

An orthodontic tooth brushing technique to enhance oral hygiene in patients with fixed appliances: interim results of a randomized controlled clinical trial

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March 2015

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ACKNOWLEDGEMENTS

This work is an example of the impossible made possible. This was only made possible with the help of so many people.

Words cannot possibly describe the amount of inspiration and guidance I have received, from my primary supervisor, Professor Mauro Farella. Thank you so much for your generosity in support, ideas, guidance, and the amount of time which you have spent with me. I am very lucky to have you as a mentor.

I would also like to express my sincere gratitude to my secondary supervisor, Dr. Li Mei. Without your expertise, knowledge, and above all, patience you've shown me, you and I both know what would, or would not have happened. Thank you for being a great mentor, and a good friend.

I would also like to acknowledge the generosity of Colgate-Palmolive and Henry-Schein, for their contribution of oral hygiene products for the research participants.

Last but not least, I would like to thank my dear family. Umma and Abba, thank you very much for your unconditional love and being the best parents one can only dream of. I have regrettably been shy in expressing my feelings back to you. Your confidence in me has fueled myself to the best I can be. Saranghapnida.

Chapter 1

Tooth brushing techniques for oral health: a systematic review

ABSTRACT

Objective: The aim of this chapter is to review different tooth brushing techniques for removing plaque and improving gingival health.

Methods: A MEDLINE, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL) and grey literature search was conducted up to and including February 2015. Studies that compared tooth brushing techniques and that improved plaque control and gingival health were considered. The efficacy of tooth brushing techniques was assessed for four different population groups: adults, children, patients with periodontal disease, and orthodontic patients wearing fixed appliances.

Results: Of the 749 articles that were screened, 23 full-text articles were retrieved and nine were included in this review. A total of five studies have been conducted on adults, three on children, none on periodontal patients and one on orthodontic patients.

Studies on adults have compared the *Modified Bass*, *Bass*, *Toothpick*, *Fones*, and *Vertical* techniques in improving oral hygiene. The techniques in descending order of effectiveness in improving oral hygiene for adults were the *Fones*, *Modified Bass* and then the *Vertical* technique. The *Toothpick* technique was found to be more effective than the *Bass* technique. Comparisons of the efficacy of the *Toothpick* and *Bass* techniques to the *Fones*, *Modified Bass* and *Vertical* techniques were not mentioned in any of the studies. Furthermore, efficacy of other techniques not included in these studies, such as the *Horizontal scrub* or *Charters' technique* remains unknown.

For children, comparisons were made between the *Bass*, *Fones*, *Horizontal*, *Modified Bass*, and *Roll* techniques. The techniques in descending order of effectiveness for children were the *Modified Bass*, *Horizontal* then *Roll* technique. The *Horizontal* technique was also found to be more effective than the *Fones* technique. The efficacy of techniques not included in these studies remains unknown.

No studies have compared tooth brushing techniques on patients with periodontal disease.

For orthodontic patients with fixed appliances, one study had compared the *Modified Stillman*, *Horizontal*, and *Bass* techniques. The *Bass* technique was found to be more effective than the

Horizontal, followed by the *Modified Stillman* technique in improving gingival health. However, the *Horizontal* technique was found to be more effective in removing plaque for patients with orthodontic appliances than the *Modified Stillman* technique, followed by the *Bass* technique.

Of the nine studies included, only one study had a low risk of bias. Meta-analysis could not be performed in all four population groups due to the heterogeneity of the studies and a high risk of bias in most of them.

Conclusions: There is a lack of evidence to support any recommendations on tooth brushing techniques for all four groups. This review highlights the need for high quality clinical trials that compare different tooth brushing techniques, before one can reach conclusions on the most effective brushing techniques for different dental populations.

1.1. INTRODUCTION

Dental caries and periodontal disease are important global oral health diseases (1). Untreated caries in permanent teeth affects 35% of the global population and is the most prevalent disease worldwide (2). Severe periodontal disease is the sixth most prevalent disease affecting 11% of the global population (2). Both of these oral diseases have a profound economic impact as 5-10% of public health expenditure is designated to improve oral health (1, 3). As a result, there is a great need for the prevention of these common oral diseases.

Dental plaque accumulation is known to be the primary cause of periodontal disease and dental caries (4, 5). Therefore, adequate removal of dental plaque is crucial in preventative dentistry. This is especially important for patients receiving orthodontic treatment, since fixed appliances encourage an increase in plaque accumulation and retention (6). Numerous interventions have emerged to enhance the removal of dental plaque, which include mechanical, chemical and biological methods (7, 8). Mechanical methods of plaque control involve tooth brushing and interdental cleaning with a wide range of products currently available (8). Chemical methods utilize compounds such as toothpastes and mouthrinses (8). Biological methods on the other hand consist of probiotics and vaccines (7), which have recently gained popularity and are being researched extensively (7, 9-11).

Of all the methods of plaque removal, tooth brushing is the most commonly used, often on a daily basis (7, 8, 12-15). Therefore, evidence on the most effective manual tooth brushing technique is important to ensure patients are as efficient as possible with the daily removal of dental plaque. Effective brushing will prevent the subsequent development of oral diseases. Tooth brushing may be performed using a powered, or a manual toothbrush. Powered tooth brushing has been shown to be superior to manual tooth brushing in the reduction of plaque and improvement of periodontal health in a recent Cochrane review (16). However, manual toothbrushes are used by the majority of patients. Three quarters of adults in the UK use a manual toothbrush (17), and manual toothbrushes represent 93% of the toothbrush sales in France (18). Tooth brushing may also be performed using toothpastes with different ingredients, where the use of triclosan/copolymer fluoride toothpastes were shown to be beneficial in improving oral hygiene compared to fluoride toothpaste without triclosan/copolymer (19). However, regardless of the efficacy of a toothpaste,

tooth brushing is still required and should be performed regularly. Therefore, an effective manual tooth brushing technique for plaque removal is important for the prevention of dental caries and periodontal disease.

To date, the optimal tooth brushing technique for good oral hygiene is still poorly understood (18, 20). Studies comparing the efficacy of different tooth brushing techniques in improving oral hygiene have concluded no techniques to be superior over another (20, 21). However, a common limitation of these studies was the comparison of only a certain number of techniques. To the best of our knowledge, pooling of evidence on the efficacy of different tooth brushing techniques has not been performed to date. This is necessary to identifying the tooth brushing technique that is most effective in plaque removal, should one exist.

Additionally, different dental population groups retain plaque in different sites of the oral cavity. In general, adults and children develop dental caries in interdental areas and occlusal fissures (22), whereas periodontal patients, often retain dental plaque around gingival margins (23). Orthodontic patients on the other hand have difficulties removing plaque around fixed appliances (24). Therefore, one cannot assume that a technique designed for the general population is equally effective on periodontal and orthodontic patients.

Consequently, the aim of this systematic review was to compare the efficacy of different tooth brushing techniques in removing dental plaque and improving gingival health in adults, children, patients with periodontal disease, and patients with orthodontic fixed appliances.

1.2. MATERIALS AND METHODS

1.2.1. Search strategy

The systematic search strategy (Table 1) was developed for MEDLINE (OVID), and was revised accordingly for each database. The following databases were searched:

- MEDLINE via OVID (1946 to 2 February 2015)
- EMBASE via OVID (1947 to 2 February 2015)
- CINAHL via EBSCO (1981 to 2 February 2015)
- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, 2 February 2015)

The search strategy attempted to identify all relevant studies irrespective of language or date of publication. Further manual searches on cited references of included trials were performed, along with grey literature searches on Google Scholar¹. When identified trials were not written in English, the translation function in Google Translate² was used, as was done in the previous study (25).

¹ <http://scholar.google.com/> accessed on 2 February 2015.

² <http://translate.google.com/> accessed on 2 February 2015.

Table 1: MEDLINE via OVID search strategy.

1	toothbrushing/mt [Methods]
2	toothbrushing/is [Instrumentation]
3	1 OR 2
4	Dental Plaque/pc [Prevention & Control]
5	Gingivitis/pc [Prevention & Control]
6	4 OR 5
7	3 AND 6
8	Limit 7 to humans
9	Limit 8 to (clinical trial or comparative study or randomized controlled trial)

1.2.2. Types of participants

No limitations were set on the age or ethnicity of the participants. Studies on participants with any disability that could affect tooth brushing ability was excluded. Studies on patients with periodontal disease and fixed orthodontic appliances were analysed independently.

1.2.3. Types of interventions

All manual tooth brushing techniques were included in the review. Trials were excluded if oral hygiene aids were used as a combined intervention with the tooth brushing technique. However, trials allowing participants' continuation of their usual oral hygiene habits were included.

1.2.4. Types of outcome measure

The primary role of a tooth brushing technique is to prevent dental caries and periodontal disease via mechanical removal of dental plaque. Therefore, quantifying indices of plaque and gingivitis were considered to be the most relevant outcome measures. Studies were included if indices of plaque (plaque index, PI) or gingival inflammation (gingival index, GI) were used as outcome measures.

1.2.5. Inclusion/exclusion criteria

The review was confined to randomised controlled trials that compared different manual tooth brushing techniques. Cross-over trials were included if carry-over effect had not been observed, in order to minimize possible bias due to this effect. The review excluded trials that allocated different toothbrush designs to different groups, as this was considered a significant confounder. Trials that compared different teeth between the groups were excluded, since different teeth were shown to accumulate different quantities of plaque (26, 27). Trials were also excluded if the participants did not do the brushing themselves, as this did not represent everyday brushing.

1.2.6. Data collection and analysis

Titles and abstracts of articles identified in the search were screened for relevance. Full reports of all relevant articles were obtained and assessed for eligibility. Reasons for exclusion of the studies are highlighted in Figure 1. The following information was collected from the included studies:

- Name of the author(s) and the publication date
- Study design
- Sample size and characteristics (age and gender)
- Measured outcome parameters, and the indices used
- Details of intervention
- Results

1.2.7. Risk of Bias

Risk of bias was assessed using the approach outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0.³ The six domains evaluated for assessment were sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias.

³ <http://Handbook.cochrane.org/> accessed on 2 February 2015.

