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RESEARCH PROPOSAL

The effect of sugar-free chewing gum on self-reported orthodontic pain and orthodontic appliance breakages associated with stainless steel archwire placement

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1.0 Introduction

1.1 Problem Statement

A large percentage of patients experience significant pain during orthodontic therapy. Matic & Nikolic (2017) stated that patients experience a period of adjustment and social discomfort after the placement of fixed orthodontic appliances. Zarif Najafi et al., (2015) stated that 95% of patients receiving orthodontic treatment experience some level of pain or discomfort with the installation of separators or archwires, for example. This occurs due to ischemia, inflammation, and edema in the pinched periodontal ligament thus generation of orthodontic pain (Farzanegan et al., 2012). The release of inflammatory mediators such as histamine, bradykinin, prostaglandins, serotonin, and substance P stimulate the pain receptors' nerve endings, which results in pain. Following the application of orthodontic force, pain gradually worsens for the first two hours, reaching its climax during the second day, and then steadily drops over the following three to seven days (Alshammari & Huggare, 2018). Also important to note is that specifically in adults, there is reduced tissue blood flow and cell turnover, which can lead to delayed initial tooth movement and possibly increased discomfort as compared to younger patients (Littlewood et al., 2019). Sandhu & Sandhu (2013) mentioned that there are many factors that influence orthodontic pain, for instance age, sex and clinical characteristics such as orthodontic force level. The orthodontic force system mostly incorporates archwires, elastics, bands, or different screws, among other materials (Yang & Tang, 2018). In a study by Sandhu & Sandhu (2013), initial superelastic nickel-titanium wire was compared to initial multi-strand stainless steel wire and there was absence of statistically significant difference in mean average pain throughout all time points. Nevertheless, to the best of our knowledge, no studies have utilized a higher orthodontic force appliance which is the final rectangular stainless steel working archwire in assessing pain perception in orthodontic patients.

Pain is a significant problem amongst patients under the treatment of fixed appliances as it influences patients' compliance (Bradley et al., 2007) and quality of life (Matic & Nikolic, 2017). Therefore, a number of pharmacological and non-pharmacological orthodontic pain managements are established to solve this issue. Non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol are pharmacological gold standard in contemporary orthodontic pain management.

NSAIDs such as ibuprofen and piroxicam inhibit prostaglandin production at the site of tissue damage. However, a study by Bradley et al., (2007) hypothesized that prostaglandin suppression might slow down orthodontic tooth movement since prostaglandin plays a significant role in promoting bone resorption during tooth movement. This would in turn prolong orthodontic treatments. Not only that, NSAIDs are also associated with thrombocytopenia, skin rashes and headaches particularly in young orthodontic patients (Farzanegan et al., 2012). On the other hand, paracetamol is thought to act centrally rather than peripherally where it inhibits COX-3 in the brain and spinal cord. Therefore, reduced peripheral prostaglandin alterations should have reduced impact upon tooth movement and be preferred over NSAIDs. In spite of that, there is growing belief of side effects from long-term treatment with paracetamol such as hypertension, cardiovascular disease, asthma and renal injury (McCrae et al., 2018). Therefore, a non-pharmacological pain management alternative which does not alter any molecules or mediators in the body directly should be sought out. Specifically in this study, chewing gum would be the alternative for orthodontic pain management. Past literature suggested the use of medicated chewing gum containing aspirin and lidocaine/prilocaine anesthetic components with reports of less discomfort up to 63% (Al-Melh et al., 2019). However, the use of medicated chewing gum is still not widespread and is restricted up to experimental use only. Therefore, it is of best interest that conventional sugar-free chewing gum is used to study its effects towards pain perception among orthodontic patients. To the best of our knowledge, no studies have been carried out regarding the effects of sugar-free chewing gum on pain perception among orthodontic patients with final stainless steel working archwire.

With regards to chewing gum, risks of bracket failure is a concern among the clinicians. In a study by Kafle et al., (2020), bonding failure rates were observed to range from 0.6% to 28%, with failure rate of less than 10% as clinically acceptable. Stasinopoulos et al., (2018) claimed that one of the most significant determinants of the length of fixed appliance treatment is bracket failure whereby possibility of treatment extension of 0.3 months for each bracket failure and up to 1.5 months for three or more failures has been reported. This is because the clinician may need to temporarily postpone the originally planned succession of wires, and numerous failures could signify that the patient is not complying with treatment instructions. Kafle et al., (2020) mentioned that the effect of masticatory force was related to posterior teeth bracket failure. However, a study by Alshammari

& Huggare (2018) showed the likelihood of bracket loss on the first day of fixed orthodontic treatment was not increased by chewing gum in which only two patients lost their brackets in the study. Despite the brief duration of the investigation, it was consistent with earlier research that revealed no link between chewing gum and bond defaults (Ireland et al., 2017). It is essential to study the effects of sugar-free chewing gum on the frequency of brackets/tubes/bands breakages especially during the later stage of orthodontic treatment using stainless steel working archwires.

