TITLE: Effectiveness, patient acceptance, and cost estimation of 3D-printed retainer compared to Hawley retainer in expansion case: a randomized controlled trial

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1.0 Duration of study

30 months

2.0 Problem Statement

Expansion of the arches is generally considered highly unstable and prone to relapse regardless of the type of expansion. Retention appliances play a vital role in preserving these changes. Hawley retainer users often avoid wearing them due to speech difficulties and less aesthetic appeal. They are also more prone to breakage, costlier, and require more labour. Despite the relatively recent introduction of 3D-printed retainers, they offer potential advantages in orthodontics, including the accuracy of digitally scanned images, reduced labour and material costs, and improved patient comfort. While 3D-printed retainers are quite new, most studies focus on laboratory testing of their mechanical properties, there is limited evidence directly comparing their effectiveness in retaining arch width increases, patient acceptance, and cost estimation. This knowledge gap creates uncertainty about the optimal choice of retainer for long-term stability, necessitating a comparative assessment of their performance. This study addresses this knowledge gap by evaluating the retention of arch width increases achieved using Hawley retainers versus 3D-printed retainers.

3.0 Research Hypothesis

Null Hypothesis

There is no significant difference in the retention of arch width increase, patient acceptance, and the cost between Hawley retainers and 3D-printed retainers.

Alternative hypothesis

There is significant difference in the retention of arch width increase, patient acceptance, and the cost between Hawley retainers and 3D-printed retainers.

4.0 Research Question

- How different is a 3D-printed retainer regarding the retention of arch width increase compared to the Hawley retainer?
- What is the difference in patient acceptance between the Hawley retainer and the 3D-printed retainer?
- How much is the cost difference for 3D-printed retainers compared to Hawley retainers?

5.0 Literature Review

5.1 Relapse

Orthodontic retention is the essential final phase of orthodontic treatment, aimed at stabilizing the functional and aesthetic alignment of the teeth. A common issue with retention is relapse. Relapse is defined as the tendency of teeth to return to their pretreatment positions (Dyer et al. 2012). Factors contributing to relapse include unfavourable skeletal growth patterns, improper treatment plans, muscular functions and habits, uncooperative patients, changes in arch forms, occlusion, and transseptal fibers (Dyer et al. 2012). Effective orthodontic treatment planning and the appropriate occlusal and soft tissue treatment goals are crucial in reducing the risk of orthodontic relapse. However, some level of relapse is almost inevitable unless an appropriate retention protocol is implemented after the removal of active orthodontic appliances. Unwanted tooth movements after treatment can also arise due to natural age-related changes (Johnston & Littlewood 2015). The persistent challenge of relapse underpins the need for efficacious retention protocols. Retainers are therefore recommended not

only to resist the tendency of relapse following orthodontic tooth movement but also to resist unwanted long-term age changes (Johnston & Littlewood 2015).

5.2 Maxillary expansion

Arch expansion is a widely used approach for treating posterior crossbites. Various expansion techniques often used in removable and fixed appliances include arch wire expansion, quad-helix, rapid maxillary expansion, and removable appliances with a midline screw. Surgical methods such as Surgically Assisted Rapid Palatal Expansion (SARPE) have also been described in severe cases. Expansion of the arches is generally considered highly unstable and prone to 40% relapse regardless of the type of expansion, primarily due to the patient's posttreatment growth pattern (Herold 1989; Lagravere et al. 2005; Melrose & Millett 1998). Maxillary dentoalveolar expansion is a procedure to correct transverse discrepancies between the maxillary and mandibular arches by applying forces to widen the maxillary arch. This procedure is inherently unstable and is susceptible to relapse (Littlewood et al. 2017).