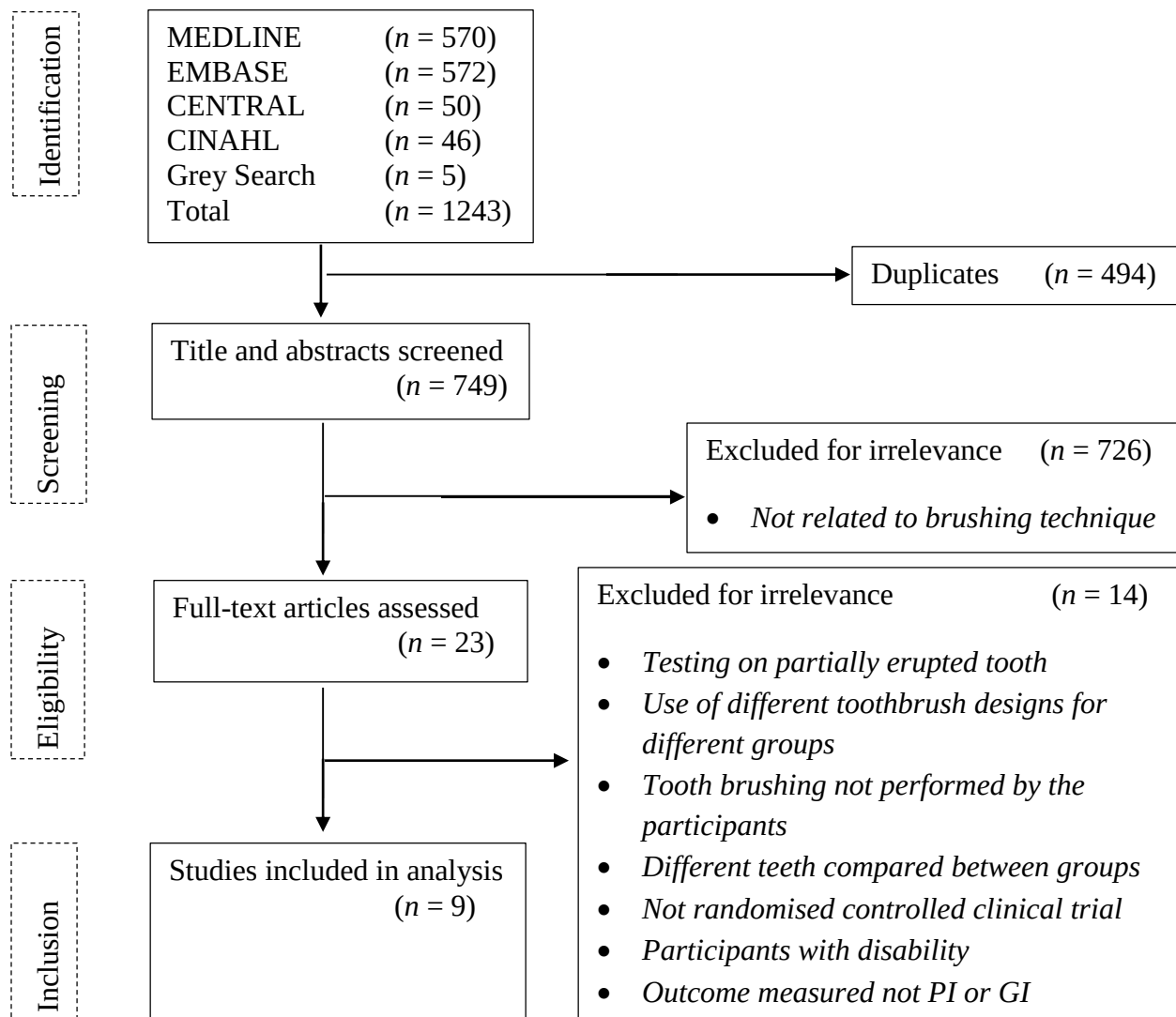


Figure 1: Overview of systematic review. Processes of identification, screening, assessment of eligibility and inclusion of studies are outlined.

1.3. RESULTS

A total of nine studies met all the inclusion criteria and were included in this review.

The tooth brushing techniques identified and included in the trials were the *Modified Bass* (27-31), *Bass* (32-34), *Fones* (29, 30), *Vertical* (31), *Modified Stillman* (34), *Roll* (35), and *Horizontal* (30, 34, 35) techniques. Few studies have included a control group (27, 28, 33), where no specific instructions on a technique were given. If a trial had included ‘*Scrub*’ as one of the techniques (30, 33, 35), description of the technique have been read to define the technique as either *Horizontal* (30, 35) or *Fones* (33). This was necessary as the term ‘*Scrub*’ was used to describe either of these techniques. The *Circular* technique was considered almost identical to the *Fones* technique, thus was classified as *Fones* (33).

Meta-analysis could not be performed due to the heterogeneity of the studies included and a high risk of bias in most studies.

1.3.1. Risk of bias

The nine studies included in the review (27-35) were assessed on their risk of bias (Table 2). Only one study was rated as being at a low risk of bias. Five studies were assessed as being at an unclear risk of bias (29-31, 33, 35). These studies did not describe either the randomisation sequence generation (30, 33, 35), concealment of allocation (30, 31, 33, 35), blinding of outcome assessment (30, 33), or loss to follow up (29-31, 33, 35). Three studies were assessed with a high risk of bias (28, 32, 34). This was because study participants were comprised entirely of dental students (28, 32), or significant differences were present between the groups in the baseline parameters (34).

Table 2: Risk of bias summary.

Author(s) and date of publication	Random sequence generation	Concealment of allocation	Blinding of outcome assessment	Complete outcome data	Non-Selective outcome reporting	Other source(s) of bias	Overall risk of bias
Schlueter et al. (2013)	+	+	+	+	+	+	Low
Graetz et al. (2013)	+	?	+	+	+	-	High
Morita et al. (1998)	?	?	+	?	+	-	High
Harnacke et al. (2012)	+	+	+	?	+	+	Unclear
Zhang et al. (2005)	+	?	+	?	+	+	Unclear
Robinson (1976)	?	?	?	?	+	+	Unclear
Patil et al. (2014)	?	?	?	?	+	+	Unclear
Sangnes (1974)	?	?	+	?	+	+	Unclear
Nassar et al. (2013)	?	?	?	?	+	-	High

+, low risk; ?, unclear risk; -, high risk.

1.3.2. Tooth brushing techniques for adults

A total of five studies (27-29, 31, 32) have compared tooth brushing techniques in adults and are summarised in Table 3. One study was assessed with a low risk of bias (27). The *Fones* technique was found to be more effective than the *Modified Bass* technique (29) in plaque removal. The *Modified Bass* technique in turn was found to be more effective than the *Vertical* technique (31). There were conflicting results when the efficacy of the *Modified Bass* technique was compared with the control group (27, 28). Significant PI reduction was observed with computer-based training in the *Modified Bass* technique (28), but not with verbal, leaflet, or model demonstrations (27). The *Toothpick* technique was found to be more effective than the *Bass* technique in plaque removal (32).

1.3.3. Tooth brushing techniques for children

A total of three studies have compared tooth brushing techniques in children (30, 33, 35) (Table 3). None of the studies in this group were assessed with a low risk of bias. *Modified Bass* was found to reduce PI significantly more than the *Horizontal* technique (30). However, the *Horizontal* technique was more effective than the *Fones* and *Roll* techniques in plaque removal (30, 35). No significant differences were found between the effectiveness of the *Bass* technique, *Fones* technique, and controls (33).

1.3.4. Tooth brushing technique for periodontal patients

No studies conducted on patients with periodontal disease fulfilled all inclusion criteria.

1.3.5. Tooth brushing technique for orthodontic patients

Only one study was found comparing tooth brushing techniques for orthodontic patients (34), summarised in Table 4. The *Bass* technique was found to be more effective than the *Horizontal* technique, followed by the *Modified Stillman* in reducing gingival index (GI). However, the *Horizontal* technique was found to be more effective than the *Modified Stillman* followed by the *Bass* technique in reducing PI.

Table 3: Summary of the studies on general patients (adults and children). RCT, randomised controlled trial; PI, plaque index; TQH, Turesky modified Quigley – Hein; PH, Podshadley and Haley; GI, gingival index; L&S, Løe and Silness; S&L, Silness and Løe; NRCT, non-randomised clinical trial; CCS, cross sectional study.

Author(s)	Study design	Sample Size (Age in years)	Outcomes	Interventions	Results
Schlueter et al. (2013)	RCT	77 (26.6 ± 4.5)	PI (TQH)	Modified Bass	Modified Bass = Control
	Single-blind		0, 2, 4 weeks.	Control	For both groups, PI decreased at week 2, and no further decrease at week 4
Graetz et al. (2013)	RCT	21 (20 - 29)	PI (TQH)	Modified Bass	Modified Bass > Control
	Single-blind			Control	
Morita et al. (1998)	RCT	20 (24 - 26)	PI (TQH)	Toothpick	Toothpick > Bass
	Single-blind		Immediately after brushing	Bass	Significant difference at the interproximal areas
	Split-mouth				No difference at buccal/lingual areas
Harnacke et al. (2012)	RCT	56 (mean 23.23)	PI (TQH)	Fones	Fones > Modified Bass = Control
	Single-blind		Marginal PI (Deinzer) 6, 12, 28 weeks later	Modified Bass Control	

Zhang et al. (2005)	RCT	40 (18 - 35)	PI (TQH)	Modified Bass	Modified Bass > Vertical
	Cross-over		Proximal Marginal PI (Benson)	Vertical	Significant difference at central margin
	Single-blind				No difference at interproximal areas
Robinson (1976)	RCT	311 (12 - 13)	PI (PH)	Bass	Bass = Fones = Control
			GI (L&S)	Fones	
			After 1 month of daily supervised brushing	Control	
Patil et al. (2014)	RCT	180 (6 - 8)	PI (S&L)	Horizontal	Modified Bass > Horizontal > Fones
			24hours post instruction	Fones	
				Modified Bass	
Sangnes (1974)	RCT	99 (6 - 7)	PI (S&L)	Roll	Horizontal > Roll
	Single-blind		Baseline, immediate and 11 weeks.	Horizontal	Parents brushing > children brushing

Table 4: Summary of the study on orthodontic patients. RCT, randomised controlled trial; L&S, Löe and Silness; S&L, Silness and Löe; PI, plaque index; GI, gingival index.

Author(s)	Study type	Sample Size (Age in years)	Parameters measured	Intervention	Results
Nassar et al. (2013)	RCT	30 (14 - 22)	PI (S&L)	Horizontal	Bass > Horizontal > Modified Stillman
			GI (L&S)	Modified Stillman	
			0, 3, 6 and 9 months later	Bass	

1.4. DISCUSSION

The review compared different tooth brushing techniques used to improve oral hygiene. Despite the fact that tooth brushing is the most common method used to prevent oral diseases, evidence was largely lacking on the optimal tooth brushing technique for improving oral hygiene in adults, children, patients with periodontal disease, and patients with orthodontic fixed appliances.

Different interventions are available to improve the effectiveness of tooth brushing. These include the use of powered tooth brushes, different toothbrush designs, and manual tooth brushing techniques. This review focused on the different manual tooth brushing techniques available as manual tooth brushes are more commonly used by the majority of patients, despite powered brushes being shown to be superior in improving oral hygiene (16). Furthermore, while different tooth brush designs are undergoing extensive research (36-41), a manual tooth brushing technique is still required with any of the brush designs.

With adults, children, patients with periodontal disease and orthodontic patients with fixed appliances having different sites of plaque retention, it cannot be assumed that tooth brushing techniques are equally effective across all groups. Thus, different tooth brushing techniques were compared independently for adults, children, patients with periodontal disease and orthodontic patients with fixed appliances.

Based on the findings of this review, only a handful of manual brushing techniques and their effect on oral hygiene have been compared for each of the population groups. Studies on adults have compared the *Modified Bass*, *Bass*, *Toothpick*, *Fones*, and *Vertical* techniques. For children, comparisons were made between the *Bass*, *Fones*, *Horizontal*, *Modified Bass*, and *Roll* techniques. No studies have compared tooth brushing techniques on patients with periodontal disease, whereas the *Modified Stillman*, *Horizontal* and *Bass* techniques were compared in orthodontic patients. Thus, the efficacy of a number of brushing techniques in each of the groups remains unknown.

