

**B2. INFORMATION SHEET FOR SUBJECTS/PARENTS/GUARDIAN**

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

**Sponsor/Grant code:** GGPM-2018-049

**Introduction** This study will present necessary information comparing the degree of relapse between the two different types of retainers. Relapse happens when the teeth move back to the pre-treatment position after orthodontic treatment. The table below shows the difference between the two types of retainers:

| 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 <i>normal VFR</i> (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 (VFR)        |  |   |
|---|--|---|
| 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) – <i>Normal VFRs</i> |
| 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

### What would the study involve?

A screening will be done among the patients in the Orthodontic Unit in Universiti Kebangsaan Malaysia (UKM), Klinik Pakar Ortodontik Klinik Kesihatan Bandar Botanik and Unit Pakar Ortodontik Klinik Pergigian Sungai Chua. **A total of 32 subjects will be required for this study.** You will be given 5-10 minutes to decide whether to participate in the study. Participants will be told the type of retainer (Hawley or modified vacuum formed) that will be given via randomization method, after that the upper and lower moulds of the mouth will be taken with an alginate material after consent is given. **There is 50% chance of getting either one type of retainer by the subject.** This mould taking procedure will take around 5-10 minutes. There is a very small risk of an allergic reaction with the alginate material, if there is any signs of this we will stop the procedure immediately and first aid treatment will be provided. The procedure of taking impressions are commonly done among children and adults in the treatment of braces and dentures, where subjects have to relax and breathe through their nose while the mould is being put in the mouth to set. These impressions will be used to calculate the degree of relapse. The impressions will need to be repeated at a 3 month, 6 month and 12 month interval from the first date of impression-taking.

### The benefits

By doing this study, we will regain information regarding the degree if relapse between the two type of retainers. Your participation could potentially help us improve on the efficiency in retainer construction in future patients.

### **The risk**

Hawley and normal Vacuum formed retainers are equally effective to be used after orthodontic treatment. In this study, we are evaluating the effectiveness of the modified version of the vacuum formed retainers on expansion cases. There is a risk of relapse (teeth moving back to original position) if the subject does not adhere to the retainer instructions. If relapse still occurs when the subject has adhered to all the instructions, a new retainer or a course of fixed/removable appliances will be provided free of charge if it occurs during the duration of the study (12 months). The re-treatment will be done at Fakulti Pergigian UKM Kuala Lumpur, where travel costs will be borne by the subject. 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, we will inform you of the findings and new Hawley retainers will be provided to the modified VFR group free of charge. If we do not contact you 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. The modified retainer does not contain any porcine and/or bovine ingredient. As a subject, you should adhere to the instruction given by compliant to the wearing of retainer. When subjects are given the retainers, clinicians will provide post-debond instructions, where the subject has to wear the retainers for 24 hours except during eating and brushing their teeth. Researcher will send reminders in 1-month interval to ensure they are following the instructions and to enquire if they have any problems.

### **Does my child/Do I have to take part?**

The participation of this study is voluntary and not consenting to participate as well as withdrawal of consent will not affect medical services entitled. You will not lose any legal rights in the event of study related injury. If you agree to take part, you will then be asked to sign the 'Informed Consent Form'. You will be given a copy of the form and this information sheet.

You will be given a retainer after removal of your fixed appliances.

Should you decide not to continue, you can still withdraw from the study without penalty. Your data up to the duration that you withdraw may still be used for research purposes. The researcher may also remove you from the study for a variety of reasons. In this event, you will not be penalised or lose your rights as a patient.

### **Data & Confidentiality**

The data from the study will be made into a report which may be published. Access to the data is only by the research team (which involves orthodontists, dentists, personnel) and the REC UKM and KKM. There may be auditing or inspecting of the data by the regulatory authorities. 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 subject 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. 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.

**Payment and compensation**

You do not have to pay nor will you be paid to participate in this study. You do have to pay for travel expenses and the usual hospital charges such as registration fees and retainer fees.

The study is being conducted with a UKM research grant (GGPM-2018-049). You will be given a sum of RM20 as a travel reimbursement for every visit of this study after your braces are removed. This does not include the appointment where your braces are removed. Should you develop complications related to the study, treatment will be given at no cost to you at Faculty of Dentistry UKM Kuala Lumpur but you will have to bear the travel expenses.

**If I have any questions, whom can I ask at any time point of the study?**

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REC UKM: Medical Research and Ethics Committee HUKM, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Batu 9 Cheras, Wilayah Persekutuan Kuala Lumpur

REC KKM: Medical Research and Ethics Committee, National Institutes of Health, Ministry of Health Malaysia, Block A, Level 2, No 1, Jalan Setia Murni U13/52, Seksyen U13, Setia Alam, 40170, Shah Alam, Selangor.

**INFORMED CONSENT FORM**

**Research Title**

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

**Researcher's Name**

I, ....., IC No : .....

- have read the information in the Subject Information Sheet **including information regarding the risk in this study**
- have been given time to think about it and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree for myself/my child/child under my care to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

.....  
(Signature)

.....  
(Date)

Please be informed that if a new information or consent sheet is revised, we will let you know and you will need to re-consent to the procedure

Subject under 18 years old will need parental consent

|                    |                     |
|--------------------|---------------------|
| .....<br>Witness   | .....<br>Researcher |
| .....<br>Signature | .....<br>Signature  |
| .....<br>IC Number | .....<br>IC Number  |
| .....<br>Date      | .....<br>Date       |