistical power. The authors found no significant differences between the 2 retainer groups when overjet, overbite, and incisor irregularity were examined over the 6-month retention period. The amount of contact point displacement (relapse) between debond and 6 months into retention was approximately 0.3 mm, which is unlikely to be clinically significant.

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However, evidence suggests that the Hawley might be the retainer of choice when a lateral open bite is present before debond. Sauget et al[4] showed that the Hawley retainer allows more vertical movement (settling) of the posterior teeth than a VFR, but their sample size was small (total, 30 patients, 15 per group).

Although both previous studies suggest that there is little to choose between Hawley and VFR, except in open-bite patients, the evidence is weak because of the small sample sizes. However, the potential cost savings in a health care system with the routine use of VFRs rather than Hawley retainers are significant. This alone justifies more research with greater statistical power to enable valid clinical and economic conclusions to be reached.

The aim of this randomized clinical trial was to compare the clinical effectiveness of Hawley and VFRs over a 6-month period after debonding. Specifically, we set out to examine whether there are any differences in the clinical effectiveness of Hawley and VFRs when used to retain the dentition in terms of Little's index of irregularity (LII), tooth rotation, intercanine width (ICW), intermolar width (IMW), overjet, and overbite in a 6-month period. Six months was chosen because it is a familiar landmark time period for most orthodontists, and it is likely that most patients will also still be complying with their retainer wear.

MATERIAL AND METHODS

This clinical trial was set in an orthodontic practice; this allowed for the recruitment of a large sample of patients treated by 1 orthodontist.[5] The study was approved by the Local Research and Ethics Committee at the United Bristol Healthcare Trust (approval number E5421). Patients who were due to have their fixed orthodontic appliances removed were assessed by the orthodontist for inclusion in the trial according to the following criteria: treated under the NHS by the same orthodontist; fixed appliance treatment involving both arches; preadjusted edgewise appliances; pretreatment records, treatment plan, and study models available; and willing to wear maxillary and mandibular retainers.

Patients were excluded for the following reasons: single-arch or sectional fixed appliance treatment, hypodontia requiring tooth replacement on the retainer as a temporary measure, rapid maxillary expansion, bonded retainers, poor periodontal status, early debonding, transfer patients, learning difficulties, or cleft lip or palate.

It was calculated that a total sample size of 388 subjects would give a power of 80% with a 5% significance level to detect a true difference in contact-point displacement of greater than 0.2 mm. Therefore, at least 400 patients (200 in each group) would be recruited to allow for dropouts and loss to follow-up.

Table I. Mean ages and sex distribution of subjects in the Hawley and the VFR groups at retainer fit

	Hawley (n = 196)	*VFR (n = 201)*
Girls	123 (63%)	118 (59%)
Boys	73 (37%)	83 (41%)
Ages	14 y 8 mo	15 y
Mean (SD)	(1 y 8 mo)	(1 y 5 mo)

Potential participants were identified by the orthodontist at their last appointment before debonding, when the orthodontist explained the study's purpose to the patients and their parents or legal guardians. Written information about the study was given to all potential participants, and written consent was obtained before the debond appointment. For patients under 16 years old, written consent was also obtained from the parent or legal guardian. Gillick competence was applied when necessary (parental right to determine whether a child below 16 years of age will undergo treatment terminates if the patient is found to have sufficient intelligence to enable him or her to understand what is proposed [http://confidential.oxfordradcliffe.net/Gillick]; if this is the case, the patient is considered to be "Gillick competent.")

Enrolment started in March 2003 and was completed by December 2004. The orthodontist assessed 531 subjects for eligibility; 55 did not meet the inclusion criteria, and 79 refused to participate, giving a recruitment rate of 75%. Three hundred ninety-seven subjects agreed to take part in the study.