1.4.1. Tooth brushing techniques for adults

For adults, the *Bass* and *Modified Bass* techniques are found to be the two most widely advocated techniques (25). However, no difference was found when the *Bass* technique was compared with the control group in plaque reduction (33), whereas conflicting results were found when the *Modified Bass* technique was compared with controls (27, 28). These conflicting results for the *Modified Bass* technique could be attributed to the different methods used to teach the technique. While a digital training system was used in one study, verbal instructions and/or model demonstrations were used in the other. It is important to consider that in the clinical setting, oral hygiene instructions would mostly be given verbally and/or with model demonstrations. When such verbal instructions or model demonstrations were used to teach the *Modified Bass* technique to the participants, an insignificant improvement in the PI was observed in comparison to controls (27). Therefore, in light of current evidence, public recommendation of the *Bass* and the *Modified Bass* techniques to adults should be reconsidered.

With the questionable effectiveness of the *Modified Bass* technique in improving oral hygiene, it seems logical to not recommend any techniques that are shown to be inferior to the *Modified Bass*. One study with an unclear risk of bias, found the *Vertical* technique to be inferior to the *Modified Bass* technique in plaque removal in adults (31). Although it is difficult to draw conclusions from the quality and quantity of evidence that is currently available, it seems that the recommendation of the *Vertical* technique to adults is better avoided until high quality evidence suggests otherwise.

Despite the fact that the *Modified Bass* technique is one of the techniques most widely advocated (25), the *Fones* technique was found to be more effective than the *Modified Bass* technique in improving oral hygiene in adults (29). Simplicity and familiarity with the movements involved with the *Fones* technique contributed to its superior efficacy in oral hygiene maintenance over the *Modified Bass* technique (29). However, the study used a digital training system to educate the participants on the particular techniques which limits the generalisability of the results.

Additionally, the *Bass* technique is widely advocated by professionals (25), however the *Toothpick* technique was found to be more effective in plaque removal in adults (32). The significant difference in the PI was seen in the interproximal surfaces, while there were no differences in the

buccal/lingual areas. However, the study was had a high risk of bias, due to the participants being comprised of dental students only, limiting the generalisability of the results.

While there are many other techniques available such as the *horizontal* or *Charter's*, no trials have investigated the efficacy of all these techniques in adults. As a result, efficacy of these techniques in improving oral hygiene in adults is unknown. This review highlights the need for high quality trials to compare all the different tooth brushing techniques in order to find the optimal technique for improving oral hygiene in adults.

1.4.2. Tooth brushing techniques for children

A recent systematic review found the *Horizontal* technique to be the most effective in improving oral hygiene in children between the ages of six and eight years (18). However care must be taken when interpreting this result, since the review looked at studies that compared the *Horizontal* technique with the *Roll* technique only. Additionally, the *Horizontal* technique was found more effective than *Fones* technique in removing plaque (30) for children of this age. However, the risk of bias in this study was unclear.

On the other hand, the *Modified Bass* technique was found to be more effective in plaque removal than the *Horizontal* technique for children of a similar age (30). As a result, the *Modified Bass* technique seems to be the most effective of all techniques tested in young children to date. However, it cannot be concluded that the *Modified Bass* technique is the optimal technique for plaque removal in young children. This is because the study comparing the *Modified Bass* technique to the *Horizontal* technique had an unclear risk of bias. Furthermore, the efficacy of other techniques, yet to be compared in young children, remain unknown.

Consequently, no conclusions can be made on the optimal brushing technique for improving oral hygiene in children between the ages of six and eight. Moreover, no studies were found comparing different techniques in children outside this age range. Thus, an effective tooth brushing technique for children of all ages remains largely unknown. This warrants the need for further high quality trials before a brushing technique can be identified as optimal for improving the oral hygiene of children.

1.4.3. Tooth brushing techniques for periodontal patients

In order to eliminate one of the confounders, periodontal patients have been excluded from studies investigating the efficacy of tooth brushing techniques in improving oral hygiene. However, one of the most important phases of periodontal treatment is home maintenance. Therefore this warrants similar studies on periodontal patients that suggest better methods of periodontal health management such as the use of an effective tooth brushing technique.

One study found the so called *Subgingival-root* brushing to be more effective than the control group in reducing PI scores and probing depths in patients with periodontal disease. This study was excluded in our review since different teeth were compared between the groups. Nevertheless, further trials on this technique may aid in improving the oral hygiene of patients with periodontal disease.

1.4.4. Tooth brushing techniques for orthodontic patients

For orthodontic patients with fixed appliances, the *Bass* technique was found to be more effective than the *Horizontal* technique, followed by the *Modified Stillman technique* in improving gingival health (34). However, in removing plaque, the *Horizontal* technique was found to be the most effective where the *Bass* technique was the least. This could be explained by the fact that the *Bass* technique characteristically targets plaque on the gingival margin and in the sulcus but is unable to clean areas around the fixed appliances. Gingival inflammation and white spot lesions are more prevalent in orthodontic patients (42-44). Thus, the *Bass* technique may be beneficial in improving gingival health, but the recommendation of the technique would not be justified if the risk of white spot lesions was to increase. Nevertheless, the efficacy of tooth brushing techniques has been compared in only one study to date, which had a high risk of bias. This highlights the need for an effective tooth brushing technique for orthodontic patients, which currently does not exist.

1.5. CONCLUSION

To date, there is a lack of sufficient scientific evidence to support any recommendations on tooth brushing techniques for adults, children, patients with periodontal disease, and patients receiving orthodontic treatment with fixed appliances. This review highlights the need for high quality clinical trials comparing all of the techniques known, prior to drawing conclusions on the most effective technique for different patient populations, if such a technique exists.

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Chapter 2

An Orthodontic tooth brushing technique to enhance oral hygiene in patients with fixed appliances: interim results of a randomised controlled clinical trial

ABSTRACT

Introduction: Traditional tooth brushing techniques, such as the *Modified Bass* technique, are designed and aimed at the general population without orthodontic appliances. An effective tooth brushing technique for patients wearing orthodontic fixed appliances is still lacking.

In this study, an *Orthodontic* tooth brushing technique was designed to enhance the oral hygiene of patients with fixed orthodontic appliances, and compared its efficacy with that of the traditional *Modified Bass* technique.

Method: This study was conducted as a single blind randomised controlled clinical trial with two parallel arms. With an aim to recruit 60 patients, this interim analysis included 34. To date, 18 patients were assigned to the *Modified Bass* technique, and 16 patients were assigned to the *Orthodontic* technique. Plaque index (PI) was assessed on four surfaces of the teeth in relation to the bracket: PI_G, gingival; PI_M, mesial; PI_D, distal; and PI_O, occlusal. Gingival index (GI) was assessed in three areas: GI_{Mid}, mid-labial; GI_M, mesial; and GI_D, distal. Outcome measurements were taken at baseline (T₀) and one-month (T₁) after the intervention.

Results: After one-month follow up, the *Orthodontic* group had a significant reduction in their overall PI (0.37 ± 0.10 , $p < 0.05$). This was mainly due to the reduction of PI_G (0.54 ± 0.16 , $p < 0.05$), and PI_{M+D} (0.43 ± 0.12 , $p < 0.05$). There was no significant reduction of the GI overall (0.08 ± 0.07 , $p > 0.05$). The *Modified Bass* group had no significant reduction of PI and GI on all surfaces ($p > 0.05$).

When comparing the two groups, the reduction of PI_G of the *Orthodontic* group was significantly higher ($p = 0.041$) than the *Modified Bass* group. No significant differences in the reduction of PI and GI were observed on all other surfaces ($p \geq 0.086$).

Conclusion: Within the limitations of the present interim analysis, the *Orthodontic* tooth brushing technique shows promising results in improving oral hygiene in patients with fixed appliances. However, our preliminary findings indicate that further research is required to verify the efficacy of the *Orthodontic* technique observed in this interim analysis. Also, the *Modified Bass* technique may not be effective in improving the oral hygiene of orthodontic patients.

2.1. INTRODUCTION

Orthodontic treatment is becoming increasingly popular. However, fixed orthodontic appliances increase the accumulation of dental plaque by reducing the efficacy of tooth brushing (1, 2). Inadequate removal of dental plaque leads to side effects such as enamel demineralisation and gingival inflammation (3-5). If not addressed adequately, these side effects may further result in cavitated lesions (6), or destruction of periodontal tissues (7), thereby impacting on treatment results and patients' quality of life.

Different strategies have been investigated to enhance the efficacy of tooth brushing around fixed orthodontic appliances, including the use of electrical tooth brushes (8-13), interdental brushes (14-16), specialised orthodontic tooth brushes (8), and mouthrinses (17). Furthermore, visual aids (18, 19), written instructions (18), and intentional use of the Hawthorne effect (20) have been tested to improve patient compliance with oral hygiene. To date, however, the difficulty in the removal of plaque around fixed appliances remains, with the reported incidence of demineralisation during fixed orthodontic treatment being as high as 72.9% (6).

Tooth brushing is the most common oral hygiene method used on a daily basis to remove dental plaque (21-25). Traditional tooth brushing techniques, such as the *Bass* technique, are often recommended when giving oral hygiene instructions to orthodontic patients (26). However, traditional techniques, were not designed for orthodontic patients and as a consequence are inadequate in removing dental plaque around fixed orthodontic appliances. Additional cleaning aids, such as interdental brushes, are therefore necessary to reinforce plaque removal around appliances and to maintain good oral hygiene in orthodontic patients (27, 28).

However, additional cleaning aids complicate a patient's oral hygiene regimen. This may discourage patients from their use and affect their compliance with oral hygiene management. A Cochrane Review found no studies to support the recommendation of interdental brushes in orthodontic patients (15). Furthermore, observational studies have shown the importance of simplicity in tooth brushing techniques, where the majority of patients brushed using simple techniques such as the *Horizontal* technique (29, 30), and difficult techniques such as the *Modified Bass* technique were not observed in any of the participants (29, 30). Therefore, while effective reinforcement is necessary in patients with orthodontic appliances, a simple brushing technique should be recommended to encourage patient compliance.

To date, effective and simplistic measures to enhance oral hygiene in patients with fixed appliances is still lacking. Furthermore, there is no effective brushing technique designed to adequately remove dental plaque around orthodontic appliances. Consequently, the objective of this study is firstly to design a simple tooth brushing technique for orthodontic patients, and secondly to compare the efficacy of this technique with the traditional *Modified Bass* technique in improving oral hygiene in orthodontic patients with fixed appliances.

The study tested the hypothesis that the *Orthodontic* tooth brushing technique improves oral hygiene outcome measures (plaque and gingival indices) more than the *Modified Bass* technique.

2.2. MATERIALS AND METHODS

2.2.1. Study population and setting

Patients receiving orthodontic treatment at the Faculty of Dentistry, University of Otago were selected for the study.