Regarding the issue of non-pharmacological approach as an alternative to pharmacological approach, several studies portrayed the effectiveness in managing orthodontic pain. A study by Konno et al. (2016) shows that gum chewing reduces stress-related reactions, which may indirectly alter pain perception and the need for analgesia by lessening the negative consequences of anxiety. Another study by Hussain et al. (2017) concluded that chewing sugar-free gum could lower the amount of ibuprofen consumption in the experimental group. This proves how non-pharmacological management of orthodontic pain is effective in orthodontic pain management. However pharmacological approach should not be neglected. This is because non-pharmacological management only offers an alternative a solution to the issue of orthodontic pain as pain as reported in the above studies are only reduced, not completely eliminated. This study will further clarify the effectiveness of reducing the need of pharmacological approach in sugar-free chewing gum usage among orthodontic patients upon managing orthodontic pain.

1.2 Research aim & objectives

1.2.1 Aim

To study the effectiveness of sugar-free chewing gum in managing orthodontic pain.

1.2.2 Research objectives

1. To study the effects of chewing sugar-free gum on self-reported pain associated with the use of stainless steel working archwires.

2. To investigate the effects of sugar-free chewing gum on the use of analgesic medications during the use of stainless steel working archwires.
3. To determine the effects of sugar-free chewing gum on the number of appliance breakages.

1.3 Research questions

1. Does sugar-free chewing gum reduce self- reported orthodontic pain associated with stainless steel archwire placement?
2. Does sugar-free chewing gum reduce the intake of analgesic medications during the use of stainless steel archwires?
3. Is there any relationship between chewing sugar-free gum with appliance breakages?

1.4 Research hypothesis

1. Sugar-free gum is associated with pain-relief effect in patients with stainless steel working archwires.
2. Sugar-free gum reduces the intake of analgesic medications in patients with stainless steel working archwires.
3. Chewing gum group is associated with increased frequency of appliances breakages compared to non-chewing gum group.

2.0 Literature Review

Pain is defined by the International Association for the Study of Pain (IASP) as discomfort in neurological and psychological experience associated with genuine or potential tissue damage (Srinivasa et al, 2020). Orthodontic appliances, specifically fixed appliances are related to the experience of mild-to-severe pain and discomfort in almost 90% of patients undergoing treatment. Due to the unpleasant experience, there was an apparent poor compliance issue, with many discontinued orthodontic treatment in 8-30% of patients (Bradley et al., 2007). Separator

placement, orthopedic force application, debonding and archwire insertion and activation are among the many procedures which are reported to have caused unpleasant experiences by patients undergoing orthodontic treatment (Al-Melh & Andersson, 2017). Orthodontic pain, like any other pain sensation in the body, involves a series of complex mechanisms. Cardoso et al., (2020) stated that pain was observed frequently following initial orthodontic force application due to the compression of periodontal ligament leading to ischemia, edema and release of inflammatory mediators during the first 24-48 hours, peaking at 24 hours and subsiding afterwards until day 7. Mediators such as prostaglandins and interleukins play a role in sensitizing nociceptors in periodontal ligament which in turn stimulate the pain sensation. Despite the major advancement in orthodontic treatment approaches, pain control during treatment is still poorly understood and little is known about the best method to manage orthodontic pain.

In recent developments, various interventions are utilized to overcome pain during orthodontic treatments including pharmacological and non-pharmacological approaches. Pharmacological management includes the use of ibuprofen, paracetamol (acetaminophen), piroxicam, meloxicam and lidocaine/prilocaine topical anesthesia (Hussain et al., 2017). In the case of NSAIDs namely ibuprofen and piroxicam, both are reported to have significantly reduced pain (Kohli & Kohli, 2011). However, debates have been going on that NSAIDs do come with unwanted side effects such as gastrointestinal tract (GIT) toxicity, root resorption and tooth movement disruptions. Despite that, NSAIDs is still considered safe and effective if used in lowered doses for a shorter duration (Hussain et al., 2017). On the other hand, paracetamol is considered as a safer alternative than NSAIDs with relatively less side effects. However, concerns have been raised with regards to its long-term treatment side effects, including hypertension, cardiovascular disease, asthma, and renal impairment (McCrae et al., 2018). A study by Zarif Najafi et al., (2015) compared the effects of preemptive paracetamol, ibuprofen and meloxicam on pain after separator placement and concluded that paracetamol does not result in GI ulcers and has no effect on the rate of teeth movement. Lidocaine/prilocaine topical anesthesia provided significant pain relief in comparison to placebo group but the use of this pharmacological approach is not routinely practiced in orthodontic settings (Al-Melh & Andersson, 2017).