At the debond appointment after appliance removal (T1), the orthodontist recorded overjet and overbite. One set of maxillary and mandibular alginate impressions was taken, and study models and working models were cast on which the retainers were to be made. All subjects were randomized by the research team to receive either maxillary and mandibular Hawley retainers or VFRs. A blocked randomization method (taken from http://www.randomisation.com) was chosen, based on equal numbers of both types of retainers allocated per block of 20 patients. Concealment of allocation was achieved by ensuring that randomization was undertaken after obtaining patient consent.

One hundred ninety-six patients were randomized to Hawley retainers and 201 to VFRs. All subjects in both groups received the allocated intervention. Table I shows the mean age and sex distribution of subjects in the Hawley and VFR groups at retainer fit. The clinical characteristics of the subjects in the random-

Table II. Clinical characteristics of subjects in the Hawley and the VFR groups

Clinical characteristics	*Hawley (n = 196)*	*VFR (n = 201)*
Incisor relationship		
Class I	67 (34%)	58 (29%)
Class II Division 1	79 (41%)	84 (42%)
Class II Division 2	37 (19%)	47 (23%)
Class III	13 (6%)	12 (6%)
Skeletal class		
Class I	97 (50%)	92 (46%)
Class II	87 (44%)	99 (49%)
Class III	12 (6%)	10 (5%)
FMA		
High	21 (11)	20 (10%)
Average	149 (76%)	156 (78%)
Low	26 (13%)	25 (12%)
Missing teeth		
None missing	185 (94%)	193 (96%)
Missing incisors	4 (2%)	1 (0%)
Missing premolars	7 (4%)	7 (3%)

FMA, Frankfort mandibular planes angle.

Table III. Treatment summary of subjects in the Hawley and the VFR groups

Treatment summary	*Hawley (n = 196)*	*VFR (n = 201)*
Extractions		
No extractions	130 (66%)	133 (66%)
Premolar extractions in both arches	35 (18%)	38 (19%)
Premolar extractions in maxilla only	21 (11%)	14 (7%)
Other extractions	10 (5%)	16 (8%)
Appliances		
Fixed only	142 (72%)	142 (71%)
Functional and fixed	31 (16%)	30 (15%)
URA, functional, and fixed	1 (0%)	1 (0%)
URA and fixed	22 (11%)	28 (14%)

URA, upper removable appliance.

ized groups are shown in Table II and the treatment details in Table III.

Two fully qualified laboratory technicians fabricated the retainers to standardized designs and were blind to the fact that they were making retainers for patients included in the trial.

The Hawley retainers were constructed with an acrylic base plate and Adams clasps fabricated of 0.7-mm diameter stainless steel wire on the first standing molars. A Hawley bow (open looped short labial bow) was also made from 0.7-mm stainless steel wire; it extended from canine to canine. The Hawley bow was then contoured with acrylic resin to contact the labial surfaces of the incisors (Fig 1).

Each VFR was constructed from an Erkodur blank

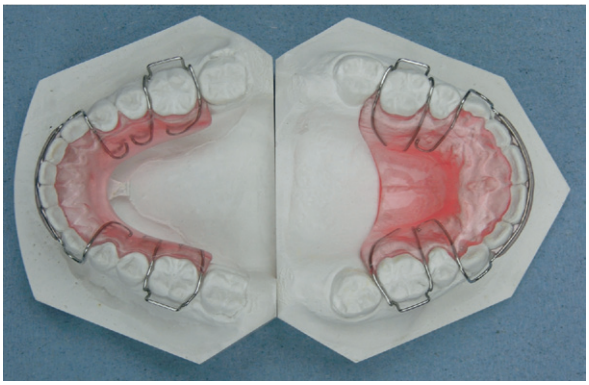

Fig 1. Maxillary and mandibular Hawley retainers.

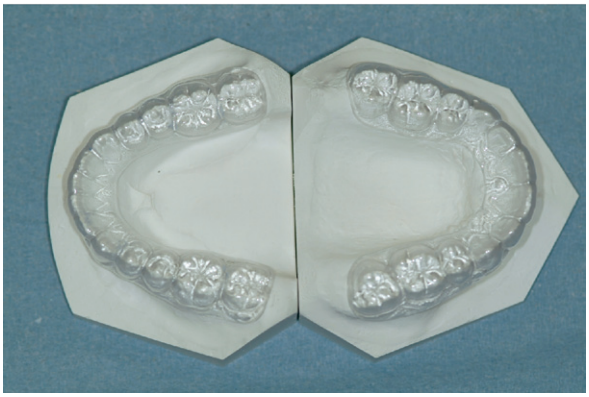

Fig 2. Maxillary and mandibular VFRs.

