Relapse in Modified Vacuum-Formed and Hawley Retainers for Transverse Expansion A Multicenter Randomized Control Trial

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Abstract

In order to minimize relapse and maintain arch form, several retention devices have been used after orthodontic treatment. To date, Hawley retainers (HRs) are more commonly used in orthodontic retention where expanded arch stabilization is needed. However, there is a notable paucity of high-quality studies comparing the effectiveness of HRs and modified vacuum-formed retainers (mVFRs).

This study aimed to compare the clinical effectiveness of HRs and mVFRs with palatal coverage in maintaining transverse expansion over a 6-month period.

This is a multicenter randomized controlled trial study. Post-orthodontic treatment patients from the Orthodontic Unit of Universiti Kebangsaan Malaysia (UKM), Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik Klang and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua Kajang, who met the inclusion criteria were invited to participate. Inclusion criteria were 13 years old or greater, existing pre-treatment model and >3 mm arch width expansion in the upper arch. Subjects were randomly allocated by using a centralized randomization technique into two groups: mVFR group and HR group. Dental casts of subjects were assessed at debond (T0), 3-month (T1), and 6-month (T2) post-debond. The intercanine width (ICW), interpremolar width (IPMW), first molar intermesiobuccal cusp width (FIMBCW) and first molar interdistobuccal cusp width (FIDBCW) were compared between groups over time by using Mixed ANOVA.

No statistically significant differences were found between the two retainer groups at ICW (P=.60), IPMW (P=.26), FIMBCW (P=.06) and FIDBCW (P=.24) during the 6-month retention period.

There were no significant differences in degree on relapse between the HR and mVFR over a 6-month retention period.

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Introduction

Orthodontic relapse is defined as the tendency of the teeth to return to the original pre-treatment position, which usually occurs in the lower labial segment teeth[1]. It is an unfortunate event of post-orthodontic treatment. A number of long term studies showed that relapse occurs in approximately 70% of the cases following orthodontic treatment[2,3]. Relapse may be the result of normal age-related consequences and orthodontic factors which include gingival factor and soft tissue pressure. Although specific predictors for relapse are yet to be discovered, some natural remedies have found to be effective in reducing orthodontic relapse in animal laboratory studies[4,5].

A recent Cochrane review has produced a very good summary and update of all the different types of retainers[6]. There were moderate quality studies with evidence supporting the equivalence of effectiveness in

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maintaining arch width between Hawley retainers (HRs) and vacuum-formed retainers (VFRs). In terms of transverse expansion, a HR has been indicated to have greater stability due to its rigidity[7]. In terms of material, methyl methacrylate is more durable than vacuum-formed polyurethane material. However, VFRs are more esthetic[8], cheaper[9] and easier to fabricate[10] when compared to HRs. In addition, the previous controlled trials did not focus on transverse expansion cases. Modified vacuum-formed retainers (mVFRs) which are effective for maintaining palatal expansion have been described[11]. The use of this mVFR was shown to be as effective as other methods of retention[12,13]. However, the majority of the studies compared the mVFRs with a fixed bonded retainer but did not compare the mVFRs with HRs. The cases selected were also Class 1 cases with normal anteroposterior and transverse skeletal dimensions, while our study would focus on patients with the expanded arch.

The mVFRs described requiring a wire outlining the cementoenamel junction of the teeth palatally[11]. This technique requires great experience from technicians, requires more laboratory time and costly in terms of labor. Hence, a simple mVFR was proposed in which the difference between the conventional VFR was that mVFR has extended palatal coverage. This version of mVFR requires the dental technician to outline and trim the retainers, where it covers the entire hard palate until the mesial of upper second molars.

Specific objective

The aim of the current randomized controlled trial was to compare the degree of relapse in expansion cases of mVFRs and HRs by measuring maxillary arch width changes over a 6-month period.

Materials and methods

Trial design

This trial was designed as a two-arm parallel prospective randomized controlled trial with a 1:1 allocation ratio. The study was approved by UKM Research and Ethics Committee (UKMREC), National Medical Research and Ethics Committee (NMREC) and registered with ClinicalTrials.gov. There were no changes to the methods after trial commencement.