Inclusion criteria were as follows:

- aged between 11 and 40 years
- undergoing orthodontic treatment with fixed appliances
- residual treatment duration of at least 2 months
- presence of 20 natural teeth or more

Exclusion criteria were as follows:

- fixed lingual orthodontic appliances
- systemic diseases that may affect oral hygiene or gingival health
- periodontal disease
- extensive dental restorations (more than five teeth with restorations)

2.2.2. Study design

This study was conducted as a single-blind randomized controlled trial (RCT) with two parallel arms (Figure 2). One group was taught the *Modified Bass* tooth brushing technique (MBT), while the other group was taught the *Orthodontic* technique (OT) designed by the authors. The follow-up period was set to one month.

2.2.3. Sample size calculation

The calculation of sample size was based on previous estimates of plaque index variability (standard deviation = 0.4), of a similar population group requiring orthodontic treatment (19), and was calculated using a computer software (G*Power, release 3.1.9.2; Heinrich Heine University of Düsseldorf, Düsseldorf, Germany). With α -error set to 0.05 and β error set to 0.20 (80% power), a total of 29 participants were required for each group to detect a plaque index reduction of 0.25 (Figure 3). It was aimed to recruit a total of 60 participants based on these parameters and accounting for the possible dropouts during the study.

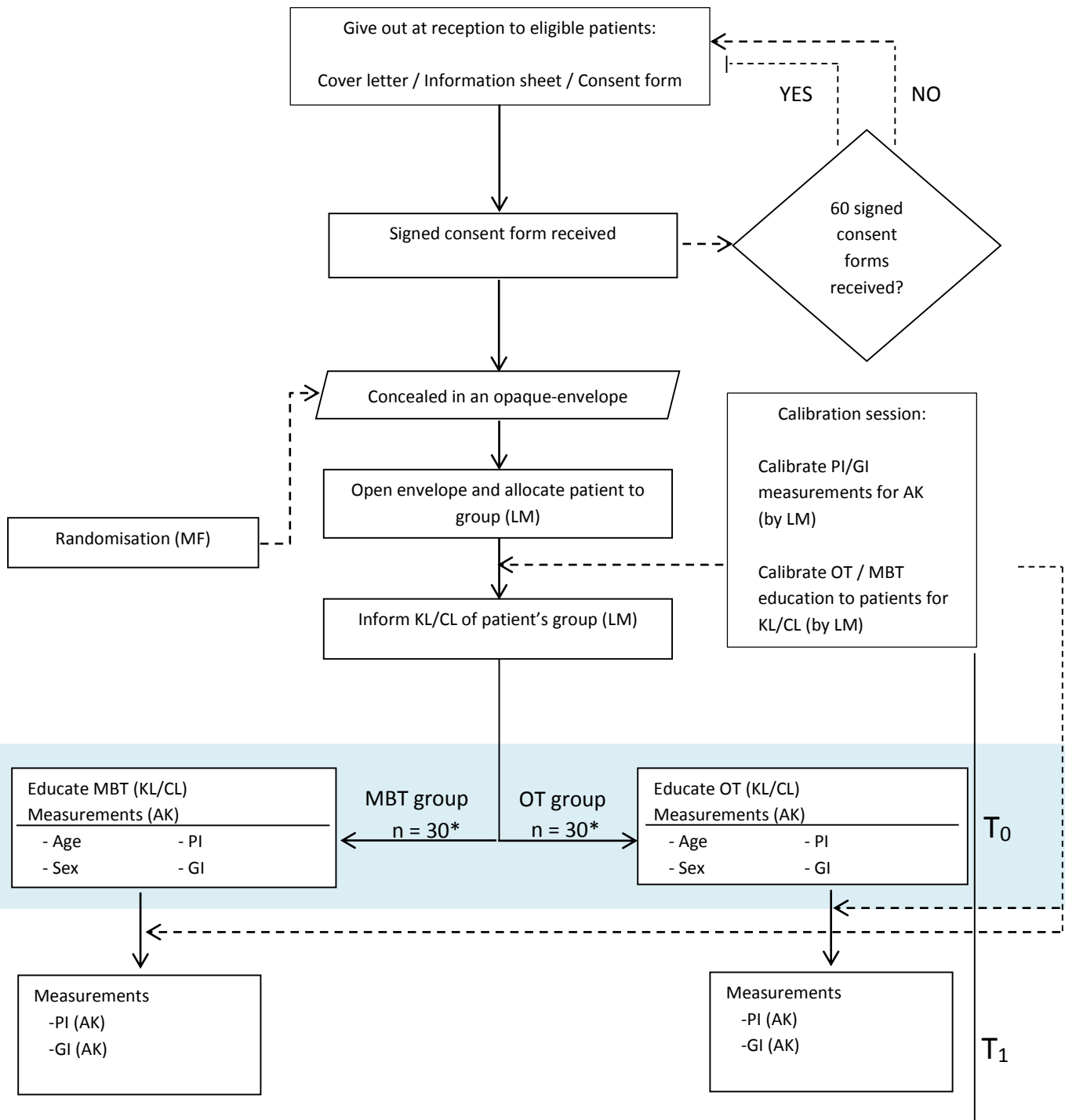


Figure 2. Summary of study design outlining participants' recruitment, group allocation and outcome measurements, along with the initials of researchers conducting each stage of the study. *Intended number of participants. This interim analysis however contains 18 in Modified Bass and 16 in Orthodontic group. MBT, Modified Bass technique; OT, Orthodontic technique; PI, plaque index; GI, gingival index.

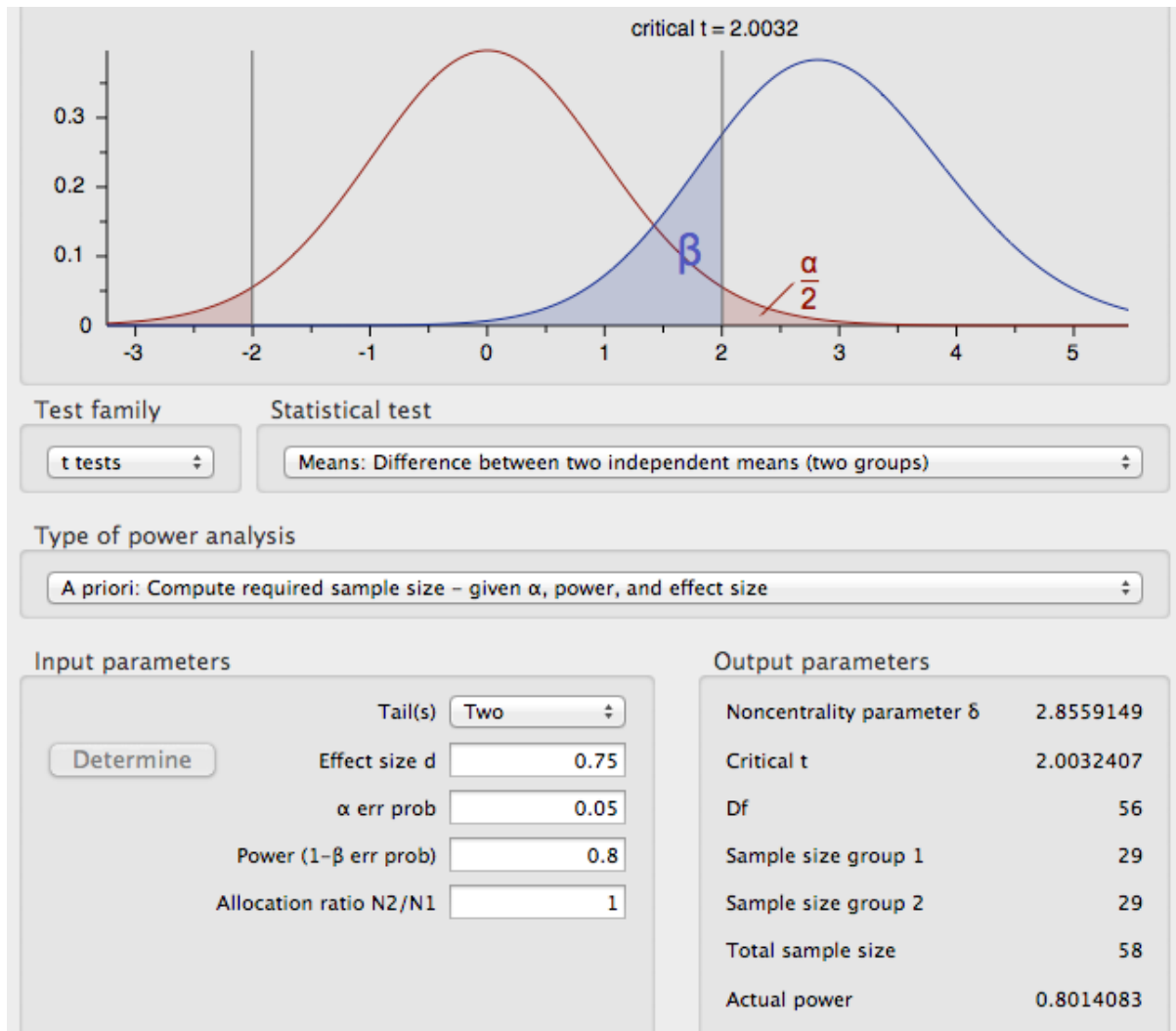


Figure 3. Outputs from sample size calculation using G*Power.

2.2.4. Ethical approval and informed consent

Ethical approval was obtained from the University of Otago Human Ethics Committee (H14/060). All participants were informed of the study design, and written, informed consent was obtained from the patients and the parents before the study.

2.2.5. Randomisation

A balanced block randomisation using a block size of six was computer generated¹ and concealed in an opaque envelope (MF). Investigator (AK) who conducted the measurements was blinded to the group allocation.

¹ <https://www.sealedenvelope.com/simple-randomiser/v1/lists> accessed on 5 May 2014

2.2.6. Tooth brushing techniques

2.2.6.1. Modified Bass technique

The *MBT* technique (Figure 4) (31, 32) involved a gentle back and forth motion with the toothbrush bristles placed 45° to the long axis of the tooth. The bristles of the brush were then swept towards the occlusal surface of the teeth (rolling motion). In order to adapt the technique to orthodontic patients, the same motion was repeated with the bristles positioned just occlusal to the brackets.

2.2.6.2. Orthodontic technique

Considering the majority of the patients brushed using horizontal motion (29, 30), the *Orthodontic* tooth brushing technique in the study was designed (Figure 5) by combining the horizontal strokes and a ‘bite and wiggle’ motion behind arch-wires.

Briefly, the toothbrush was firstly placed gingival to the brackets and angled 45° towards the occlusal surface. The same motion was repeated with the bristles perpendicular to the labial surface of the brackets. Lastly, with the toothbrush perpendicular to the occlusal area of the brackets, the individual was asked to ‘bite and wiggle’. By biting on the toothbrush head, bristles entered into the space behind the arch-wire and between the brackets (Figure 6).

2.2.7. Delivery of intervention

Two independent dental investigators (KL/CL) taught the two techniques to the participants using verbal instructions and a demonstration on an orthodontic model. Participants were then asked to repeat the technique intra-orally and corrections in technique were given to participants if necessary.

The teaching of the techniques to the participants was calibrated, prior to the study, using videos and models for the two investigators.

