RESEARCH PROPOSAL

Comparison of relapse arch width in modified vacuum formed retainers covering the palate versus Hawley retainer – A prospective randomized control trial

Grant code: GGPM-2018-049
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1.0 EXECUTIVE SUMMARY

Relapse is inevitable in orthodontic treatment. Teeth will want to return to their original position after fixed appliances are removed. Regardless with or without fixed appliances, changes and physiological relapse will still occur due to time and age changes. This is why retention is a crucial part in orthodontic treatment, where it would aim to maintain the corrections achieved after orthodontic treatment.

Literature regarding retainers is quite substantial, where a recent Cochrane review was published comparing the different types of retainers. However, evidence is lacking in terms of comparison of arch width relapse between modified vacuum formed retainers and Hawley retainers specifically in expansion cases.

This study aims to compare the relapse in arch width in expansion cases with modified vacuum formed retainers with palatal coverage versus Hawley type retainers in Unit Ortodontik Universiti Kebangsaan Malaysia (UKM), Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua patients. Although other types of modified vacuum formed retainers effective for maintaining palatal expansion have been described, these retainers require a wire outlining the Cementoenamel junction of the teeth palatally. This technique requires experience of the technician, is at a higher cost and requires more lab time. The modified retainer that we described in this study would be as efficient and as quick as the normal vacuum formed retainers, which would usually take a couple of hours to make (same day or next day fit). The present practice at all 3 locations constructs Hawley and normal VFR retainers for all orthodontic patients. There are technicians and laboratory facilities to construct normal VFR as well as Hawley retainer. The only difference between modified and normal vacuum formed retainer is the outline of the retainers where the technician would trim the retainer, where it would cover the hard palate. Therefore it is only the location of trimming that is different using the same special trimming appliances for normal VFRs.

A number of subjects who fulfil the criteria will be invited to participate in this study. The study will involve arch width analysis using study models pre, post-debond, 3 months review post-debond, 6 months review post-debond and 12 months review post-debond. All data will be analyses using Statistical Package for Social Sciences (SPSS). The arch width of subjects post-fixed appliances will be compared. Most studies compare the arch width, as well as lower incisor irregularity in evaluating relapse in different groups of retainers. However, there are currently no randomized control trials comparing expansion cases of Hawley vs vacuum formed retainers, hence why this study will be conducted.

We expect to see no difference between the modified vacuum formed retainer and Hawley retainer in terms of maintaining arch expansion post-orthodontic treatment. This would therefore mean that there would be a simpler method and would be a suitable more cost-effective alternative as compared to constructing Hawley retainers or adding a palatal wire on the vacuum formed retainers.

2.0 INTRODUCTION

Relapse is an unfortunate event post-orthodontic treatment. Around 70% of patients post-orthodontic treatment are subjected to relapse (1,2). Patients usually talk about retention in a negative light in social media(3), where the main themes expressed included compliance, impact, maintenance, patient-clinician relationship, and positive and negative feelings. It is therefore important to ensure that the retention regime is effective and convenient for the patient.

Arch expansion is a common modality of treatment in correcting posterior crossbites. Methods of expansion often used in removable/fixed appliances would include archwire expansion, quadhelix, rapid maxillary expansion or removable appliances with a midline screw. Surgical methods have also been described (SARPE- Surgical Assisted Rapid Palatal Expansion) for severe cases. Expansion of the arches is considered very unstable and prone to 40% of relapse, regardless of any type of expansion, and this is mostly due to post-treatment growth pattern of the patient (4,5).