In the current times, non-pharmacological management of orthodontic pain consists of low level laser therapy (LLLT) (Bicakci et al., 2012), acupuncture (Boleta-Ceranto et al., 2014), dietary

modification (Riordan, 1997), bite wafer (Murdock et al., 2010) and sugar-free chewing gum (Ireland et al., 2017). Nevertheless, the quality of evidence using non-pharmacological interventions was questionable and required follow-ups (Hussain et al., 2017). The studies mentioned also involve elastomeric separator placement only (Kohli & Kohli, 2011), unspecified orthodontic appliance used (Boleta-Ceranto et al., 2014) and heterogeneity of orthodontic appliances investigated (Riordan, 1997). To better elucidate the effects of a non-pharmacological approach on pain control, a standardized orthodontic appliance will be investigated for more accurate comparison.

Sugar-free chewing gum is one of the growing alternatives in the management of pain in orthodontic treatments. In contrast to NSAIDs where GIT toxicity, root resorption and tooth movement disruptions could occur, sugar-free chewing gum may be a safer alternative. The study by Da Silva (2021) concluded that orthodontic pain relief was achieved efficiently with the aid of sugar-free chewing gum prior to initial archwire placement. To the best of our knowledge, current literature on the effectiveness of pain control by chewing gum is only limited to initial phase of orthodontic treatment and no study has been further conducted on later stage of orthodontic treatment, such as using final stainless steel working archwire.

Archwire provides force to correct irregularities in tooth position (Sharma et al.,2022). Theoretically, different types of archwires exhibit different amounts of force. Initial archwires placed at the start of orthodontic treatment are primarily used to align teeth by addressing crowding and rotations (Wang et al., 2018), with nickel titanium (NiTi) archwires being the preferred choice in the initial stages of treatment (Mcnamara et al., 2009). However, it is ineffective for the middle and end stages of orthodontic therapy due to its superelasticity and inability to close extraction space using these soft wires (Krzysztof Schmeidl et al,. 2021). During the later space closure stage, 99% of clinicians stated that they used stainless steel as a preferred archwire material for closure of premolar extraction spaces (Mcnamara et al 2009). Because of their lower spring back qualities, stainless steel wires may create stronger forces in a shorter amount of time, storing less energy than NiTi and beta titanium wires (Ravlyk, 2022). Aslihan et al., (2004) argued that no significant correlation was found for the time at which initial pain was perceived after insertion of two initial archwires of different sizes. In another study, Sandhu & Sandhu (2013) compared the pain perception between two initial archwires used for initial leveling and aligning phase; superelastic

NiTi and multistrand stainless steel archwires, with no statistically significant difference in the mean average pain across all time points between these archwires. To the best of our knowledge, there have not been any studies investigating the pain associated with the insertion of final rectangular stainless steel working archwires.

3.0 Materials and Methods

3.1 Study design and setting

This will be a randomized clinical trial conducted at the Department of Orthodontics, Kulliyyah of Dentistry, IIUM, from January 2023 to February 2024 after ethical clearance from IIUM Research Ethics Committee (IREC).

3.2 Sample size determination

Using G*Power 3.1.9.7 for One-Way Repeated Measure ANOVA between factors, the sample size was computed. The power was set at 90%, the alpha was set at 0.05, the number of groups was 2, the number of measurements was 8, and the correlation was set at 0.5. Taking into consideration the 10% dropout rate, a total sample size of 40/(1-0.1) = 44 will be needed for the investigation.

3.3 Inclusion criteria

- Healthy female
- 20-40 years old
- Upper and lower 0.019” x 0.025” rectangular stainless steel archwires
- Non-smoker
- No craniofacial anomalies

3.4 Exclusion criteria

The exclusion criteria are patients:

- Only had upper or lower stainless steel archwires
- Receiving any form of analgesics
- Oral surgery in the previous four weeks.
- Pregnant woman
- Previous orthodontic/orthognathic treatment

3.5 Subjects randomisation

The randomization process will be carried out using random table generation (WebPower Statistical power analysis online). Patients will then pick a sealed envelope from a basket containing a number generated by random table generation. They were randomly allocated into one of the two groups of 22 subjects each: the chewing gum group (experimental group) and the control group, according to the number. To avoid bias, this will be done prior to subject recruitment. Informed consent will be obtained, and patients will be given information leaflets summarizing the proposed study. They will be asked to sign a written consent form. Following the placement of stainless steel archwires, all patients will receive a standardized set of oral instructions regarding general dental and orthodontic care.