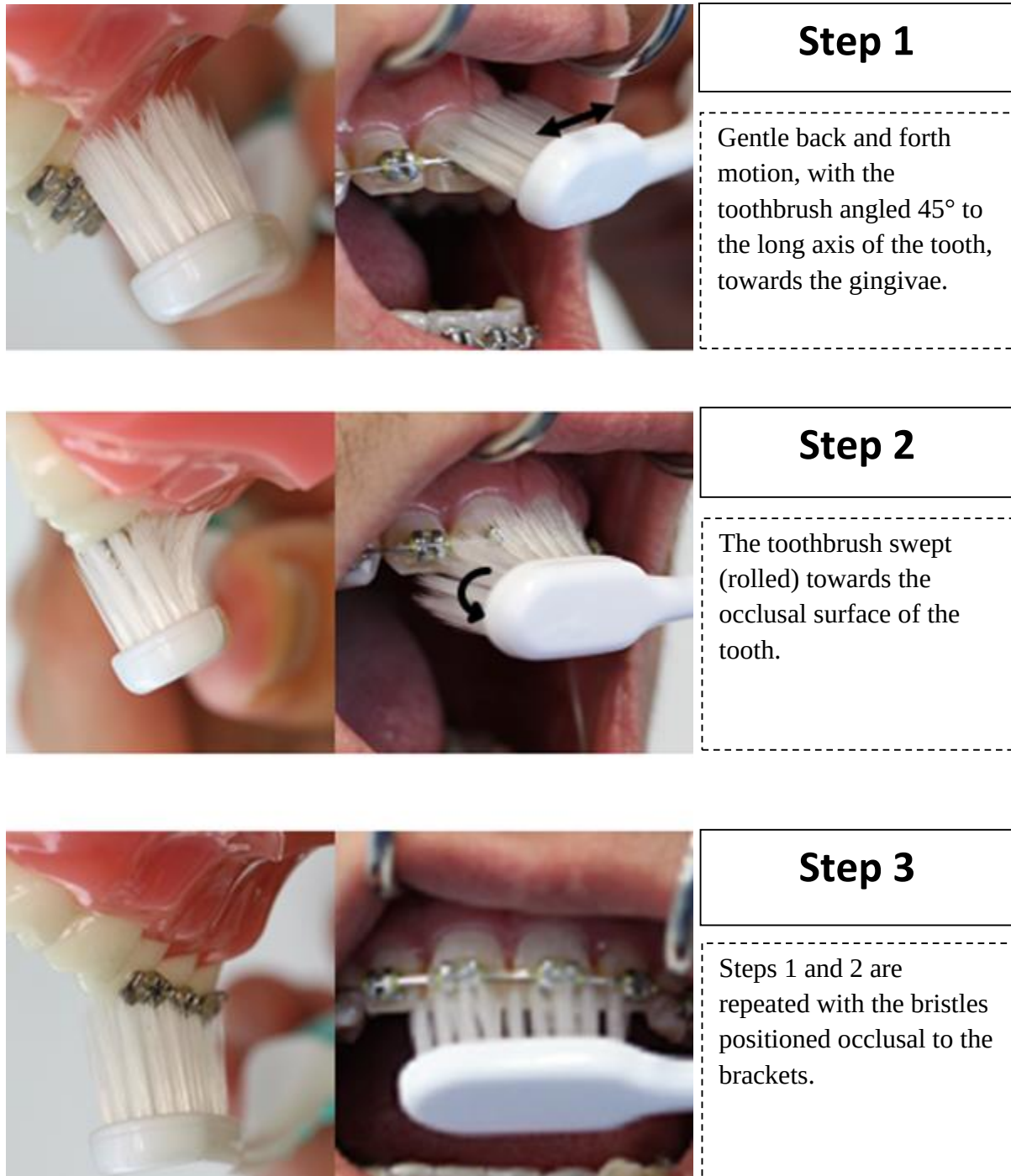


Figure 4. The Modified Bass technique.

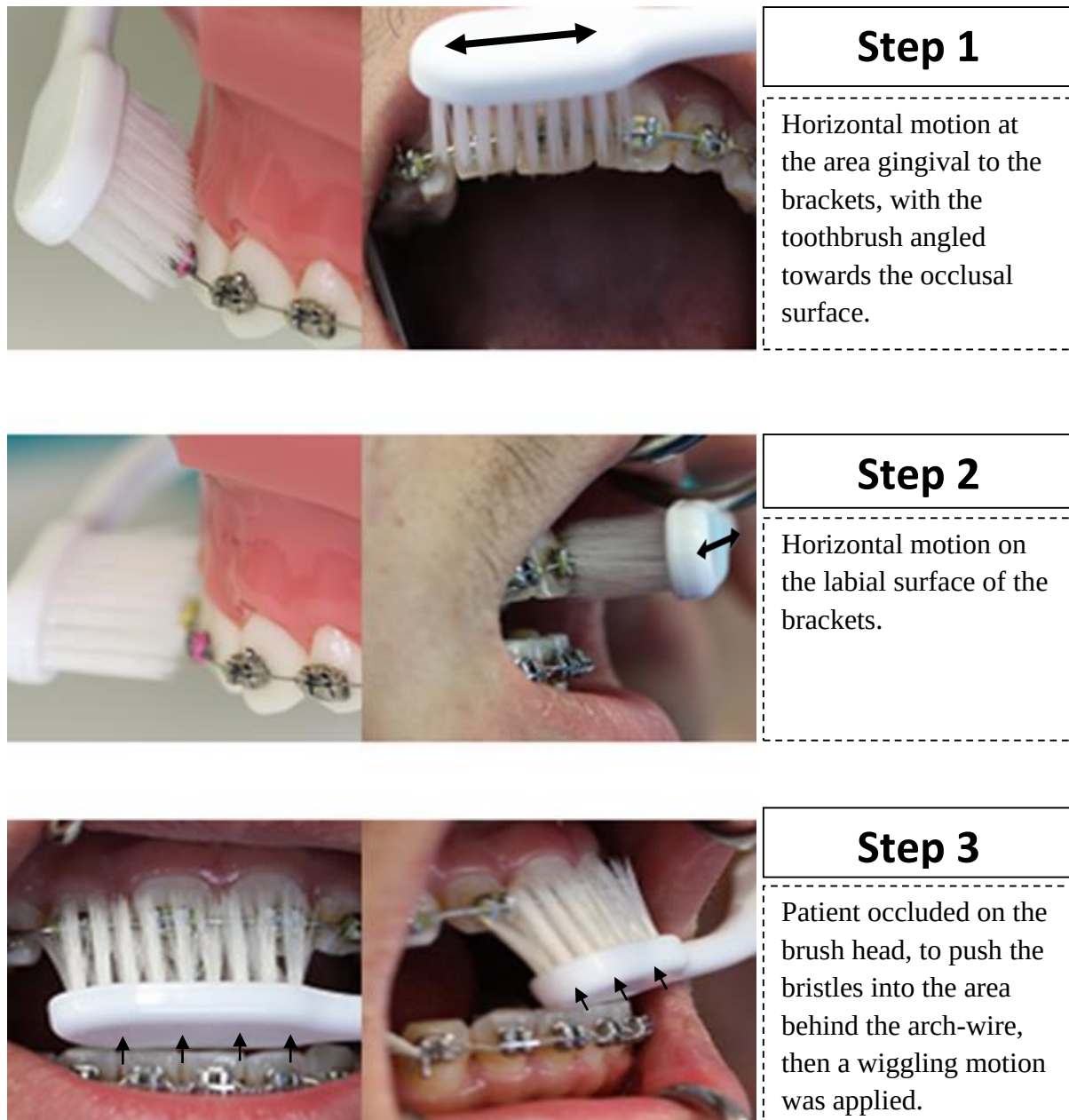


Figure 5. The Orthodontic toothbrushing technique designed and used in this study.

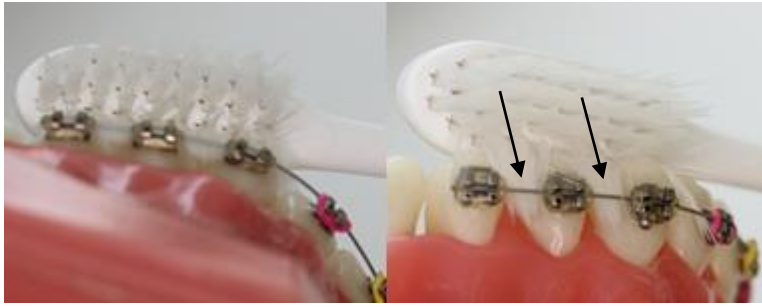


Figure 6. The bristles reach the areas between the brackets and behind the arch-wire, during Step 3 of the Orthodontic toothbrushing technique.

2.2.8. Outcome measurements

The Modified Silness and L  e plaque index (PI) was used to examine the amount of plaque on all teeth except for the second and third molars (33). The labial surface of each tooth was divided into four areas in relation to the position of the bracket: M = mesial; D = distal; G = gingival; and O = occlusal (Figure 7). Each surface was then scored according to the original Silness and L  e plaque index (34) (Table 5). Teeth with molar bands, and unattached brackets were not measured.

The Modified L  e and Silness gingival index (GI) was used to assess gingival inflammation around all teeth except for the second and third molars. The labial gingival margin of each tooth was divided into three areas: M = mesial; mid = mid-labial; and D = distal (Figure 8). Each area was then scored according to the original L  e and Silness gingival index (34) (Table 6).

PI scores were analysed as an average of all four surfaces (PI_{Total}), and individually for the gingival (PI_G), interproximal (PI_{M+D}), and occlusal (PI_O) surfaces on each of the participants. GI scores were also analysed as an average of all three areas (GI_{Total}), and individually on the mid-labial (GI_{mid}), and interproximal (GI_{M+D}) areas.

PI and GI Measurements were taken at baseline (T_0) and after 1 month of follow-up (T_1) by a single calibrated and blinded examiner (A.K.). Participant information, including age and gender were also collected at T_0 . To assess participants' adherence to the technique instructions, self-reports on the technique used during the study were collected at T_1 . All of the participants were given the same toothbrush (Colgate   Slim-soft; Colgate-Palmolive; Manhattan, NY) and toothpaste (Colgate Total  ; Colgate-Palmolive; Manhattan, NY) for use throughout the study.

Table 5: Silness and Løe plaque index (34).