There are various methods of retention, and a recent Cochrane review (6) has produced a very good summary and update of all the different types of retainers. In terms of expansion, a Hawley type retainer was indicated to be the best type of retainer to maintain expansion. In terms of material, acrylic is more durable than vacuum formed polyeurethane material, which explains the property. There is limited evidence comparing the relapse in expansion between these two methods. This is mainly due to the fact that there is acrylic coverage of the palatal surfaces, as compared with a vacuum formed retainer where the coverage only extends a few millimetres beyond the cement-enamel junction of the palatal surfaces of the teeth. A modified vacuum formed retainer was described where the vacuum formed retainer was extended for palatal coverage, which in theory could maintain expansion better. Different versions of this modified retainer were described (7). The only difference in constructing the retainers would be the outline where the technician would trim the retainer, where it would cover the hard palate. **The use of this modified vacuum formed retainer was shown to be as effective as other methods of retention such as fixed bonded retainer (8)(9). The systematic review by Littlewood also showed that the normal vacuum formed retainer to be as effective as other retainers in terms of maintaining the inter-arch width (6**). However, the cases selected were normal Class 1 cases with normal antero-posterior and transverse skeletal dimensions, where our study would focus on expansion cases as the main subjects. Even with the robust evidence showing the strength of the vacuum formed retainer, clinicians in general still use the Hawley retainer in expansion cases with no existing clinical trial evaluating its effectiveness. However in the United Kingdom, there have been noted usage of this modified vacuum formed retainer in expansion cases, especially in emergency situations where retainers need to be made quickly.

Therefore, this study will focus on the relapse of arch width in two types of retention regimes, which are modified vacuum formed retainers and Hawley type retainers in patients after fixed appliance treatment. This will subsequently be of valuable information for clinicians in choosing the appropriate type of retainers after removal of their fixed appliances. This is because the modified vacuum formed retainers will be significantly

cheaper, quicker and easier to fabricate. There is a small risk of relapse using the modified vacuum formed retainers in expansion cases, however as mentioned earlier a lot of studies show good maintenance of arch width in normal cases (6)(8)(9). If relapse does occur, we anticipate that it will be minimal and a new retainer or retreatment can commence to easily rectify the situation as the patients are reviewed every 3 months. Other advantage is that most patients would prefer the appearance of vacuum formed retainers and superiority in terms of incisor alignment (6)(10). Literature showed that 40%-60% of allergic reaction was caused by formaldehyde (11). Formaldehyde may be released from methacrylate-based dental materials, such as composites and denture bases (12). An vitro study reported that there was minimal leaching of formaldehyde from thermoplastic materials (e.g. VFRs) while it was found higher leaching from poly-methyl methacrylate (PMMA) based orthodontic materials of the powder and liquid type (e.g. Hawley retainers) (13). Up to date, there is no reported case of sensitivity and contact allergy to VFRs while there was reported case of oral lesion in patient with Hawley retainer (14).

Hawley retainer		
Characteristics	**Benefits**	**Risks**
Clasps and wires anchored in a relatively thick plastic body	Personal opinion: suggested retainer to maintain expansion (Blake & Garvey 1998) compared with *normal VFR* (not modified)	More likely to break (Hichens et al. 2007)
Steel wire run across front teeth	More durable from patients' perception (Saleh et al. 2017)	Higher cost (Hichens et al. 2007)
		Require greater man power (Hichens et al. 2007)
		More difficult to fabricate (Saleh et al. 2017)
		Less aesthetic (Saleh et al. 2017)
		Heavier (Saleh et al. 2017)

Normal & Modified vacuum-formed retainer		
Characteristics	**Benefits**	**Risks**
Made up of thin and strong copolyester plastic sheets	Low cost (Hichens et al. 2007)	Less durable from patients' perception (Saleh et al. 2017) – *Normal VFRs*
Transparent	Easy to fabricate (Hichens et al. 2007) Require less man power (Hichens et al. 2007) More aesthetic (Saleh et al. 2017) Lighter (Saleh et al. 2017) Less likely to break (Hichens et al. 2007)	

Blake, M. & Garvey, M. T. 1998. Rationale for retention following orthodontic treatment. *Journal of the Canadian Dental Association* 64(9): 640–643. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9812432