Settings, subjects' recruitment and eligibility criteria

This study was a multicenter trial that was conducted in the Orthodontic Unit of Universiti Kebangsaan Malaysia (UKM), Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik Klang and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua Kajang from August 2019 to January 2020. All orthodontic patients were screened at debond. Patients who fulfilled the inclusion criteria were invited to participate in the study. The following inclusion criteria were met:

- Aged thirteen years or older at the time of debond
- Existing pre-treatment model
- More than 3 mm arch width expansion in the upper arch when comparing the arch width differences measured at the completion of active treatment (debond) to pre-treatment study model

An information sheet was given to each patient and further explanation regarding the study was given by the researcher. Subsequently, written informed consent was obtained from patients who agreed to participate in the study.

Interventions

Following informed consent, subjects were randomly allocated into two groups, and they were given either:

(a) An upper removable HR
(b) An upper removable mVFR covering the palate.

Figure 1. Hawley retainer used in the study.

Lower retainers were decided by the orthodontists. The HRs and mVFRs were constructed as shown in Figure 1 and Figure 2. All retainers were fitted within 24 hours of debond. Subjects were instructed to wear the retainers full time for 6 months.

Figure 2. Modified vacuum-formed retainer with palatal coverage used in the study.

They were asked to remove their retainers only when cleaning, drinking or eating. Verbal instructions about the possible consequences of not complying with retainers were explained to the subjects upon fitting.

Outcomes

Upper impressions were taken and dental casts were measured on three occasions:

(a) At debond and retainers were fitted (T0)
(b) 3-month retention (T1)
(c) 6-month retention (T2)

Data collection was performed by an independent researcher (LX) with a Tuten electronic digital caliper (CSM Engineering Hardware (M) Sdn. Bhd, MY) to a precision of 0.01 mm. The following linear arch width measurements were made on each dental cast:

- Intercanine width (ICW) in the maxilla- the distance between the canine cusp tips
- Interpremolar width (IPMW) in the maxilla- the distance between the premolar cusp tips
- First intermolar width (FIMW) in the maxilla- the distance between the mesiobuccal (FIMBCW) and distobuccal cusp (FIDBCW) tips of the first molars.

There were no changes to the trial outcomes after trial commencement.

Method errors

Systematic error

The digital caliper was calibrated to zero every time before the measurement was made.

Random error

To assess the reproducibility and consistency of the researcher, 20 dental casts were randomly selected and measured. The average of three measurements was taken for every point of measurement. If one reading was out of the other two readings, then it would need to be repeated. These dental casts were re-measured after 1 month. Intra-class-correlation coefficient (ICC) was employed to assess intra-rater reliability or random error.

Sample size

The sample size was determined based on the previous study done by Tynelius et al.[13] with a significant level of 0.05 and 80% power to detect a clinically meaningful difference of 2.0 mm, standard deviation (SD=2.0 mm) between the two groups in terms of arch width difference. The power analysis gave a total sample size of 16 subjects in each group. To account for attrition, a total of 35 subjects were recruited.

Interim analyses and stopping guidelines

Interim analyses and stopping guidelines were not applied in this trial.

Randomization, allocation concealment mechanism and implementation

The generation of randomization sequence was performed in blocks of 16 to ensure that an equal number of subjects were allocated to each of the two retention groups: (a) HR group (b) mVFR group. A randomized generator was used for allocation. The randomization sequence was generated by an independent researcher (KE) who also acted as a central method center. In this multicenter trial, a centralized randomization technique that incorporated external involvement was employed. Co-researchers or clinicians at-site recruited eligible subjects and contacted the center of a central method by phone after patients agreed to participate as a subject in order to prevent selection bias and protect the assignment sequence until allocation. The materials used for fabrication of mVFRs and HRs at the three dental laboratories were standardized: (a) Essix plastic sheet 0.40″ (1

mm) (Dentsply Raintree Essix, Sarasota, USA), (b) Acrylic resin (Scheu-Dental, Iserlohn, GER), (c) Alginate (Major Prodotti Dentari S.p.A., Moncalieri, ITL), (d) Yellow stone (Samwoo Co Ltd, Ulsan, KR), (e) Stainless steel wire Chromium Coil 0.70 mm (Scheu-Dental, Iserlohn, GER). The technicians involved were also trained to ensure the standardized design of the retainers.