(Erkodent, Erich Kopp, GmbH, Pfalzgrafenweiler, Germany) 1.5 mm in thickness. The retainer was trimmed to provide 1 to 2 mm buccal and 3 to 4 mm lingual extensions past the gingival margin. All occlusal surfaces were covered up to and including the most distal tooth (Fig 2).

The retainers were fitted by the orthodontist within 1 week after debond. The duration of retainer wear was standardized for each retainer type and was based on the standard protocol for retainer wear in the practice. The patients were instructed to wear the maxillary and mandibular Hawley retainers 24 hours a day for 3 months, including while eating, but to remove them when brushing their teeth. After 3 months, wear time was reduced to 12 hours a day. The patients were instructed to wear the VFRs 24 hours a day for the first week and remove them only for eating and brushing their teeth. After the first week, wear time was reduced to 12 hours a day.

The subjects were reviewed by a member of the research team at 2 intervals; 3 months and 6 months after debond (T2). At the 6-month review appointment,

overjet and overbite were recorded, and alginate impressions for end-of-trial study models were taken. The subjects were asked to remove their retainers before their appointments so that the research team would be blind to the type of retainers that they were wearing.

Orthodontic study models were collected at T1 and T2. The models were examined by 1 researcher (H.R.), who was blind to the subjects' retainer allocation. Casts were excluded from the analysis if they were of poor quality. For example, if there were voids or blebs on the plaster model so that teeth were obscured or if the teeth on the models were fractured or missing, these casts were excuded. The number of models excluded and the reasons for exclusion were documented.

The method used to measure changes in the study models between debond and 6 months was based on the study of Tran et al,[6] in which the LII was measured on 2-dimensional scanned and printed images of study models. In our study, a customized computer program was developed to digitize the printed images of the scanned study models and also to calculate the various outcome parameters.

The analysis of the study models used the following methodology. The heels of the maxillary and mandibular models were trimmed so that all occlusal surfaces of the teeth contacted the glass bed of the scanner. The mesiopalatal/mesiolingual cusp of the molars, the buccal and mesiopalatal/mesiolingual cusps of the premolars, and the canine cusp tips were marked with a pencil. The models were then placed on the glass of the flatbed scanner (Agfa SnapScan 1236 flatbed scanner; Agfa-Gevaert N.V., Mortsel, Belgium), with their occlusal surfaces facing down and in contact with the glass. Each was scanned at a resolution of 600 dpi, and the resulting image was saved to a PC as a JPEG file. The JPEG image was enlarged to 200% by using Paint Shop Pro 9 software (Corel UK Limited, Maidenhead, Berkshire, United Kingdom) to make point identification easier during subsequent digitizing. The image was then printed in color with a laser printer (Fig 3). A total of 34 points were digitized in sequence from point 1 to point 34 by using a GTC digitizer (GTCO CalComp, Columbia, Md) on each printed image of a study model (Fig 4). A computer program, written specifically for the study, automatically calculated the following outcomes in both arches for each digitized image.

1. Tooth rotations mesial to the first permanent molars. The rotation of the incisors and the canines was determined by constructing a line that bisected 2 points per tooth that best marked its rotational angulation (Fig 5). The angle formed by the intersection of this line with the line forming arch depth gave the measurement of rotation of the tooth. Arch depth was defined as the length of a line perpendicular to the intermolar width that passed through the midpoint of the contact points of the central incisors.