5.3 Hawley retainer

Retainers can be fixed or removable. The Hawley retainer, fabricated from acrylic resin and wire, is the most commonly used removable retainer (Lyros et al.2023). The type of retainer is now considered equally important as retention duration (Lang et al. 2002). Vacuum-Formed Retainers (VFR) and Clear Bow Hawley's (CBR) are equally effective against relapse; CRs can be considered an excellent alternative to VFRs (Devi & Jain 2022). A systematic review also concluded that VFRs are equally effective as HRs in maintaining alignment, arch widths, and arch length (Hussain et al. 2024). Additionally, VFRs demonstrate similar efficacy to Fixed Bonded Retainers (FBRs) in preserving the alignment of the lower arch (Hussain et al. 2024)

Hawley retainers are more effective at maintaining the transverse expansion of the maxilla, which may account for their continued popularity in the maxilla in all practice settings (Singh et al. 2009). The Hawley retainer consists of multiple components that require more processes to produce the final product (Da Tan et al. 2024). Regarding life cycle assessment, Hawley retainers are more environmentally sustainable than Essix retainers (Da Tan et al. 2024). However, Hawley retainer users have reported not wearing retainers is difficult for people with speech difficulties (Lim et al. 2023) and less aesthetic (Saleh et al. 2017). Hawley retainers are also more likely to break, higher in cost, and require greater manpower and time to make (Hichens et al. 2007).

While Hawley retainers have served as the established standard for retention after maxillary expansion, a recent trial suggests that modifying vacuum-formed retainers by adding palatal coverage is as effective in maintaining post-expansion arch width (Ashari, Xian, et al. 2022). The same author had previously conducted a similar study; they concluded that over a 24-month retention period, mVFR and HR have identical clinical effectiveness for retaining transverse expansion cases. Both retainers were considered equivalent in terms of fitting, speech, oral hygiene, durability, and comfort. However, subjects in the mVFRs group felt that their retainers were significantly more aesthetic than those in the HRs group (Ashari, Nik Mustapha, et al. 2022). This finding suggested a possible alternative or modification that can be on par with the gold standard.

5.4 3D-printed retainer

With the advent of 3D printing, it has provided valuable insights into various areas of medicine and dentistry, including orthodontics. In dentistry, CAD-CAM and 3D printing have been utilized to fabricate crowns, bridges, dentures, occlusal splints, surgical guides, allogeneic bone blocks, orthodontic retainers, orthodontic brackets,

and Twin block appliances (Graf et al. 2022; Hegele et al. 2021; Pfaffeneder-Mantai et al. 2022). The scope of application is likely to expand as the technology continues to evolve, and more clinicians are increasingly embracing the technology.

Despite this emerging trend, the available data regarding the fabrication of orthodontic retainers using CAD technology and additive manufacturing is still limited. VFRs fabricated from ABS-based 3D-printed models showed no differences in stability or patients' oral health-related quality of life (OHRQoL) compared to conventionally made retainers (Mohd Tahir et al. 2019). A study clinically evaluated the efficacy of clear retainers produced through conventional and digitally manufactured models over six months. Results showed minimal and non-significant differences in mesiodistal, buccolingual widths, and extraction space reopening measurements (Sharma et al. 2024). Statistically significant values were mainly attributed to the polymerization shrinkage of the stereolithographic 3D printer, which exhibited a slight potential for transverse dimensional shifts (Sharma et al. 2024). However, the difference observed between all the models printed was minimal and clinically insignificant (Sharma et al. 2024)

Advantages of 3D printing in orthodontics include the accuracy of digitally scanned images, potential labor and material cost savings, and enhanced patient comfort (Cousley 2020; Tsoukala et al. 2023). Studies have demonstrated that 3D-printed retainers possess acceptable in vitro precision and accuracy (Boyer et al. 2021; Naeem et al. 2022). Unlike the thermoform group, 3D-printed retainers have significantly superior compression and tensile properties at all thicknesses (Nakornnoi et al. 2024). A recent study by (Neoh et al. 2025) also demonstrated that 3D printing materials with a high degree of crosslinking will have greater strength and more resistance to aging, although they may have low ductility. It was supported by (Stoev et al. 2023), who reported that the 3D printing material has more rigidity than the vacuum-forming material. (Firlej et al. 2022) also suggested that 3D-printed retainers may be a suitable alternative to metal retainers. Greater rigidity is desirable for retainers, as more rigid appliances demonstrate improved retention and are more effective at resisting forces that could contribute to orthodontic relapse (Hussein et al. 2022). This was also why the study proposed a 3D-printed retainer of a normal shape rather than a modified shape. However, a recent systematic review highlighted a critical gap in knowledge regarding the long-term clinical efficacy and durability of 3D- printed retainers (Tsoukala et al.2023). With the growing popularity of 3D-printed retainers, as the demand for orthodontic clear retainers has increased due to their aesthetic appeal, there is still a limited number of clinical studies to assess their effectiveness in preventing arch-width relapse in maxillary expansion cases.