<i>Score</i>	<i>Criteria</i>
0	No plaque
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.
2	Moderate accumulation of soft deposits within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

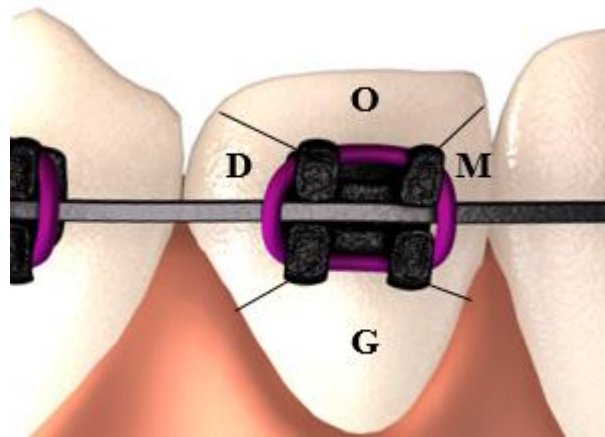
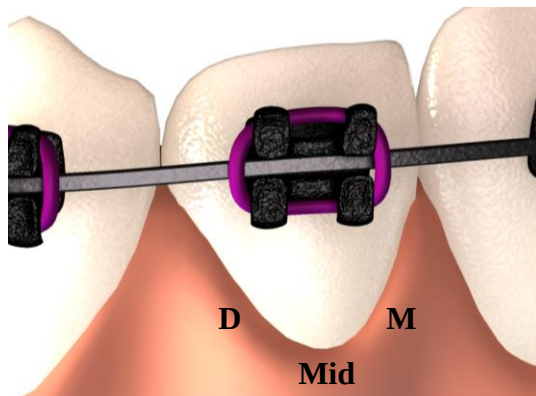
**Figure 7. Surfaces measured for PI: O, Occlusal; M, Mesial; D, Distal; G, Gingival (33).**

Table 6: Löe and Silness gingival index (34).

Score	Criteria
0	No inflammation.
1	Mild inflammation, slight change in colour, slight oedema, no bleeding on probing.
2	Moderate inflammation, moderate glazing, redness, bleeding on probing.
3	Severe inflammation, marked redness and hypertrophy, ulceration, tendency to spontaneous bleeding.

**Figure 8. Areas measured for GI: M, mesial; Mid, mid-labial; and D, distal).**

2.2.9. Statistical analysis

The null hypothesis states that there is no difference between the *Orthodontic* technique and the *Modified Bass* technique in the reduction of oral hygiene outcome measures (PI or GI). The data collected was first tabulated in a Microsoft Excel spreadsheet, with the outcome measures of PI and GI calculated for each of the participants. The data was then analysed using SPSS (version 22.0. for Macintosh; IBM Corp.; Armonk, NY). An intention-to-treat analysis (35, 36) was carried out, with α -error set to 0.05, using the Mann-Whitney U test to compare PI and GI at baseline, and the Wilcoxon test to assess PI and GI reduction between T₁ and T₀ for both groups. *P*-values of less than 0.05 were considered to be statistically significant.

2.3. RESULTS

A total of 56 patients were recruited, of which T_0 and T_1 measurements were completed on a total of 34 patients as an interim analysis. No participants were lost to follow-up. Only T_0 measurements were completed for the remaining 22 participants and were not included in the analysis, but will be added in the future with the completed T_1 measurements.

2.3.1. Baseline characteristics

The baseline measurements for the 34 patients included are summarised in Table 7. There were no significant differences ($p > 0.05$) between the *MBT* group and the *OT* group in all parameters.

Table 7. Baseline characteristics of participants.

	Modified Bass technique (n = 18)	Orthodontic technique (n = 16)
Demographic parameters		
Age (years)	14.8 ± 2.4	15.3 ± 2.1
Gender, n (%)		
Female	13 (72.2)	9 (56.2)
Male	5 (27.8)	7 (43.7)
Oral hygiene parameters		
PI _{Total}	0.68 ± 0.41	0.77 ± 0.45
GI _{Total}	0.63 ± 0.31	0.50 ± 0.36

2.3.2. Reduction of PI/GI during the study

For the *MBT* group, there were no significant reductions ($p > 0.05$) of PI_{Total} (0.02 ± 0.08), PI_G (0.02 ± 0.09), PI_{M+D} (0.01 ± 0.12), and PI_O (0.05 ± 0.06) between T_0 and T_1 (Figure 9). There were also no significant reductions ($p > 0.05$) of GI_{Total} (-0.02 ± 0.08), GI_{Mid} (-0.03 ± 0.07), and GI_{M+D} (-0.02 ± 0.10) between T_0 and T_1 (Figure 10).

For the *OT* group, the reductions of PI_{Total} (0.37 ± 0.10), PI_G (0.54 ± 0.16), and PI_{M+D} (0.43 ± 0.12) were statistically significant ($p < 0.05$) between T_0 and T_1 (Figure 11). However, the reduction of PI_O (0.09 ± 0.05) was not significant ($p > 0.05$). There were no significant reductions ($p > 0.05$) of GI_{Total} (0.08 ± 0.07), GI_{Mid} (0.07 ± 0.06) and GI_{M+D} (0.09 ± 0.09) between T_0 and T_1 (Figure 12).

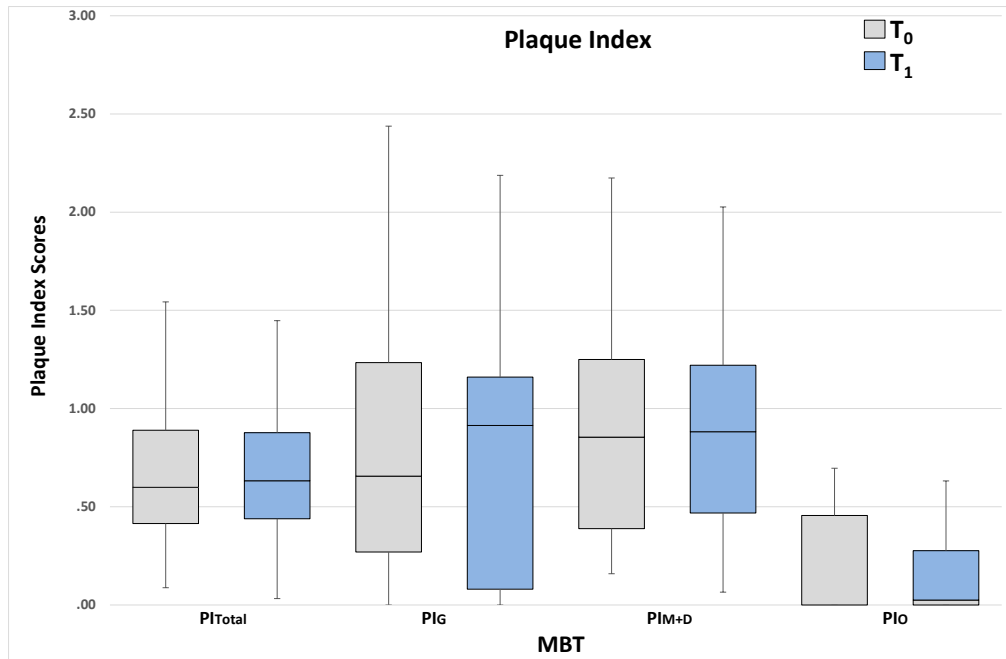


Figure 9: Box-and-Whisker plot comparing PI at T₀ and T₁ for the MBT group. There were no significant differences of PI on all surfaces between T₀ and T₁ ($p > 0.05$). T₀, Baseline; T₁, 1 month; PI, plaque index; G, gingival; M+D, interproximal; O, occlusal; MBT, Modified Bass technique.

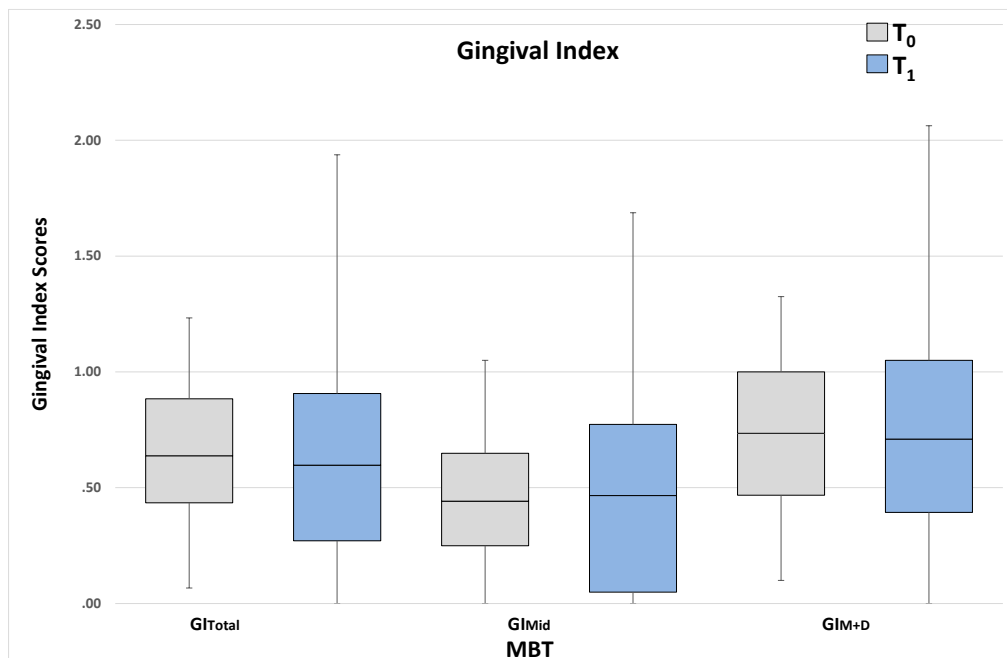


Figure 10: Box-and-Whisker plot comparing GI at T₀ and T₁ for the MBT group. There were no significant differences of GI on all areas between T₀ and T₁ ($p > 0.05$). T₀, Baseline; T₁, 1 month; GI, gingival index; Mid, mid-labial; M+D, interproximal; MBT, Modified Bass technique.

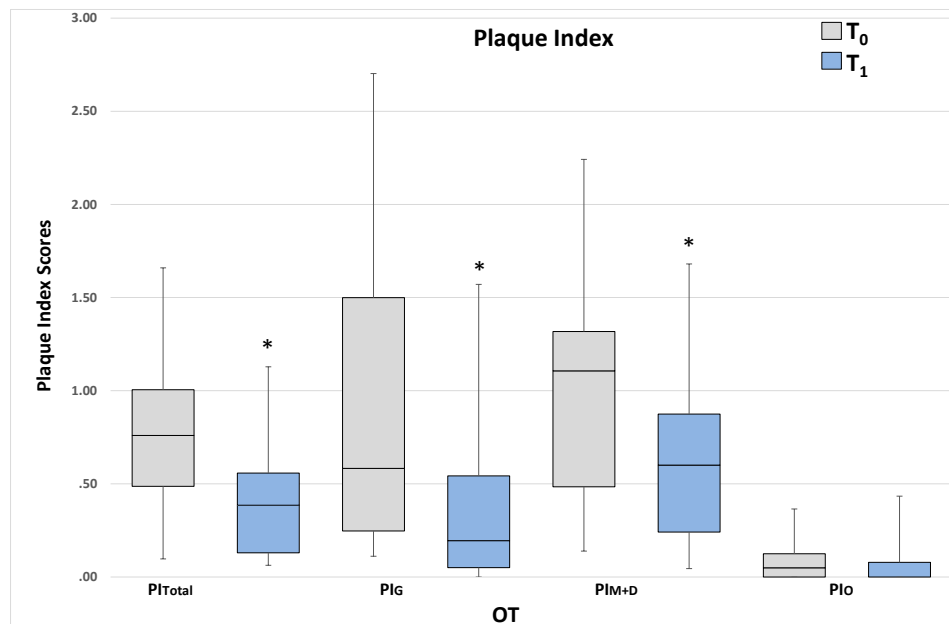


Figure 11: Box-and-Whisker plot comparing PI at T₀ and T₁ for the OT group. There were significant reductions of PI_{Total}, PI_G, and PI_{M+D}, between T₀ and T₁ ($p < 0.05$), but the reduction of PI_O was statistically insignificant ($p > 0.05$). *statistically significant ($p < 0.05$). T₀, Baseline; T₁, 1 month; PI, plaque index; G, gingival; M+D, interproximal; O, occlusal; OT, Orthodontic technique.