Blinding

In order to achieve blinding, each dental cast with an identity document was measured by a calibrated researcher who was blinded to the retention regime provided to each subject. Subjects' identity number on dental casts was covered with an opaque tape by the technicians once they were ready for measurement. Only one dental cast at a time was picked out of its box without showing any previous measurements or retainer being assigned. Two dental casts from the same subjects were not measured in connection with each other. Due to the prospective nature of the study, it was inconvenient to anonymize dental casts from the start of the study. Clinicians, dental surgery assistants and subjects were also not feasible to be blinded in this trial.

Statistical methods

Descriptive and inferential statistics were performed by using Statistical Package for Social Sciences (version 24.0, International Business Machines Corporation, Armonk, NY). ICC was used to assess intra-rater reliability. The normal distribution of data was confirmed by the Shapiro-Wilk test (*P*>.05). The mean arch width changes over time between retention regime groups over the follow-up period were evaluated by using Mixed ANOVA. Significant level was set at 0.05. Intention-to-treat (ITT) analysis was performed for lost to follow-up subjects.

Results

Participants flow

A CONSORT flow diagram of enrollment, allocation, follow-up and analysis was given in Figure 3. From the screened 274 patients, only 35 patients fulfilled the inclusion criteria. There were 239 patients who were not eligible due to the following reasons: 225 had inadequate expansion, ten had no pre-treatment model and four had special conditions where randomized retainers were not suitable. One patient declined to participate in the study.

Baseline data

The age and gender distributions between groups were similar and showed no significant differences (P>.05) (Table 1).

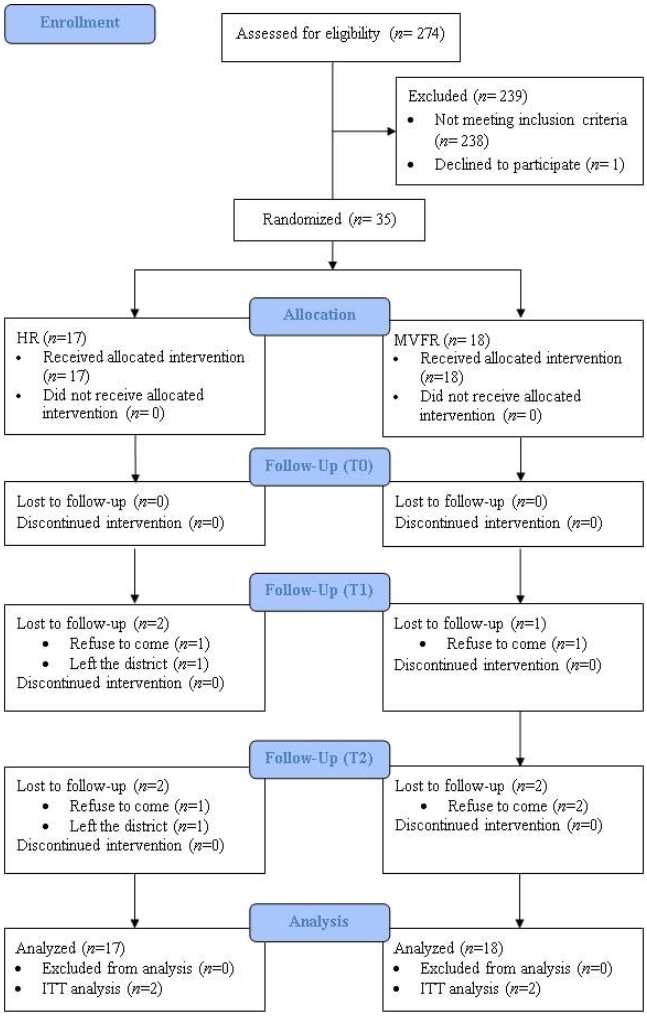

Figure 3. CONSORT participant flow diagram.

Variable	HR group (*n*=17)	mVFR group (*n*=18)	Total (*n*=35)	*P*-value
Age at debond (mean ± SD)	21.88 ± 4.12	22.06 ± 5.88	21.97 ± 5.03	.92
Gender: *n* (%)				.56
Male	5 (29%)	7 (39%)	12 (34%)	
Female	12 (71%)	11 (61%)	23 (66%)	

Table 1. Mean ± Standard deviation (SD) of age at debond and gender distribution of subjects in Hawley (HR) and modified vacuum-formed retainer (mVFR) groups.

Error of method

Intraclass correlation coefficient scored over

100% in the arch width measurements, indicating excellent consistency (Table 2).