Hichens, L., Rowland, H., Williams, A., Hollinghurst, S., Ewings, P., Clark, S., Ireland, A., et al. 2007. Cost-effectiveness and patient satisfaction: Hawley and vacuum-formed retainers. *The European Journal of Orthodontics* 29(4): 372–378. doi:10.1093/ejo/cjm039

Saleh, M., Hajeer, M. Y. & Muessig, D. 2017. Acceptability comparison between Hawley retainers and vacuum-formed retainers in orthodontic adult patients: A single-centre, randomized controlled trial. *European Journal of Orthodontics* 39(4): 453–461. doi:10.1093/ejo/cjx024

3.0 HYPOTHESIS

There is a difference in the degree of relapse in terms of relapse of arch expansion between Modified Vacuum formed retainers and Hawley retainers.

NULL HYPOTHESIS

There is no difference in the degree of relapse in terms of arch expansion between Modified Vacuum formed retainers and Hawley retainers.

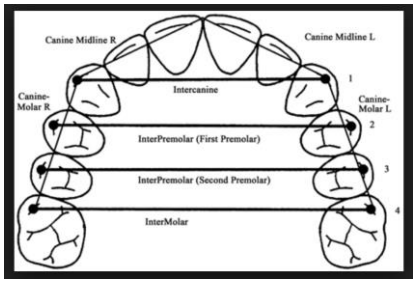
4.0 AIMS AND OBJECTIVES

To measure the effectiveness of two different retainers in maintaining arch width post orthodontic treatment:

i) Modified vacuum formed retainers
ii) Hawley retainers

Measurement in terms of:

i) Canine arch width
ii) Premolar arch width
iii) Molar arch width



5.0 METHODOLOGY

5.1 Participants Sampling

The sample will be selected from patients attending for orthodontic debond appointments at the Orthodontic Unit of Universiti Kebangsaan Malaysia (UKM), Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua patients. The present practice at all 3 locations constructs Hawley and normal VFR retainers for all orthodontic patients. There are technicians and laboratory facilities to construct normal VFR as well as Hawley retainer. The only difference between modified and normal vacuum formed retainer is the outline of the retainers where the technician would trim the retainer, where it would cover the hard palate. Therefore it is only the location of trimming that is different using the same special trimming appliances for normal VFRs. Clinicians from KKM involved would be Dr Malathi Deva Tata and Dr Yeoh Chiew Kit. A screening will be done to select patients who are suitable of the study. Only patients who fulfil the criteria will be invited to participate in this study. Participant will be approached in the dental chair once deemed suitable, and will be given 5-10 minutes to decide on participation of the study. Consent will be gathered from the patients or the carer if the patient is below 18 years of age. The patients will then be randomly allocated into two groups using a randomized number computer generator, either the Hawley or the modified vacuumed formed retainers. The expected sample size to be of statistical significance will be calculated using the formula of sample size calculation relevant to this study. The sample size

calculation is based on a significance level of 0.05 and 80 percent power to detach a clinically meaningful difference of 2.0mm (SD=2.0mm) between the two groups in terms of arch width differences, where this difference are based on previous studies by Tynelius et al. (9) and Shawesh et al. (15). The power analysis gave a total sample size of 16 patients in each group. To account for attrition, 24 patients will be recruited in each group

The inclusion criteria of the subjects that will be included in the study are:

a. Patients who are at least 13 years old at time of debond.
b. Treatment plan of extraction or non-extraction followed by straight wire appliances in the upper arch only or both arches
c. Undergone expansion treatment in the upper arch causing an arch width increase of 3-10mm, either using a Quadhelix, Rapid Maxillary Expansion, expansion with archwires, or URA with midline screw. Patients' interarch measurements at the time of debond will be compared with their interarch measurements using the pre-treatment model available at the clinic.
d. No chronic medical conditions

The criteria for suspending or terminating the study are:

a. Relapse due to compliance issue
b. Relapse due to investigative product
c. Subject did not come for follow-up