Thus, the present study aimed to address this research gap by comparing the clinical performance of Hawley retainers and 3D-printed retainers in maintaining arch width after maxillary expansion at 3 months, 6 months, and12 months.

6.0 Research objectives

General Objective: To assess the retention of arch width increases between 3D-printed retainers and Hawley retainers in patients who have undergone maxillary arch expansion.

Specific Objectives:

1. To determine the relapse by **measuring changes in arch** width at 3 months, 6 months, and 12 months of wearing Hawley and 3D-printed retainers.

2. To assess patient **acceptance** in 3D-printed and Hawley retainers.
3. To estimate and compare the **cost** between 3D-printed retainers and Hawley retainers.

7.0 Research methodology

7.1Study design

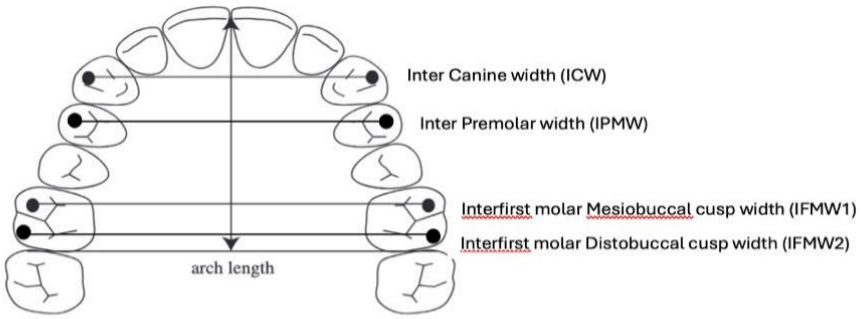
This study will be a multicentre prospective randomized controlled clinical trial conducted at Universiti Kebangsaan Malaysia (UKM), Universiti Malaya (UM), and Universiti Teknologi MARA (UiTM).

The PICO of the present study is as follows:

1. Participant: Orthodontic patients with > 3mm maxillary arch expansion.
2. Intervention: 3D-printed retainer (without palatal coverage)
3. Control: Hawley retainer (the current gold standard retainer for expansion case)
4. Outcome:
    a. Primary outcome: Arch width changes at T0-T3
    b. Secondary outcomes: Patient acceptance, cost estimation.

Four linear measurements will be used to assess the arch width:

- Inter canine width (ICW): the distance between canine cusp tips,
- Interpremolar width (IPMW): the distance between premolar cusp tips,
- Interfirst molar width 1 (IFMW1): the distance between the mesiobuccal cusps and
- Inter-first molar width 2 (IFMW2): the distance between the distobuccal cusps

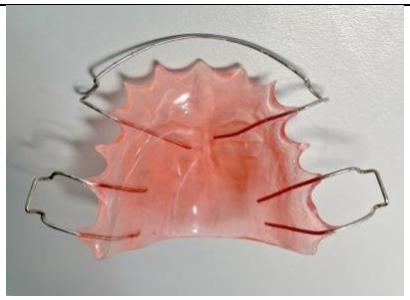


On the day of debonding (T0), ICW, IPMW, IFMW1, and IFMW2 are measured intraorally on pre- and post-treatment casts. The measurements will be performed using a Tuten electronic digital calliper (CSM Engineering Hardware (M) Sdn. Bhd, MY) with a precision of 0.01 mm. They will be taken twice to ensure measurement accuracy. Subjects with at least two or more points expanded (> 3 mm) are eligible for this study.

A screening will be done to select suitable patients for the study. Only patients who fulfil the criteria will be invited to participate in this study. Participants will be approached in the dental chair once deemed suitable and given 5-10 minutes to decide on study participation. Consent will be gathered from the patients or the carer if the patient is below 18. Following informed consent, eligible subjects will be randomly allocated into one of two groups:

Group 1: Hawley retainer.