   The measurement of rotation for the premolars was calculated by constructing a line that bisected the buccal and the palatal/lingual cusp tips (Fig 6). In premolars with 2 lingual/palatal cusps, the mesiopalatal/mesiolingual cusp was bisected to form the line. The angle formed by the intersection of this line with the line forming arch depth gave the rotation of the tooth.
2. ICW was the distance between canine cusp tips (Fig 7).
3. IMW was the distance between the mesiopalatal/mesiolingual cusps of the first molars (Fig 7).
4. The LII was defined as the sum of the displacements of the 5 contact points of the incisors. The method described by Little[7] used the true anatomic contact point to assess tooth displacements. However, with a printed 2-dimensional image, it was almost impossible to determine the true anatomic

Fig 3. Scanned printed images of dental study models.

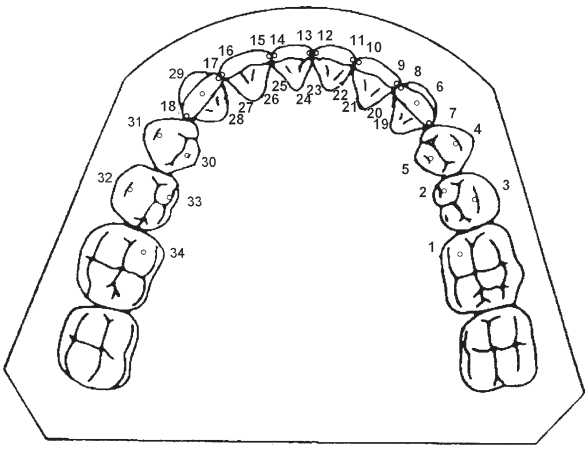

Fig 4. Points digitized: 1, 2, 5, 30, 33, and 34, mesiopalatal cusp tips; 3, 4, 31, and 32, mesiobuccal cusp tips; 6 and 29, canine tips; 7-18, points for angular change; 19-28, contact points.

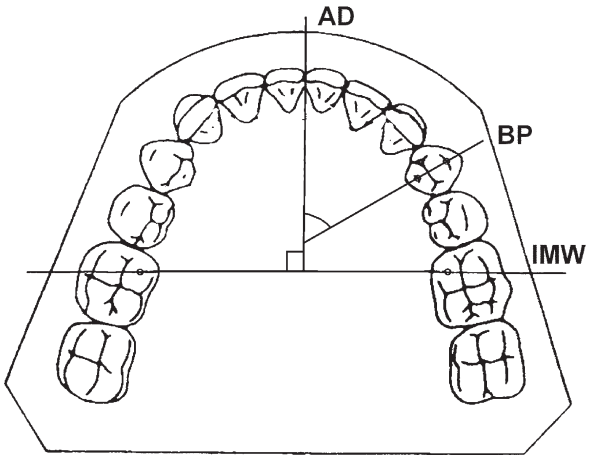

Fig 6. Calculation of premolar rotation (angle B): angle B is formed by the buccal-palatal line (*BP*) with the arch depth (*AD*).

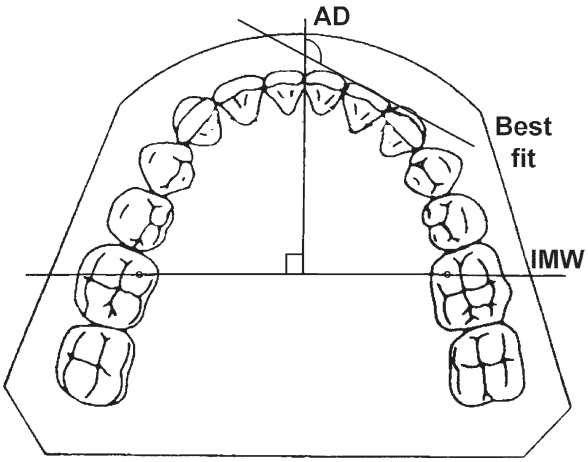

Fig 5. Calculation of incisor rotation (angle A): angle A is formed by the *line of best fit* with the arch depth (*AD*).