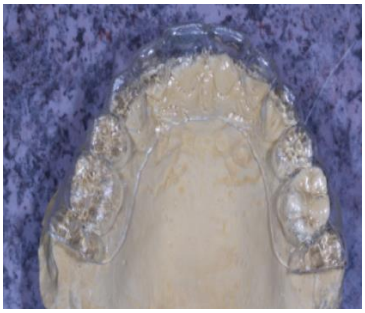
The subject withdrawal criteria are:

a. Voluntary

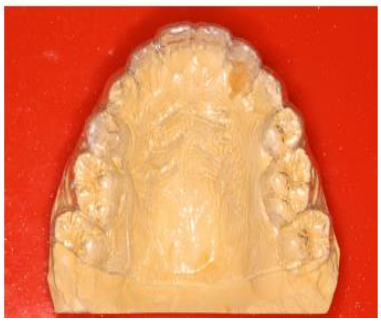
If relapse is found and/or if subjects request to withdraw from the study, subjects will be informed that they will not need to take impressions at follow-up but they still can make appointment with their orthodontist for a normal retainer review. If insignificant relapse is found, new Hawley retainers will be provided free of charge. If significant relapse is found in subjects from intervention group, free treatment will be provided. The withdrawn subjects will not be replaced and an Intention to Treat analysis (ITT) will be done.

The generation of randomization sequence will be performed in blocks of 12 to ensure that equal number of patients was allocated to each of the two retention groups. A randomized generator will be used for allocation. In this multi-centre trial, a centralized randomization technique which incorporated external involvement is used. Individuals who recruit subjects from each centre will contact a central methods centre by phone after patient enrolled in order to prevent selection bias and protect the assignment sequence until allocation. Calibrated researcher will collect the study models which the ID and intervention are covered by opaque tape once they are ready for measurement. Only one dental cast at a time will be picked out of its box without showing any previous measurements. Two dental casts from the same patient will not be 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.

Hawley retainer



Normal VFR retainer



Modified VFR (palatal coverage)

5.2 Study design

This is a prospective randomised controlled trial to evaluate the differences in relapse after expansion treatment between a Hawley and a modified vacuum formed retainer.

The study will involve:

a. **Clinical**: An upper and lower impression with alginate will be taken for dental cast and retainer construction. **This procedure is a normal procedure done in all orthodontic appointments upon removal of fixed appliances.** However one extra upper impression will be taken for the research. It will take approximately 5-10 minutes. All retention appliances will be distributed within 24 hours after debonding. The retainers will be washed under tap water before delivering to the patient. When subjects are given the retainers, clinicians will provide post-debond instructions, where the patient has to wear the retainers for 24 hours except during eating and brushing their teeth. Researcher will send reminders of wearing retainer in 1-month interval to ensure they are following the instructions and to enquire if they have any problems. The patients will be instructed to wear the retainers for 24 hours for the next 6 months and night-time only for month 7 to month 12. At a 3 month and 6 month follow-up, an upper alginate impression will be taken for a dental cast construction at each follow-up visit. Clinical examination will allow clinician to detect relapse which is by examining the arch width.The whole duration of participation of each patient may total up to 40 minutes overall. If any unknown allergic reaction to alginate impression occurs, the procedure will be terminated immediately and appropriate first aid action will be given to participant, however these will most likely be anticipated as these subjects have had impressions taken at the start of treatment.

b. **Data Measurement**: Dental casts will be analysed using digital callipers and arch width will be recorded in the posterior region.

c. **Data analysis**: Data will be analysed using SPSS. The descriptive statistics on group level at times corresponding to measurements at removal of fixed appliances (T0), 3 months post retention (T1), 6 months post retention(T2) and 12 months post retention(T3) will be calculated for each variable.