Group 2: 3D-printed retainer

 Figure 1 Hawley retainer	 Figure 2 3D-printed retainer
Standard design of Hawley Retainer: - Labial bow (0.8mm hard stainless steel) from canine to canine - Adam clasp on the molar (0.7mm hard stainless steel) - acrylic baseplate (2-3mm thickness)	Standard design of 3D printed retainer: - Monolithic design (no wires) - No palatal coverage - Fully cover the teeth and part of the gingiva (1-2mm) - Same printing angulation, same brand and printing company

Randomization will be performed using a randomized number computer generator (random.org). In this multicentre trial, a centralized randomization technique that incorporates external involvement is used. Individuals who recruit subjects from each centre will phone a central method centre (independent researcher, AA) after the patient is enrolled to prevent selection bias and protect the assignment sequence until allocation. Subjects will receive the retainers within 24 hours or maximum 3 days after debonding and be provided with instructions on retainer wear. Orthodontists, technicians, and researchers will be trained and calibrated prior to the start of the study. Fabrication of Hawley retainers and 3D-printed retainers will be done using a standardized design across all centres. Designing and manufacturing of 3D-printed retainers will be done with computer-aided design computer-aided manufacturing (CAD/CAM) software (3Shape Dental System & 3Shape Ortho Suite, 3Shape, Denmark) prior to 3D-printing with NextDent 5100 3D printer (NextDent, Netherlands) using Ortho Flex (NextDent, Netherlands), a clear biocompatible Class IIa acrylic resin. The maximum thickness for the customized fabrication of a 3D-printed retainer (1mm) will be chosen for the retention of the maxillary expansion case. Text reminders will be sent to the patient by phone to emphasize the importance of compliance with the retainer and appointment.

Primary outcome:

1. Subjects will be scheduled for follow-up at T1-T3 after the initiation of retention wear. During these visits, impressions will be acquired with alginate impression material, and ICW, IPMW, IFMW1, and IFMW2 will be measured intraorally and on dental casts.
2. Calibrated researchers will collect the study models, and the ID and intervention will be 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. Due to the prospective nature of the study, it was inconvenient to anonymize dental casts from the start of the study.
3. Intraclass correlation coefficient (ICC) will be done within and between researchers one week after the T0.

Secondary outcomes:

1. To assess patient acceptance:

Subjects will be given and asked to complete a questionnaire on patient acceptance (see attachment) at 6 and 12 months post-debond. The Questionnaire has been validated and published by (Saw et al. 2025). It uses a Visual Analogue Scale (VAS) to ask six questions related to subject acceptance of orthodontic retainers in fitting, speech, appearance, oral hygiene, durability, and comfort.
Refer to Attachment 1 (Malay version) and Attachment 2 (English Version) for the questionnaires.

2. To estimate and compare the cost:

The researcher will conduct the cost estimation and comparison 6 months to 12 months after the debond from the perspectives of healthcare providers. The Direct and indirect cost components that will be collected alongside the clinical trial involve identifying, measuring, and valuing relevant resource use and associated costs, including appliance fabrication, maintenance, follow-up visits, and any additional healthcare services required based on the references (Hichens et al. 2007; Tynelius et al. 2014). This rigorous methodology provides valuable insights into the economic implications of using 3D-printed versus Hawley retainers, aiding healthcare decision-makers in resource allocation and treatment selection. The findings also help to determine the study's limitations and risks. In this study, the focus will primarily be on the clinical perspective, as it offers a more relevant context for real-world implementation. Specifically, the cost analysis will explore two key scenarios:
(1) clinics that already possess 3D printing infrastructure and thus only incur marginal production costs, and
(2) clinics that would need to invest in acquiring 3D printing technology to adopt this retainer type as standard practice.
Replacement of broken retainers will not be a major component of this analysis, as the cost impact on the provider is generally comparable between both retainer types and does not significantly influence provider-side economic outcomes.

7.2 Type of sampling

Participants were recruited based on predefined inclusion and exclusion criteria. Eligible participants were then subjected to simple random sampling to allocate them into groups using a randomized number computer generator (random.org). In this multicentre trial, a centralized randomization technique that incorporates external involvement is used. Individuals who recruit subjects from each centre will phone a central method centre (independent researcher, AA) after the patient is enrolled to prevent selection bias and protect the assignment sequence until allocation.