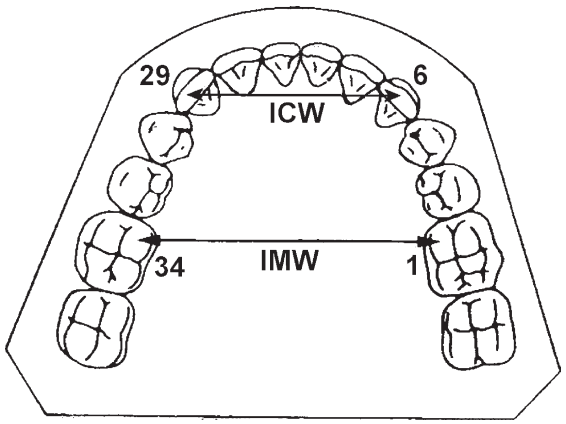

Fig 7. ICW and IMW.

contact point. The LII was therefore redefined for this study as the displacement between the midpoint of the incisor edges.

The digitization of 1 model resulted in creation of a "comma-separated-variable-string" file that enabled the data to be exported electronically into a database (version 13.0; SPSS, Chicago, Ill) for statistical analysis.

To record the reproducibility of the method, 1 examiner (H.R.) made all measurements on 30 models on 2 occasions a week apart. Intraobserver reliability coefficients were then calculated.

An intention-to-treat analysis was used wherever data were available so that the data from all patients who were successfully randomized and for whom baseline and final records were available were included in the analysis. When there were missing values (eg, if models could not be located), the subjects were excluded from the analysis. One member of the research team (L.H.) entered the data into the database.

Relapse amounts for LII, ICW, IMW, tooth rotation, and overjet were determined by comparing the difference between the measurements at T1 and T2. Absolute values for these outcome measures were calculated because any change in either a positive or a negative direction could be considered relapse. The absolute difference was calculated so that positive and negative changes did not cancel each other.

Visual inspection of the histograms showed that the data were considerably skewed and did not follow a

Table IV. Changes in Little's index of irregularity, intercanine width, and intermolar width for the Hawley and the VFR groups

	Hawley	*VFR*	
	Median (interquartile range)	*Median (interquartile range)*	*Mann-Whitney* P *value*
Mandibular measurements			
Intercanine width			
T1	26.22 (25.19-27.56)	26.28 (25.26-27.27)	
T2	26.16 (25.1-27.60)	26.37 (25.36-27.26)	
Change	0.32 (0.12-0.60)	0.28 (0.10-0.49)	.09
Intermolar width			
T1	34.09 (32.09-35.32)	33.84 (32.01-35.41)	
T2	34.20 (32.44-35.78)	33.99 (32.06-35.37)	
Change	0.43 (0.16-0.76)	0.37 (0.16-0.65)	.17
Little's index			
T1	0.50 (0.06-0.90)	0.33 (0.07-0.83)	
T2	1.69 (0.89-2.39)	1.08 (0.40-1.85)	
Change	1.02 (0.38-1.71)	0.46 (0.12-1.22)	<.001
Maxillary measurements			
Intercanine width			
T1	34.29 (32.91-35.73)	34.28 (33.25-35.67)	
T2	34.70 (33.03-36.12)	34.49 (33.5-35.90)	
Change	0.50 (0.22-0.93)	0.44 (0.17-0.73)	.12
Intermolar width			
T1	39.28 (37.14-41.21)	39.79 (37.03-41.13)	
T2	39.44 (37.23-41.41)	39.61 (37.20-41.21)	
Change	0.34 (0.13-0.72)	0.38 (0.16-0.78)	.53
Little's index			
T1	0.06 (0.03-0.57)	0.07 (0.02-0.66)	
T2	0.84 (0.13-1.57)	0.64 (0.06-1.28)	
Change	0.51 (0.05-1.07)	0.26 (0.05-0.70)	.013

normal distribution. The median and the interquartile range were therefore calculated for each outcome at T1 and T2. Mann-Whitney tests were used to compare the Hawley and the VFR groups in terms of the changes between T1 and T2.