RELAPSE DUE TO POOR COMPLIANCE:

- Poor compliance can be detected by the clinician, such as poor adaptation to speech, appliance looks "clean", patient unable to seat and remove the appliance, or appliance is lost and not looked after properly.
- Arch width reduced
- Retainer will not fit in mouth

RELAPSE DUE TO INTERVENTION

- Patient able to adapt to retainers well, good adaptation to speech, appliance looks used, patient able to seat and remove retainers easily
- Arch width reduced
- Retainer should still fit in the mouth if patient wears it all the time

Compliance can be confirmed by the use of Thermosensors. Thermo-sensor is not used in this study because it is costly, not entirely accurate and it will not reflect the real-life situation. Most clinical studies do not use Thermosensors to ensure compliance. Using sensors will give out the Hawthorne effect where subjects will tend to perform better since they are aware of the presence of thermos-sensors. This as mentioned earlier does not reflect the real-life scenario.

Monitoring for adverse events

T0: Removal of braces	**T1: 3-month review**	**T2: 6-month review**
-Duration: 10-20 minutes -Subjects who have had 3mm of expansion (compared with pre-treatment models) will be selected, subjects given 5-10 minutes to think if they want to participate -Impression will be taken for construction of retainer and study models which will take 5-10 minutes -Adverse reaction i.e. allergic reaction to the impression material will be monitored however this would have been anticipated or recorded in the notes as these patients	-Duration: 5-10 minutes -Subjects will be reviewed and any adverse effect such as relapse will be detected at this point -An upper impression will be taken -Adverse reaction i.e. allergic reaction to the impression material will be monitored however this would have been anticipated or recorded in the notes as these patients would have had impressions taken at the start of orthodontic treatment. -If any allergic reaction occurs, first aid	-Duration: 5-10 minutes -Subjects will be reviewed and any adverse effect such as relapse will be detected at this point -An upper impression will be taken -Adverse reaction i.e. allergic reaction to the impression material will be monitored however this would have been anticipated or recorded in the notes as these patients would have had impressions taken at the start of orthodontic treatment. -If any allergic reaction occurs, first aid

would have had impressions taken at the start of orthodontic treatment -Using the randomized generator, patient will be allocated to either a: 1- Hawley retainer 2-Modified vacuum formed retainer -If any allergic reaction occurs, first aid management will be provided and an alternative impression material will be used	management will be provided and an alternative impression material will be used	management will be provided and an alternative impression material will be used

5.3 Ethics

A detailed protocol, ethical approval and site approval will be obtained from the KKM Ethics Committee before the study commenced. This research has been approved by the UKM Research Ethics Committee (Ethical approval number, UKM PPI/111/8/JEP-2018-724). All researchers in the study will adhere to the Good Clinical Practice Guidelines. A letter of consent will be obtained from each participant after explaining the nature and purpose of the study in verbal and in written. The data from the study will be made into a report which may be published. Participant's identity will be private and confidential, and will not be reported in any form of report. During the study, with respect to method of retention, if found in any patient for the relapse with VFR to be significant; new Hawley retainers (2-3 days) or retreat of fixed appliances (estimated 6-12 months) without any charge will be provided to the patient. Should subjects develop complications related to the study, treatment will be given at no cost at Faculty of Dentistry UKM Kuala Lumpur but subject will have to bear the travel expenses. Although theoretically the material of Hawley is more durable, there are no high quality long term studies comparing durability of both Hawley and VFRs. In fact long term follow-up studies have shown Hawley to have more breakages (Hitchens et al 2007). However if it does break, since it is an investigative product, we will replace the retainer with Hawley and subject will be considered dropout. During or after the study is completed, at any point if the research results are validated and if the modified VFR were found to be significantly less retentive than the Hawley retainer, subjects will be informed of the findings and new Hawley retainers will be provided to the modified VFR

group free of charge. If subject is not contacted regarding the results, it would mean that the modified vacuum is just as superior as the Hawley and the subjects in the modified vacuum can continue to use their retainer.

5.4 Data management and analysis

Intra-examiner reliability of the measurements will be undertaken on two occasions in a random order and following an interval of two weeks.

A normality test will be conducted to determine whether a parametric or non-parametric test should be conducted. The outcome measures assessed will be the differences in means between groups, which will be assessed by one-way analysis of variance, using Statistical Package for Social Sciences (SPSS) version 17.0.