7.3 Inclusion and exclusion criteria

Inclusion Criteria:

- Patients aged 16 years or older at the time of debonding
- Treatment plan of extraction or non-extraction followed by straight wire appliances in the upper arch only or both arches
- Undergone expansion treatment in the upper arch causing an arch width increase of 3-10mm, either using a Quadhelix, expansion with archwires, or URA with midline screw
- Had pretreatment dental cast
- Had no chronic medical condition

Exclusion Criteria:

- Cleft lip and palate
- Chronic medical conditions
- Broken teeth or bubbles on study model at site of measurement.

The criteria for suspending or terminating the study are:

- Relapse due to compliance issue
- Relapse due to investigative product
- The subject did not come for a follow-up

The subject withdrawal criteria are:

1. Voluntary

Relapse due to poor compliance:

- Poor compliance can be detected by the clinician, such as poor adaptation to speech, the appliance looking "clean," the patient's inability to sit and remove the appliance, or the appliance being lost and not looked after properly.
- Arch width reduced
- Retainer will not fit in the 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 the patient wears it all the time

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

7.4 Study population

Patients who underwent orthodontic treatment at the dental clinics of Universiti Kebangsaan Malaysia (UKM), Universiti Malaya (UM), and Universiti Teknologi MARA (UiTM).

7.5 Sample size calculation

The sample size is based on a previous study by (Ashari, Xian, et al. 2022) and calculated using the G* power 3.1. The sample size for a repeated measures ANOVA with a between-group factor was calculated using the following parameters: effect size f=0.512, alpha level (α) = 0.05, power (1−β) = 0.8, 2 groups, five repeated measurements, and a correlation of 0.5 among measurements. The required total sample size was 22, achieving an actual power of 0. 839. A 20% sample size attrition is included. A combined total of 28 participants were required for two groups.

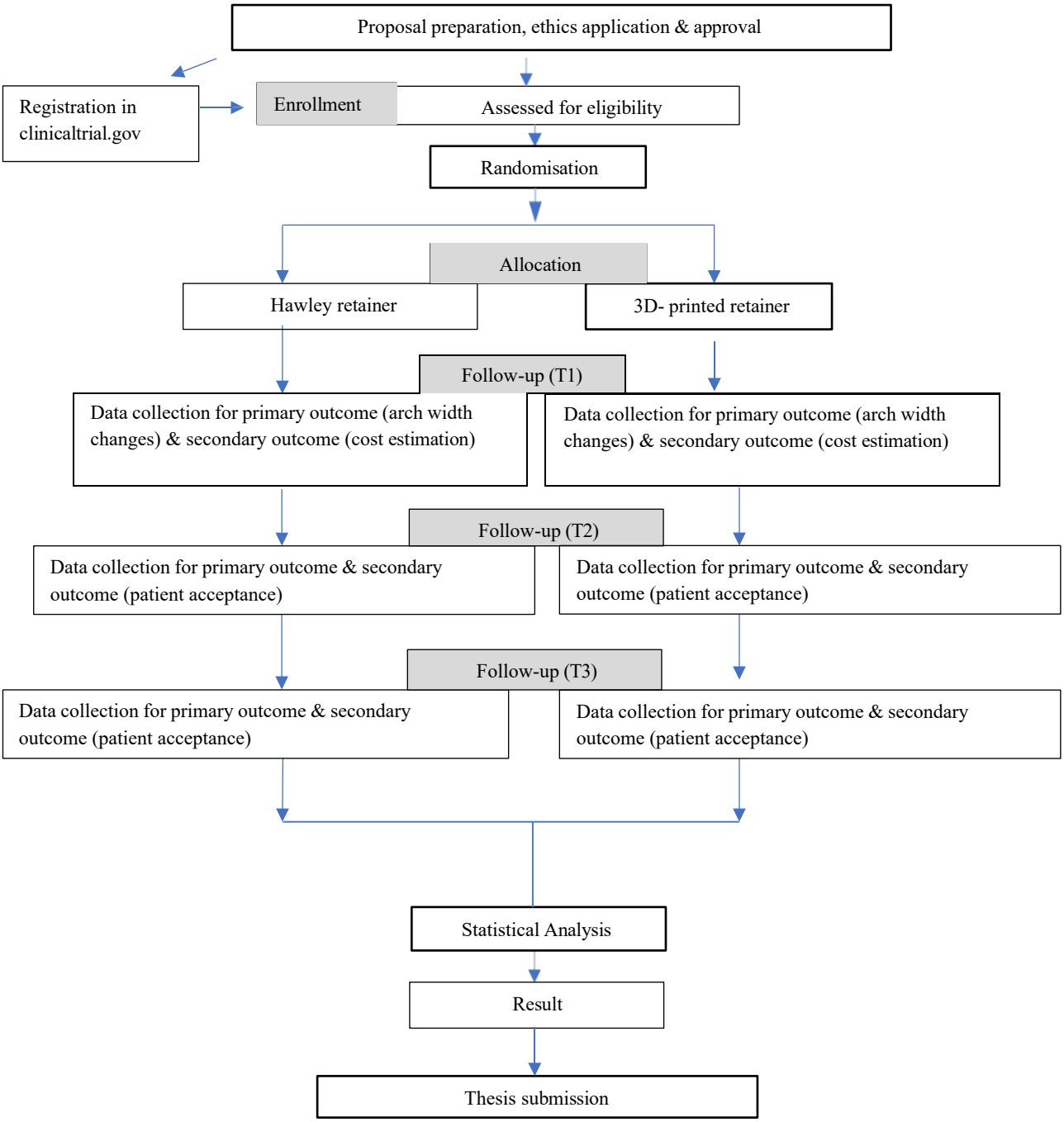
F tests - ANOVA: Repeated measures between factors