ICC	95% Confidence interval		*P*-value	
	Upper bound	Lower bound		
1.00	1.00	1.00	<.001	HS

Table 2. Intra-class correlation coefficient (ICC) in the arch width measurements (n=20)
*HS= Highly significant [1]

Transarch stability for HR and mVFR

Table 3 presented the mean and standard deviations of arch width changes of HR and mVFR groups at three assessment time points. There were no statistically significant differences between the two retainers group over the retention period at ICW, IPMW, FIMBCW and FIDBCW (*P*=.60, .26, .06, .24). The largest change between baseline and the final assessment was observed in mVFR group with a decreased mean FIMBCW from 53.35 mm to 53.01 mm. All mean arch widths in both groups tended to decrease over the study period except the mean IMW in HR group where both FIMBCW and FIDBCW increased between T0-T1 and deceased between T1-T2.

	HR group	mVFR group	
	Mean ±SD (mm)	Mean ±SD (mm)	Mixed ANOVA *P*-value* (Interaction effect)
Maxillary measurements			
ICW			.60
T0	37.20±2.46	38.04±2.00	
T1	37.17±2.57	37.93±2.02	
T2	37.05±2.54	37.79±1.92	
IPMW			.26
T0	45.39±1.88	47.10±1.84	
T1	45.35±1.89	46.86±1.91	
T2	45.25±1.94	46.77±2.08	
FIMBCW			.06
T0	51.16±1.73	53.35±2.29	
T1	51.31±1.67	53.15±2.35	
T2	51.16±1.79	53.01±2.43	
FIDBCW			.24
T0	52.34±2.09	54.26±2.56	
T1	52.49±2.16	54.20±2.70	
T2	52.27±2.15	54.11±2.76	

Table 3. Mean ± Standard deviation (SD) of intercanine width (ICW), interpremolar width (IPMW), first molar intermesiobuccal cusp width (FIMBCW) and first molar interdistobuccal cusp width (FIDBCW) for Hawley (HR), modified vacuum-formed retainer (mVFR) groups and P-value of Mixed ANOVA test
*Level of significance set at 0.05 [1]

The failure of retainers could be summarized as loss of retainers (6% in HR group versus 0% in mVFR group) and breakage of retainers (6% in HR group versus 22% in mVFR group).

Harms

No harm was reported in this trial.

Discussion

Main findings

Retention and relapse are the major challenges for clinicians in orthodontic treatment. The results in this trial revealed that both mVFR and HR were equally effective in their stability for the expanded arch over a 6-month retention period. The recent idea has been suggested that the indefinite wearing of removable retainers is necessary in order to reduce relapse[6,14–17].

In cases of which expanded arch is involved, HR is indicated to be superior to a normal VFR in maintaining the treatment result[7]. The present study is the first to compare the effectiveness in maintaining the expansion of a mVFR versus the standard retention regime, HR although this mVFR has been introduced in the previous studies[13]. Hence, no direct comparison can be made with previous studies.

To account for attrition, more subjects were recruited in this study. The dropout rate of 0%, 9%, 11% at T0, T1 and T2 respectively in the present study may have slightly biased the results, however subjects' dropout in a follow-up trial is highly anticipated according to previous studies[13,18]. Some authors suggested that >95% follow-up rate leads to little bias while <80% causes a serious threat to validity and others suggested 80% should be the minimum acceptable follow-up rate[19]. Nevertheless, this trial has achieved at least 89% of the follow-up rate at each time point. A few steps were carried out in this present study to minimize the dropout rate and optimize subjects' compliance with retainer wear. One of the steps undertaken was by using ITT analysis to predict the missing outcomes which not only helped to preserve the randomization sequence until allocation but also helped to preserve the sample size. Furthermore, text message reminders were sent to remind subjects of follow-up review appointment and adhering to retainer wear instruction provided by clinicians. Study showed that text message reminder system was effective for improving oral

hygiene compliance, we expected this finding might apply equally well to retainer wear[20].

However, we believed that any non-compliance might indicate other significant aspects relating to the retainers such as durability and comfort which would need further investigation. As shown in Table 1, The age and gender of this study were evenly distributed which indicated that this study did take benefit from a randomized controlled trial design where the potential confounding factors were evenly distributed among retainer groups and pre-treatment equivalence was ensured.