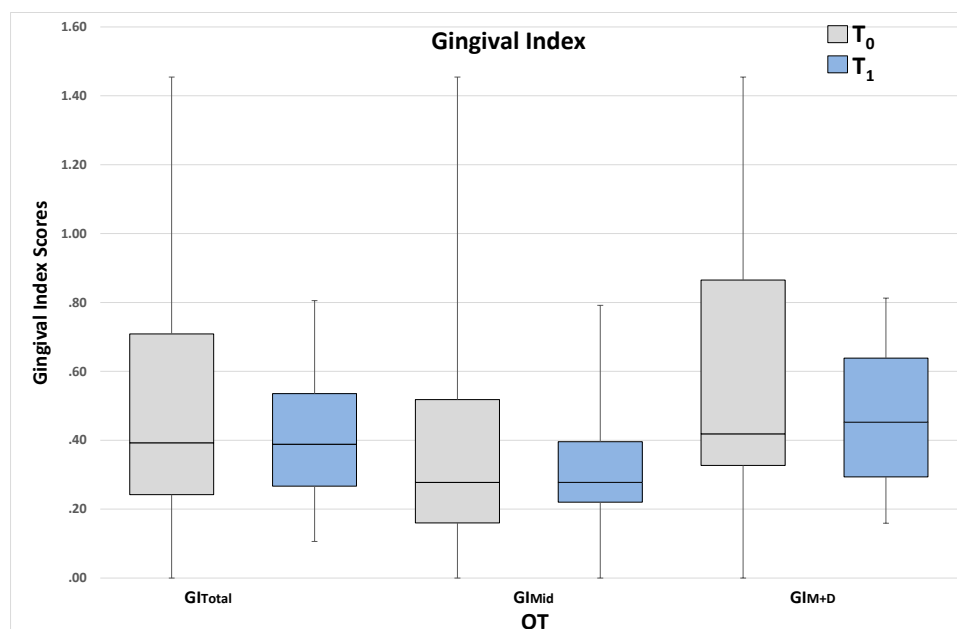


Figure 12: Box-and-Whisker plot comparing GI at T₀ and T₁ for the OT group. There were no significant differences of GI on all areas between T₀ and T₁ ($p > 0.05$). T₀, Baseline; T₁, 1 month; GI, gingival index; Mid, mid-labial; M+D, interproximal; OT, Orthodontic technique.

2.3.4. Comparisons of PI/GI between groups.

The reduction of PI_G for the *OT* group was significantly higher ($p = 0.041$) than the *MBT* group between T_0 and T_1 . No significant differences were found between the two groups in the reduction of PI_{Total} , PI_{M+D} , and PI_O .

There were no significant differences ($p \geq 0.086$) in the reduction of GI_{Total} , GI_{Mid} , and GI_{M+D} between the *MBT* group and the *OT* group.

Twelve participants in the *MBT* group (67%) and 11 in the *OT* group (68.75%) have reported adherence to the assigned technique. Of the six non-adherent participants in the *MBT* group, three have reported using the *Circular* technique, whereas three have reported to have used the *Horizontal* technique. For all the non-adherent participants in the *OT* group, steps one and two of the *Orthodontic* technique were performed correctly, but not step three.

2.4. DISCUSSION

The primary aim of this study was to develop a simple tooth brushing technique for patients with fixed orthodontic appliances, and compare its efficacy with that of the traditional *MBT*. In our study, the *OT* improved plaque control of orthodontic patients wearing fixed appliances, although there were no improvements on the gingival health. The *OT* was designed to specifically remove dental plaque effectively around the orthodontic appliances. This intended effect of the *OT* was observed with the reduction of PI in the gingival and interproximal surfaces in relation to the bracket. As traditional techniques are not designed for patients with fixed orthodontic appliances, the study have compared the efficacy of the *OT* to the traditional *MBT* in reducing PI and GI. However, the significant differences were found in the plaque control on the gingival surfaces only, where the reduction of PI on all other surfaces and GI were not significant.

A major limitation of the present study is the small sample size as an interim analysis. This may lead to false negative findings, i.e. limited power of statistical tests. The true efficacy of the *OT*, compared to the *MBT*, in improving oral hygiene will be better understood with the analysis of our completed data. Furthermore, participants with poor oral hygiene would have typically received oral hygiene reinforcements, which the treatment providers were systematically trained to do. This would improve on the PI and GI for patients with poor oral hygiene, again increasing the chance of false negative results.

On the other hand, one of the strengths of the study was no loss on follow-up. Furthermore, the study had attempted to address the measurement errors from the subjectivity of PI and GI measurements, which leads to inter and intra-examiner variabilities. With the single examiner conducting all outcome measurements, inter-examiner variability was not an issue of this study. To minimize the intra-examiner variability, regular calibrations were conducted using the same clinical photographs each time.

In this study, the *OT* was significant in reducing PI_{Total} of orthodontic patients wearing fixed appliances. Specifically, PI was reduced on the gingival and interproximal surfaces in relation to the bracket, but not on the occlusal. This showed that the *OT* were effective in areas that commonly accumulate dental plaque, where the brushing movements were designed to avoid the fixed appliances. No significant reductions of PI_o were observed with the *OT*, which is where the least amount of plaque was detected at baseline. It may be that brushing of occlusal surface had always been adequate, where the *OT* did not provide any further benefits.

No significant GI reductions were observed with the *OT*. However, GI may not have been a suitable index to assess the gingival inflammation of patients with orthodontic appliances. Where colour of the gingivae is one of the determinants of GI score, attachment of fixed appliances casted shadows on the gingival margins making the judgement difficult. Furthermore, bleeding on probing was another determinant of GI which was physically difficult to assess due to the bracket and the arch-wire. Therefore different indices to assess gingival inflammation for patients wearing fixed appliances would be more accurate.

The *OT* was compared with the *MBT* in improving oral hygiene of the patients with fixed appliances. The only significant difference found was the reduction of PI_G . This was unexpected, since the *MBT* puts emphasis on the removal of plaque on the gingival margins (31, 37). The higher efficacy of the *OT* in removing plaque on the gingival area, compared to the *MBT*, may be due to the following reasons. Firstly, angulation of the toothbrush during the *OT* avoids the fixed appliances, whereas the *MBT* is likely to encounter interferences from the fixed appliances. Secondly, the *OT* involves simpler movements than the *MBT*. The complex movements involved in the *MBT* may discourage patients' proper adoption of the technique. In fact, another study had shown the *Bass* technique, essentially a simpler version of the *MBT*, to be effective in reducing gingival inflammation (26). Thus, simplicity of the technique may be crucial to effectiveness in plaque removal and this will require further investigation.

Within the limitations of the findings, no improvements of PI or GI were observed with the *MBT*. To the best of our knowledge, no randomised controlled trials have tested the efficacy of the *MBT* on orthodontic patients wearing fixed appliances in improving oral hygiene. Therefore, no evidence yet supports the recommendation of the *MBT* to orthodontic patients.

Hawthorne effect was observed in previous studies which improved plaque scores on orthodontic patients wearing fixed appliances (20). This effect was not evident in this study where no reduction of PI or GI was found between T_0 and T_1 with the *MBT* group. However, the PI scores of the participants at baseline were lower than previous studies (19, 38, 39), where Hawthorne effect may have been induced from T_0 . Potential participants were initially informed of the study design, with participants who were keen to take part returning at a later date for their baseline measurements. Therefore, improvement of oral hygiene may have occurred from baseline, where no further improvements were seen due to this effect throughout the study.

One of the aims of the *OT* was to enhance the control of plaque in the interproximal areas around the orthodontic fixed appliances and to reduce the need for additional oral hygiene aids such as interdental brushes. The *OT* was found to reduce plaque in the interproximal areas, but the difference in the reduction to the *MBT* was not significant. This result is likely to be a false negative, since no significant reductions of interproximal plaque was observed for the *MBT* during the study. Where increased sample size would lead to a better understanding of the efficacy of *OT* in the interproximal areas, our study design did not compare the *OT* to the use of additional aids. As a result, no conclusions can be made on whether the *OT* would reduce the need for additional oral hygiene aids.

Another one of our aims was to improve technique-adherence of the patients, with the simplification of the tooth brushing technique. It was hypothesized that the complexity of techniques such as *MBT* would discourage patients from correct adoption of the technique. However, adherence rates were found to be similar between two groups. Nevertheless, an analysis of the reasons behind non-adherence in two groups revealed an interesting finding. Non-adherent participants in the *OT* group correctly performed the first two steps of the technique, but not step three. In contrast, non-adherent participants in the *MBT* group adopted completely different *Horizontal* or *Circular* techniques. Considering non-adherent participants in both groups adopted simpler techniques, it seems simplicity may still be a crucial determinant for compliance of patients to the oral hygiene regimen. Therefore, future studies that look at the simplicity of an oral hygiene regimen in enhancing compliance may be valuable.

Though the *OT* showed promising results in improving the oral hygiene of patients with fixed appliances, its long-term effects need investigation. This would include both the sustainability of improved oral hygiene, prevalence of subsequent oral diseases, as well as any possible adverse effects such as toothbrush abrasion. Furthermore, the efficacy of the *OT* in comparison to all other known techniques, such as *Charters'* and *Horizontal* techniques, remains unknown. Additional research is needed to identify an optimal tooth brushing technique and, thus, a conventional technique for orthodontic patients with fixed appliances. This is important for evidence-based public recommendations of a tooth brushing technique for orthodontic patients, as well as in clinical research, to consistently compare manual tooth brushing to other interventions, such as powered tooth brushing.

2.5. CONCLUSION

Within the limitations of the present interim analysis, the *Orthodontic* tooth brushing technique shows promising results in improving oral hygiene in patients with fixed appliances. However, our preliminary findings indicate that further research is required to verify the efficacy of the *Orthodontic* technique observed in this interim analysis. Also, the *Modified Bass* technique may not be effective in improving the oral hygiene of orthodontic patients.

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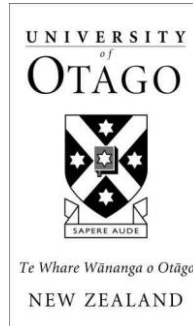
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2.7. APPENDICES

2.7.1 Information sheet for participants 16 and over.



Modified orthodontic toothbrushing technique for enhancing oral hygiene in patients with fixed appliances: A randomized controlled trial

INFORMATION SHEET FOR PARTICIPANTS.

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you of any kind and we thank you for your consideration.

What is the Aim of the Project?

Wearing braces makes tooth brushing difficult. If patients do not brush their teeth carefully during their orthodontic treatment, build-up of plaque increases the likelihood of developing tooth decay and/or gum disease. Therefore, an effective tooth brushing technique is very important.