Analysis:	A priori: Compute required sample size		
Input:	Effect size f	=	0.5122908
	α err prob	=	0.05
	Power (1-β err prob)	=	0.80
	Number of groups	=	2
	Number of measurements	=	5
	Corr among rep measures	=	0.5
Output:	Noncentrality parameter λ	=	9.6228683
	Critical F	=	4.3512435
	Numerator df	=	1.0000000
	Denominator df	=	20.0000000
	Total sample size	=	22
	Actual power	=	0.8389660

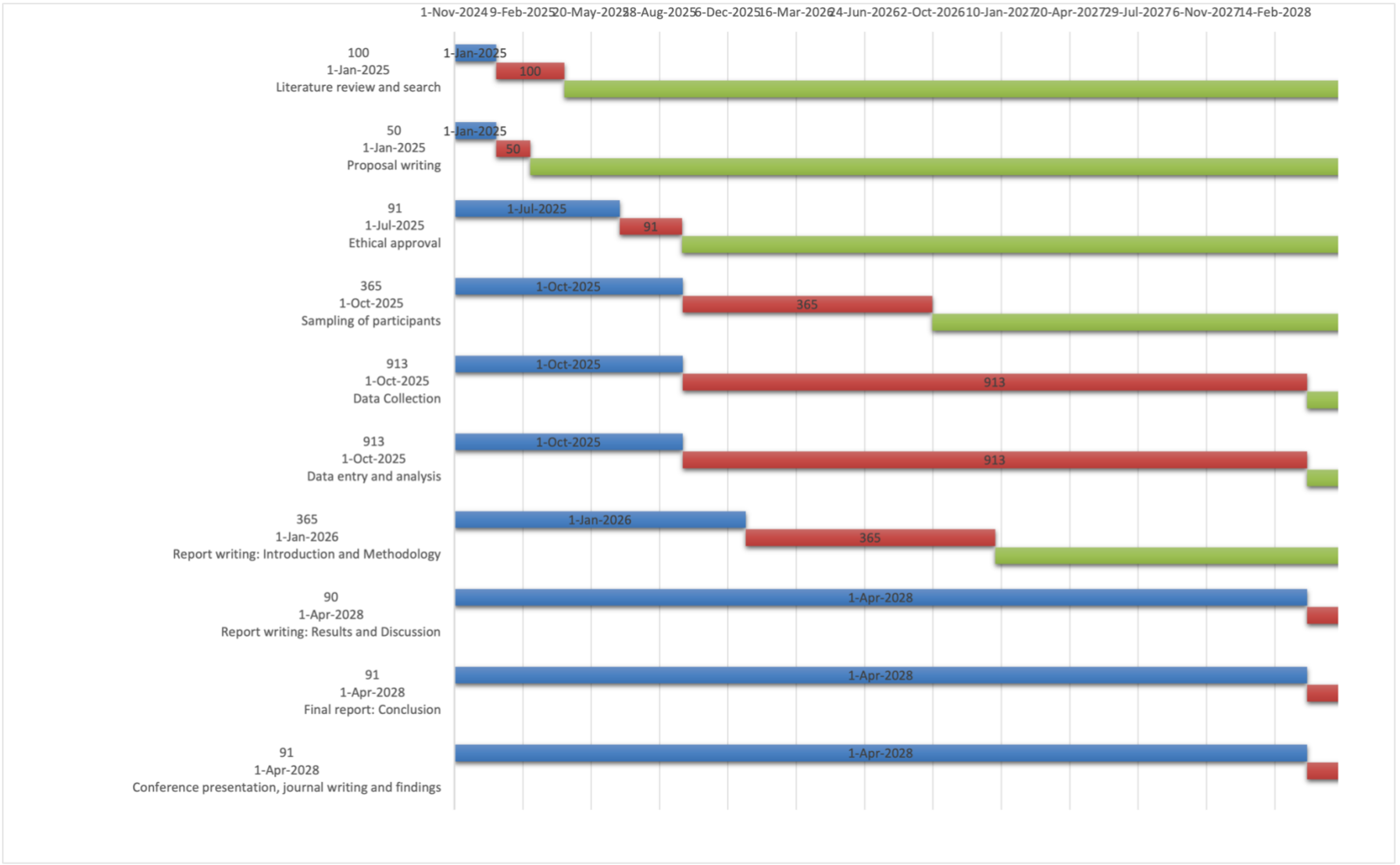
7.6 Study location

Dental clinics of Universiti Kebangsaan Malaysia (UKM), Universiti Malaya (UM), and Universiti Teknologi MARA (UiTM).

8.0 Research Flow Chart



9.0 Gantt Chart



9.1 Milestones

Milestones	Dates
Literature review and search Proposal writing Ethical approval	31-Sept-2025
Sampling of participants Measurements from study casts	1-Oct 2026
Data collection Data entry and analysis	1-Apr-2028
Report writing: Introduction and Methodology Report writing: Result and Discussion Conference presentation, journal writings of findings	1-May-2028
Final report: Conclusion Conference presentation, journal writing of findings	01-Apr-2028

10.0 Reasonable budget

Template for budget application

Date start: sept 2025 Date end: july 2028

Total Approved:

			1A					
Vote	**Category /Items**	**Details - to be completed by**	**Year 1 (RM)**	**Year 2 (RM)**	**Total (RM)**	**Total for vote**	**Spent (RM)**	**% spent**