The present study evaluated the effectiveness of HR versus mVFR covering the palate among patients who had undergone expansion (≥3mm) during treatment either with quad helix, rapid maxillary expansion, removable appliances with midline screw or by archwires. By taking the largest value among the measurement points, there was an average 6.52 mm arch width of dentoalveolar expansion at either ICW, IPMW or FIMW. Any changes in the arch widths from debond to follow-up stage was considered a relapse. Overall, there were no significant variations between retainer groups in terms of baseline data. Thus, it was believed that the results were not influenced by the age and gender of subjects. The mean ICW, IPMW and FIMW reduced over the study period regardless of retention regime. This could be explained by relapse following orthodontic treatment where the arch widths were expanded and reverted back their original position. Another possible reason was due to age-related changes[21–23]. Table 3 showed that all mean arch widths in both groups decreased over the retention period except FIMW in the HR group which increased at T1 and decreased at T2. It could be believed the consistent increase of mean IMW between T0-T1 was not solely due to measuring error since both measuring points of first molar tooth, FIMBCW and FIDBCW showed a similar pattern of changes over follow-up stages. This might be attributed to the presence of clasps in HR. The insertion and removal of the retainer may slightly tip the molar buccally. It is believed that initially, Adam's clasps were usually more tightly fitted, and this may cause the molar tooth to displace buccally and reverted back to the values closer to T0. Clasps over the molars become looser over time and could explain the values that reduced consistent with other teeth. However, the changes were not statistically significant either between retainer groups or between time points.

The main outcomes of the present study suggested that there were no statistically significant differences between retainer groups in all arch width mean changes over the 6-month follow-up period (Table 3). The finding is consistent with the previous studies[24–28] which also found that over the retention period, there were no significant differences of ICW and IMW in normal VFR without palatal coverage and HR groups, however these were not in expansion cases. In the present study, mVFR with palatal coverage was investigated. These findings indicated that mVFR could maintain arch expansion as effective as a HR. One explanation could be the extended palatal coverage of the mVFR which mimics a HR. Despite a popular view among orthodontists suggesting that HR has better transarch stability in the maxilla[7], the present study added to the latest evidence that showed mVFR with extended palatal coverage was just as effective, and could be a more cost-effective[29] alternative of HR for patients where expanded arch stabilization is needed, especially in cases with time constraints. Since relapse followed by orthodontic treatment is found less likely to be affected by retainer choice between mVFR and HR, or group of patients with transverse expansion, other factors such as esthetic durability, the cost might be more important to consider when deciding the type of the retainer to be fitted. As recorded, there were higher numbers of breakages in mVFR group than HR. This might due to the more durable acrylic material in HR. Findings were consistent with the study by Saleh et al.[30] however contradicted the study by Hichens et al. which found that HRs are more likely to break[29]. No subject lost their retainers in mVFR group and only one subject found to have lost the HR.

Limitations

After orthodontic treatment, the responsibility of complying with retainer wear to maintain the treatment result falls on patients and it was out of control of the clinicians. Although verbal instruction was given by clinicians during every follow-up visit and text message reminders were sent to subjects every month, subjects' compliance was still unpredictable. The incorporation of an electronic device can document the time of retainer wear objectively but it was not implemented in this study because

the Hawthorne effect is highly anticipated where patients change their behavior in response to their awareness of being observed. On the other hand, self-reporting compliance may also not be accurate and the introduction of bias was expected. Certain studies assess compliance by relying on instructions given by clinicians which reflects the real-life scenario. Therefore results of studies involving retainer compliance need to take these limitations into consideration. There could also potentially be the variability of the quality of the retainers depending on the skill of the dental technologists in the different centers, especially in the construction of HRs as they require more technical skill and labor. The short follow-up period and small sample size may be another drawbacks. Since relapse happens over a period of time after treatment, future studies with a longer follow-up period are warranted.

Generalizability

The present study was undertaken in multicenter, the generalizability of these findings is considered well. Random allocation ensured each subject had an equal chance of being placed in any group. Thus, any differences between and within the groups which could be the potential confounding variables were distributed evenly between two groups.

Conclusions

No statistically significant interaction was found between the two retainer groups (HR and mVFR) over a 6-month retention time. Therefore, mVFR could be an equally effective alternative to HR for maintaining maxillary arch expansion.

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Declaration of Interest

The authors do not have any conflict of interest to declare.

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