Relapse of overbite between T1 and T2 was calculated by first determining the numbers of subjects who stayed the same and whose overbite changed in each group. The differences between the overbite change for both groups were assessed by using the Fisher exact test.

Because of the number of tests performed, a *P* value of .01 was taken to be statistically significant.

RESULTS

Three hundred fifty-five subjects (172 Hawley, 183 VFR) attended for the 6-month review appointment, giving a completion rate of 89%. One hundred fifty-five models were analyzed in the Hawley group and 155 in the VFR group (Fig 8).

Both groups had a median change in overjet between T1 and T2 of 0.5 mm ($P = .24$). In 54 subjects (32%) in the Hawley group and 49 subjects (27%) in the VFR group, a change in overbite was observed at T2 ($P = .32$). Overall, there was no statistically significant difference in overbite between the 2 retainers.

The intraobserver reliability coefficients ranged from 0.96 to 1.0 for linear measurements and from 0.93 to 1.0 for angular measurements, demonstrating that the method had good reliability.

Table IV shows the change in outcome measures between debond and 6 months for ICW, IMW, and LII for both arches. There was no significant difference in the ability of the Hawley and the VFR to retain the dentition in terms of tooth rotation (data not shown), ICW, and IMW. There was greater change in mandibular and maxillary incisor irregularity as measured by the LII in the Hawley group compared with the VFR group. The median changes in the LII over 6 months in the mandibular arch were 1.02 mm (interquartile range, 0.38-1.71) for the Hawley group and 0.46 mm (interquartile range, 0.12-1.22) for the VFR group ($P < .001$). The median changes in the LII over 6 months in the maxillary arch were 0.51 mm (interquartile range, 0.05-1.07) for the Hawley group and 0.26 mm (interquartile range, 0.05-0.7) for the VFR group ($P < .05$). In both groups, there was