Vote 11000 - Salary and wages								
					0	0		
Vote 21000 - Travelling and Transportation								
1	**Travelling - abroad (flight ticket)**				0	0		
2	**travelling domestic**		150	150	300	300		
Vote 24000 - Rent								
					0	0		
Vote 27000 - Research Materials & Supplies								
1	**Paper A4 & stationary**		100		100			
						100		
Vote 28000 - Maintenance and Minor								
1	**Maintenance of research equipment**				0	0		
Vote 29000 - Professional Services								
1	**Printing/Publication services**	*e.g. posters, brochure, forms, meeting materials, presentation materials*		1000	1000			
2	**Honorarium - patients/paticipants**	30 x 5 (T0-T4) x rm 20	1500	1500	3000			
3	**Payment for professional service**	proof reading		2000	2000			
4	**Payment for sample analysis/lab service**	3d printed retainer Rm350 x 14	4900		4900			
5	**Retreatment if relapse due to intervention**	40% of intervention group = 6 patient 200 x 6 = 1200		1200	1200			
6	**Publication fee**			2500	2500			
7	**Conference fee**				0			
					0	14600		
Vote 35000 - Accessories and Equipment								
1					0	0		
	Total / Year (RM)		**6650**	**8350**	**15000**	**15000**		
	Overall total (RM)			**15000**				

Source of funding: Student Bench Fees

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