[4] -- *Monday, July 08, 2019 -- 15:58:42*

F tests - ANOVA: Repeated measures, between factors

Analysis:	A priori: Compute required sample size		
Input:	Effect size f	=	0.42
	α err prob	=	0.05
	Power (1-β err prob)	=	0.80
	Number of groups	=	2
	Number of measurements	=	3
	Corr among rep measures	=	0.5
Output:	Noncentrality parameter λ	=	8.4672000
	Critical F	=	4.1708768
	Numerator df	=	1.0000000
	Denominator df	=	30.0000000
	Total sample size	=	32
	Actual power	=	0.8038973

A reliability test will also be performed to calibrate the measurements made. The data will be reported in a collective manner with no reference to the specific individual. Publication policy by most journals would require removal of any personal details of any patient in any part of the article or in any supplementary materials (including all illustrations and videos) prior to submission, therefore the personal information from each individual will remain confidential. Access to the data is only by the research team (which involves orthodontists, dentists, personnel) and the REC UKM and KKM. The hard copy of the data obtained will be stored in a locked cupboard in a private room that could only be accessed by the research team. Soft copy of the data will be contained in a USB protection lock which password is only known to the research team. Data will be allowed for inspection or auditing by regulatory authorities. Data could be stored for at least 7 years before being destroyed (shredded) or deleted (electronic copy). Individuals have a right to know the results of their study and can contact the researchers if interested.

5.4.1 Dental casts

Dental casts of four occasions will be obtained, on the day of removal of orthodontic appliances (T0), 3 months post- removal of orthodontic appliances (T1), 6 months post-removal of orthodontic appliances (T2) and 12 months post-removal of orthodontic appliances (T3). Based on a previous study (9), linear measurements will be made with an electronic digital calliper on the dental cusps to a precision of 0.01mm:

- Intercanine width in the maxilla- the distance between the canine cusp tips
- Interpremolar width in the maxilla- the distance between the premolar cusp tips
- Intermolar width in the maxilla- the distance between the mesiobuccal cusp tips of the first molars

Landmarks of cusp tips are identified based on guidelines described in the literature, where the most prominent tip is selected (9). If attrition is present, the centre of the surface area is determined to be the point of measure.

5.4.2 Resources

A researcher will assist in screening and randomizing, while site investigators from MOH and their qualified staff will assist in screening and taking impressions. Technicians will facilitate in preparing the dental casts and retainers. Cast preparation will be done in the dental laboratory of the Faculty of Dentistry, UKM, and dental laboratory of Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua.

Equipment that is readily available includes alginate impression material, impression trays, digital callipers, examination tray and data analyses software (SPSS version 17.0)

5.4.3 Result presentation

Results will be presented in a table and chart format

6.0 MILESTONES

Milestones	Dates
Literature review and search Proposal writing Ethical approval	15 June 2019
Sampling of participants Measurements from study casts	15 November 2020
Data collection Data entry and analysis	15 July 2021
Report writing: Introduction and Methodology Report writing: Result and Discussion Conference presentation, journal writings of findings	15 Mac 2022
Final report: Conclusion Conference presentation, journal writing of findings	14 April 2022