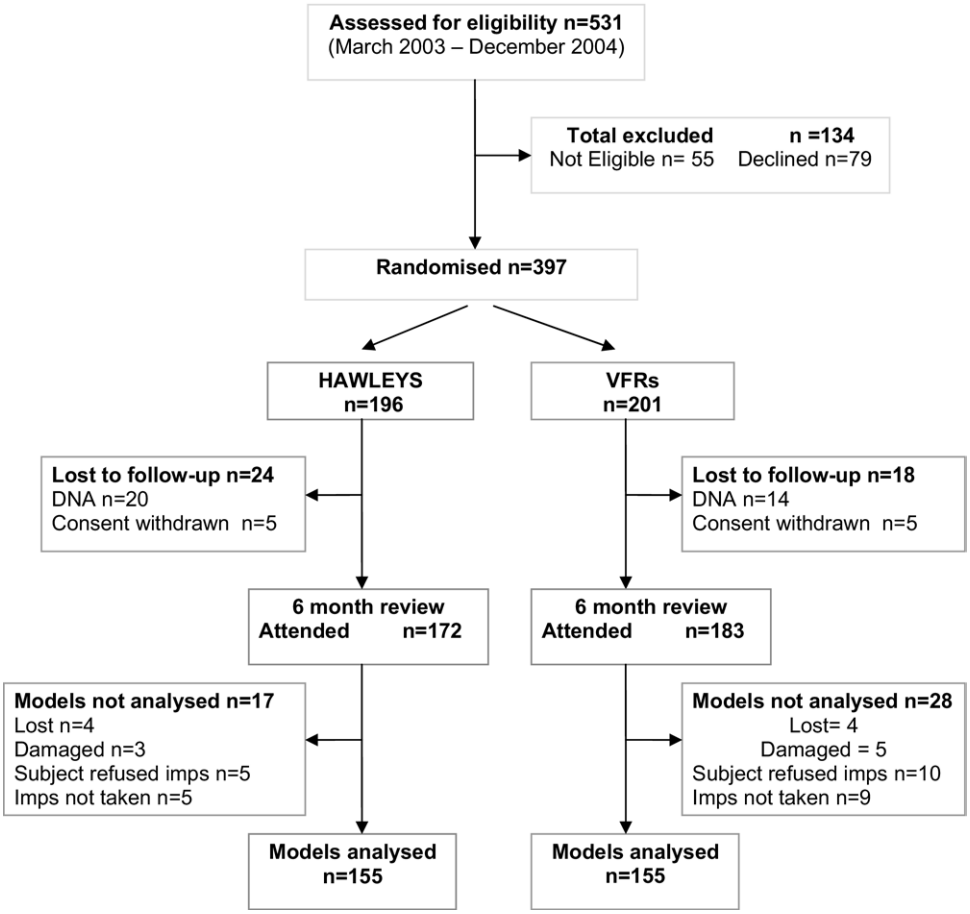

Fig 8. CONSORT flow diagram.

greater irregularity at 6 months in the mandibular labial segment than in the maxillary labial segment.

DISCUSSION

Conducting this study in a practice setting enabled the research team to recruit and randomize 397 patients treated by 1 operator over a relatively short time period (18 months). To date, this is the largest such clinical trial on the effectiveness of the Hawley and the VFR.

In this study, the retainer groups matched favorably for baseline characteristics, and it is therefore likely that the 2 groups were equally matched and that the randomization process worked well.

No statistically significant differences were found in the effectiveness of the Hawley and the VFR to retain tooth rotations, ICW, and IMW in both arches. Anecdotal concerns from clinicians that VFRs lack rigidity and might not support transarch stability were not upheld in this study.

However, a statistically significant difference was found between the retainers in the maintenance of incisor irregularity, because the Hawley group had double the change in irregularity over 6 months compared with the VFR group. These differences were 0.56 mm in the mandibular arch and 0.25 mm in the maxillary arch. Although this difference is unlikely to be clinically significant in the maxillary arch, it might be considered clinically significant in the mandibular arch, particularly if the relapse was located to a single tooth displacement. The results contrast with those of the previous studies comparing the Hawley and the VFR. We found that the VFRs were significantly better at retaining the labial segments than the Hawley retainers. The differences in results from the previous trials might in part be explained by our much larger sample and its considerably greater statistical power. In agreement with the current trial, Lindauer and Shoff[3] found more irregularity in both arches in the Hawley group compared with the VFR group, although this did not

reach statistical significance. We also found greater irregularity in the mandibular labial segment compared with the maxillary labial segment. With regard to long-term occlusal changes, this follows the trend that irregularity is most marked in the mandibular labial segment.[8,9]

This study can perhaps be criticized for using 2 retainer wear regimens. However, the protocols were chosen to match the wear regimens already in place at the practice. An advantage of conducting a trial in this manner is that the findings should be more representative of what occurs in everyday clinical practice, measuring effectiveness rather than efficacy. It is generally recognized in the literature that there is no universal agreement regarding retention regimens and that wide variations in retention protocols exist among clinicians.[10] Although the Hawley retainers were worn full time for a longer period than the VFRs in this study, the latter were still more effective in maintaining incisor alignment, particularly in the mandibular arch. It could perhaps be argued that if relapse of incisor position is truly to be minimized, then consideration should be given to the use of a bonded retainer. However, a recent Cochrane review examining a number of aspects of retention, including removable vs fixed retention, found the quality of the studies to be poor, and there is as yet no reliable evidence that fixed retainers are more effective than VFRs.[11]

If there is little difference in the clinical effectiveness between the 2, questions could arise as to whether any other factors might influence the choice of retainer, including cost, ease of fabrication, risk of breakage, patient compliance, and patient preference or satisfaction. The answers to these questions will be addressed in a parallel study. Each patient should, however, be assessed individually because Hawley retainers still offer the additional benefit of allowing superior vertical setting compared with VFRs.[4]

CONCLUSIONS

The results of this study suggest that VFRs are more effective than Hawley retainers at holding corrections of the maxillary and mandibular labial segments. This is likely to be clinically significant only in the mandibular arch if located to a single tooth displacement. In addition, this trial supports the need for further research in primary care.

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