3.6 Clinical procedure

A Visual Analogue Scale (VAS) (Figure 1) measurement instrument will be used to assess pain felt by the participants throughout the placement of stainless steel archwire. The scale is set at 0 mm (no pain) and 100 mm (pain) (worst pain imaginable) and participants will be asked to put the mark corresponding to their pain level on the straight line. Subjects in both groups will measure the perception of pain at baseline (before placement of stainless steel archwires), immediately after placement (0 hour), at 12, 24, 36, 48, 60 and 72 hours after archwire placement.

Subjects in the experimental group will be instructed to chew a sugar-free chewing gum (Wrigley's Extra, Malaysia) for 5 minutes immediately after stainless steel archwire placement. They will chew the gum every 12 hours for the next three days. They will also be instructed to make a vertical mark on the VAS scale after 5 minutes of gum chewing, and to note any bracket/tube/molar band dislodgement during the gum chewing within 3 days of the experimental period. At the next appointment approximately one month after placement of stainless steel archwire, the treating orthodontist will verify bracket dislodgement noted by the patients in the questionnaires. The distance (in mm) from point 0 to the mark set by the subject to indicate their pain sensation at each assessment will be transcribed from each individual VAS recording as the pain scoring. A simple plastic transparent ruler will be used to measure the line by one operator (M.I.) and intra-examiner reliability for the measurements will be tested by re-measuring the questionnaires two weeks later.

No chewing gum will be given to the control group. All subjects are permitted to take analgesic medication as needed and to document this information in the provided questionnaire. The subjects will record the type, dosage, time, and frequency of pain tablets taken for analgesic consumption. In order to assess the effect of chewing gum on pain perception, analgesic use and appliance breakages, each patient in both the experimental and control groups will be asked to complete the questionnaire and send it back during the next appointment.

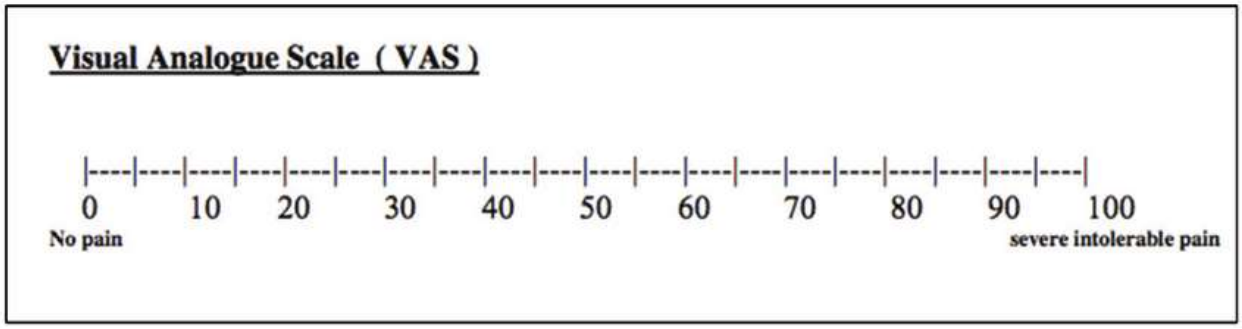


Figure 1: Visual Analogue Scale (VAS) (0-100mm)

3.7 Statistical analysis

All statistical tests will be performed using IBM SPSS software version 25.0 (Chicago, Illinois, USA) with a significance level set at $p < 0.05$. Descriptive statistics will be used to summarize the mean and standard deviation of patients' age, and the frequency of analgesics intake and appliance breakages. The effects of sugar-free chewing gum on the mean pain score at different time points will be compared using a one-way repeated measure ANOVA. The questionnaires will be analyzed by one operator who is blind to the group allocation. Intra-examiner reliability of the VAS measurements will be tested by intraclass correlation coefficient (ICC) following the re-measurement of subject questionnaires.

Chi-square test will be used to detect any statistically significant differences on the usage of analgesics and appliance breakages between experimental group and control group.

4.0 Expected Results (Dummy tables)

Table I: Mean pain score, standard deviation and *p* value at baseline, immediately after wire placement which is 0 hour,12 hours and at 24 hours for 3 days interval among two groups.