7.0 BUDGET

Bil	Butiran Belanjawan	Perihalan	Jumlah yang dipohon mengikut tahun semasa		Jumlah
			Tahun 1	Tahun 2	
1	Vote 11000 Upah dan Elaun	Lantikan Pembantu Penyelidik Siswazah (GRA)	8000.00	8000.00	16000.00
		Jumlah Vote 11000	8,000.00	8,000.00	16,000.00
2	Vote 21000 Perjalanan dan Pengangkutan	Tiket penerbangan luar negara		6000.00	6000.00
		Jumlah Vote 21000	0.00	6,000.00	6,000.00
3	Vote 24000 Sewaan				
4	Vote 27000 Bekalan dan Bahan Penyelidikan	Bahan Kimia Tidak Berbahaya	3515.00		3515.00
		Alat Tulis	900.00		900.00
		Jumlah Vote 27000	4,415.00	0.00	4,415.00
5	Vote 28000 Baik Pulih Kecil dan Ubahsuai				
6	Vote 29000 Perkhidmatan Ikhtisas	Bayaran yuran persidangan	800.00	4470.00	5270.00
		Bayaran suntingan (proof reading)	2000.00		2000.00
		Bayaran khidmat Perundingan / konsultasi	2000.00		2000.00
		Bayaran yuran penerbitan	4000.00	4000.00	8000.00
		Honorarium/saguhati	2815.00		2815.00
		Jumlah Vote 29000	11,615.00	8,470.00	20,085.00
7	Vote 35000 Aksesori dan Peralatan	Nama Alat: Sebutharga :			
		Jumlah Keseluruhan	24,030.00	22,470.00	46,500.00

8.0 REFERENCES

1. Paquette DE, Beattie JR. A long-term comparison of nonextraction and premolar extraction edgewise therapy in " borderline " Class II patients. Am J Orthod Dentofac Orthop. 1992;102(l):1–14.
2. Little RM, Riedel RA, Artun J. An evaluation of changes in mandibular anterior alignment from 10 to 20 years postretention. Am J Orthod Dentofac Orthop. 1988;93(5):423–8.
3. Al-Moghrabi D, Johal A, Fleming PS. What are people tweeting about orthodontic retention? A cross-sectional content analysis. Am J Orthod Dentofac Orthop [Internet]. American Association of Orthodontists; 2017;152(4):516–22.
4. Herold JS. Maxillary expansion: a retrospective study of three methods of expansion and their long-term sequelae. Br J Orthod [Internet]. 1989;16(3):195–200.
5. Melrose CA, Millett DT. Toward a perspective on orthodontic retention? Am J Orthod Dentofac Orthop. 1998;113(5):507–14.
6. Littlewood SJ, Millett DT, Doubleday B, Bearn DR, Worthington H V. Retention procedures for stabilising tooth position after treatment with orthodontic braces. Cochrane Database Syst Rev. 2016;2016(1).
7. Theroux KL. A new vacuum-formed phase I retainer. J Clin Orthod [Internet]. 2003;37(7):384–7. A
8. Cope JF, Lamont T. Orthodontic retention - Three methods trialed. Evid Based Dent [Internet]. Nature Publishing Group; 2016;17(1):29–30.
9. Edman Tynelius G, Petrén S, Bondemark L, Lilja-Karlander E. Five-year postretention outcomes of three retention methods - A randomized controlled trial. Eur J Orthod. 2015;37(4):345–53.
10. Rowland H, Hichens L, Williams A, Hills D, Killingback N, Ewings P, et al. The effectiveness of Hawley and vacuum-formed retainers: A single-center randomized controlled trial. Am J Orthod Dentofac Orthop. 2007;132(6):730–7.
11. de Groot, A., White, I. R., Flyvholm, M.-A., Lensen, G. & Coenraads, P.-J. 2010. Formaldehyde-releasers in cosmetics: relationship to formaldehyde contact allergy. Contact Dermatitis 62(1): 18–31.
12. International Agency for Research on Cancer. 2006. IARC monographs on the evaluation of carcinogenic risks to humans. World Health Organization Press 88: 280.
13. Kopperud, H. M., Kleven, I. S. & Wellendorf, H. 2011. Identification and quantification of leachable substances from polymer-based orthodontic base-plate materials. The European Journal of Orthodontics 33(1).
14. Bishara, S. E. 1995. Oral lesions caused by an orthodontic retainer: A case report. American Journal of Orthodontics and Dentofacial Orthopedics 108(2): 115–117.
15. Shawesh M, Bhatti B, Usmani T, Mandall N. Hawley retainers full- or part-time? A randomized clinical trial. Eur J Orthod. 2010;32(2):165–70.