Time intervals (Hours)	**Chewing gum group**		**Control group**		***p* value**
	***Mean* pain score(mm)**	***Standard deviation***	***Mean* pain score(mm)**	***Standard deviation***	
Baseline					
0 (immediately after wire placement)					
12					
24					
36					

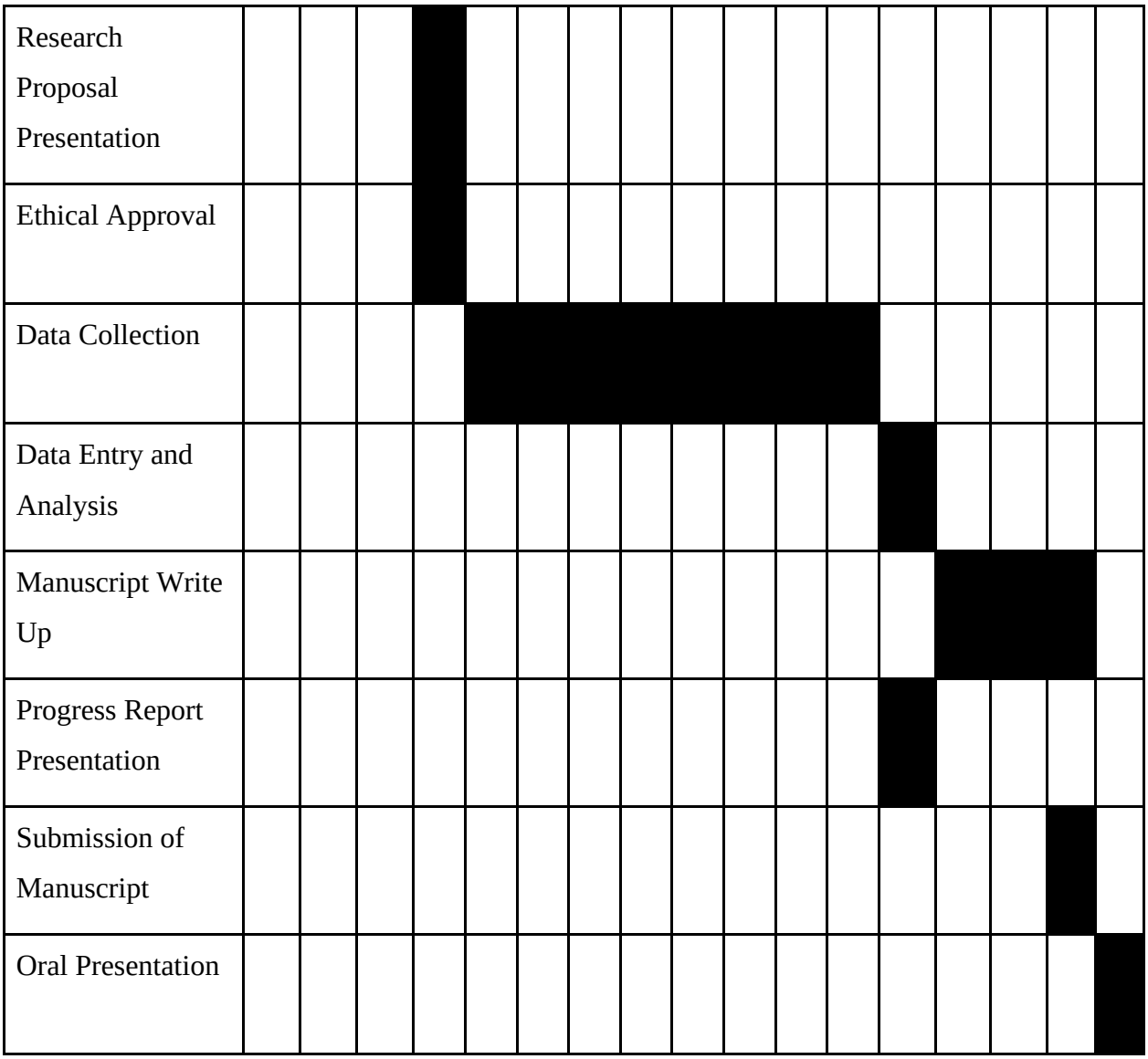
48					
60					
72					

Table II: Usage of other analgesics and bracket dislodgement, Chi-square and *p* value differences between experimental group and control group.

	Experimental group		**Control group**		**Chi square *p* value**
	Yes	**No**	**Yes**	**No**	
Analgesic intake					
Bracket/tube/bands dislodgement					

5.0 Timeline/Gantt chart

Project Activities	2022			2023												2024	
	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2
Literature Review																	
Proposal Writing																	



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