The aim of this study is to compare a modified tooth brushing technique with the traditional technique in improving oral care of patients wearing braces.

This project is being undertaken as part of the requirements for the Masters degree of Oral Sciences in the Faculty of Dentistry, University of Otago.

What Type of Participants are being Sought?

Patients wearing braces from the Discipline of Orthodontics, Faculty of Dentistry, University of Otago, will be included.

We aim to recruit patients aged 11-40 years, having at least 20 natural teeth, wearing braces and are willing to participate.

We cannot include patients fitting in any the following criteria: wearing lingual braces, have gum diseases, a history of extensive dental work, systemic diseases or currently on antibiotic therapy.

What will Participants be Asked to Do?

Participants will be taught one of the two tooth brushing techniques to carry out during the study duration. To ensure that the participants have correctly understood the technique, participants will be asked to demonstrate the technique they have been shown and corrections will be provided if necessary.

From then on during the regular monthly orthodontic visits, the researchers will be measuring the amount of plaque and gum health of the participants, which is estimated to take around 10 minutes. If the amount of plaque is minimal, a harmless dental plaque-colouring tool may be used to aid in detection.

During the study duration, participants will be given free professional dental checks, as well as free toothbrushes and toothpastes at each of the monthly appointments.

The study will continue for 3 months. Please be aware that you may decide not to take part in the project, anytime, without any disadvantage to yourself of any kind.

What Data or Information will be Collected and What Use will be Made of it?

The following information will be collected:

Patients' age, gender and oral hygiene status (amount of plaque and gum health)

Privacy protection:

Patients' information will be kept anonymous; no contact details will be collected. Data will be stored in a password-protected database and only the student investigators (Austin, Krystal and Chin Hui) and their supervisors (Dr. Li Mei and Prof Mauro Farella) will have access to the collected information. Furthermore all the collected information will be destroyed permanently, 10 years after completion of the research.

Data will be used to:

Compare the two different tooth brushing techniques in improving oral care in patients wearing braces.

Can Participants Change their Mind and Withdraw from the Project?

Participants may withdraw from the study any time and without any disadvantage of any kind.

What if Participants have any Questions?

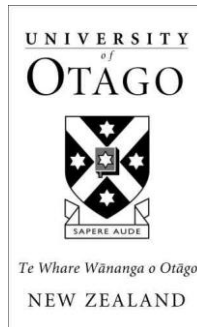
If you have any questions about the project, please feel free to contact us:

Dr. Austin Kang:	021 178 4340	kanau469@student.otago.ac.nz
Dr. Li (Peter) Mei:	03 479 7480	li.mei@otago.ac.nz
Prof. Mauro Farella:	03 479 5852	mauro.farella@otago.ac.nz

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 03 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

2.7.2 Consent form for participants 16 and over.

[H14/060]



***Modified orthodontic tooth brushing technique for enhancing
oral hygiene in patients with fixed appliances:
A randomized controlled trial***

CONSENT FORM FOR***PARTICIPANTS***

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:

1. My participation in the project is entirely voluntary;
2. I am free to withdraw from the project at any time without any disadvantage;
3. Personal identifying information will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for ten years;
4. I will be given free professional examination, instructions on oral hygiene, free toothbrushes and toothpastes during the study;
5. The researchers will write up the results from this study for their University work. The results may also be written up in journals and talked about at conferences. My name will not be on anything the researchers write up about this study.

I agree to take part in this project.

.....
(Signature of participant)

.....
(Date)

.....
(Printed Name)

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 03 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

2.7.3 Information sheet for participants under 16.

[H14/060]



Modified orthodontic tooth brushing technique for enhancing oral hygiene in patients with fixed appliances:

A randomized controlled trial

INFORMATION SHEET FOR CHILD PARTICIPANTS.

Thank you for your interest in this study. Please read this information sheet carefully before agreeing to take part. If you decide to participate we thank you. If you decide not to, nothing bad will happen to you.

What is the Study Wanting to Do?

Wearing braces makes tooth brushing difficult. If patients who wear braces do not brush their teeth carefully, they will get tooth decay and/or gum disease. Therefore, a good tooth brushing technique is very important.

The study is trying to compare two different ways of tooth brushing to see which one is more effective for patients wearing braces.

This study is being done as part of the university requirements for the students of the Dental School.

Who can take part in the study?

Patients wearing braces from the Dental School at the University of Otago will be asked to take part.

We are looking for patients who are 11 to 40 years old, have at least 20 natural teeth, wears braces and are willing to take part.

We cannot include patients who wear lingual braces, have gum disease, have had a lot of dental work done already, have systemic diseases or on antibiotic therapy.

What will you be Asked to Do?

If you agree to take part, you will be taught one of two ways to brush your teeth over the next 3 months. Then, we will ask you to show us how it is done, so that we can fix any mistakes.

During your next 3 normal braces appointments, we will measure how clean and healthy your teeth and gums are. This will take about 10 minutes. If your teeth are very clean, we may colour your teeth to help us see how clean they are. The tooth colouring is not bad for you.

During the study, you will be given free toothbrushes, toothpastes, and dental checks at every orthodontic visit, as a thank you for helping out.

What Information will be Collected and What Use will be Made of it?

Following information will be collected:

Age, gender, health of teeth (amount of plaque) and gums.

How to make sure what you say and what is measured is kept private:

Your name and contact details will not be collected, so we do not know who you are from your collected information. The paper and computer file with your answers will be seen only by the researchers and the people they are working with. We will keep whatever you say private. All the information will be deleted after 10 years when the study is done.

Information will be used to:

Compare two different ways of tooth brushing for patients with braces.

Can You Change your Mind and Stop Taking Part?

You can stop taking part at any time without giving a reason. Nothing bad will happen to you when you stop.

What if Participants have any Questions?

If you have any questions, you can ask one of us:

Dr. Austin Kang: 021 178 4340 kanau469@student.otago.ac.nz

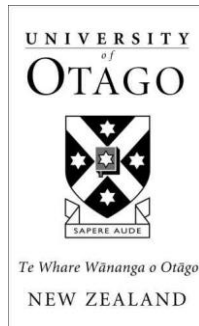
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2.7.4 Consent form for participants under 16.

[H14/060]



Modified orthodontic tooth brushing technique for enhancing oral hygiene in patients with fixed appliances: A randomized controlled trial

CONSENT FORM FOR CHILD PARTICIPANTS

I have been told about this study and understand what it is about. All my questions have been answered in a way that makes sense.

I know that:

1. Participation in this study is voluntary, which means that I do not have to take part if I don't want to and nothing will happen to me.
2. I can stop taking part at any time and don't have to give a reason.
3. If I have any worries or if I have any other questions, then I can talk about these with the researchers.
4. The paper and computer file with my information will only be seen by the researchers and the people they are working with. They will keep whatever I say private.
5. I will receive free toothbrushes, toothpastes, and dental checks at every orthodontic visit during the study, as thanks for helping out.
6. The researchers will write up the results from this study for their University work. The results may also be written up in journals and talked about at conferences. My name will not be on anything the researchers write up about this study.

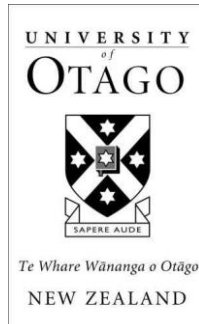
I agree to take part in the study.

.....
Signed

.....
Date

2.7.4 Information sheet for parents/guardians of participants under 16.

[H14/060]



Modified orthodontic toothbrushing technique for enhancing oral hygiene in patients with fixed appliances: A randomized controlled trial

INFORMATION SHEET FOR PARENTS / GUARDIANS.

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you of any kind and we thank you for your consideration.

What is the Aim of the Project?

Wearing braces makes tooth brushing difficult. If patients do not brush their teeth carefully during their orthodontic treatment, build-up of plaque increases the likelihood of developing tooth decay and/or gum disease. Therefore, an effective tooth brushing technique is very important.

The aim of this study is to compare a modified tooth brushing technique with the traditional technique in improving oral care of patients wearing braces.

This project is being undertaken as part of the requirements for the Masters degree of Oral Sciences in the Faculty of Dentistry, University of Otago.

What Type of Participants are being Sought?

Patients wearing braces from the Discipline of Orthodontics, Faculty of Dentistry, University of Otago, will be included.

We aim to recruit patients aged 11-40 years, having at least 20 natural teeth, wearing braces and are willing to participate.

We cannot include patients fitting in any the following criteria: wearing lingual braces, have gum diseases, a history of extensive dental work, systemic diseases or currently on antibiotic therapy.

What will Participants be Asked to Do?

Participants will be taught one of the two tooth brushing techniques to carry out during the study duration. To ensure that the participants have correctly understood the technique, participants will be asked to demonstrate the technique they have been shown and corrections will be provided if necessary.

From then on during the regular monthly orthodontic visits, the researchers will be measuring the amount of plaque and gum health of the participants, which is estimated to take around 10 minutes. If the amount of plaque is minimal, a harmless dental plaque-colouring tool may be used to aid in detection.

During the study duration, participants will be given free professional dental checks, as well as free toothbrushes and toothpastes at each of the monthly appointments.

The study will continue for 3 months. Please be aware that you may decide not to take part in the project, anytime, without any disadvantage to yourself of any kind.

What Data or Information will be Collected and What Use will be Made of it?

The following information will be collected:

Patients' age, gender and oral hygiene status (amount of plaque and gum health)

Privacy protection:

Patients' information will be kept anonymous; no contact details will be collected. Data will be stored in a password-protected database and only the student investigators (Austin, Krystal and Chin Hui) and their supervisors (Dr. Li Mei and Prof Mauro Farella) will have access to the collected information. Furthermore all the collected information will be destroyed permanently, 10 years after completion of the research.

Data will be used to:

Compare the two different tooth brushing techniques in improving oral care in patients wearing braces.

Can Participants Change their Mind and Withdraw from the Project?

Participants may withdraw from the study any time and without any disadvantage of any kind.

What if Participants have any Questions?

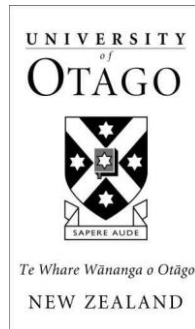
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2.7.6 Consent form for parents/guardians of participants under 16.

[H14/060]



Modified orthodontic toothbrushing technique for enhancing oral hygiene in patients with fixed appliances: A randomized controlled trial

CONSENT FORM FOR PARENTS/GUARDIANS

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:-

1. My child's participation in the project is entirely voluntary;
2. I am free to withdraw my child from the project at any time without any disadvantage;
3. Personal identifying information will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for ten years;
4. My child will receive free professional examination, instructions on oral hygiene, free toothbrushes and toothpastes during the study;
5. The results of the project may be published and my child's name will not be on anything the researchers write up about this study.

I agree for my child to take part in this project.

.....
(Signature of parent/guardian)

.....
(Date)

.....
(Name of child)

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 03 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

2.7.7 T₀ outcome measurement form.

Date: __/__/__

Patient Unique Identifier #: _____ Age: _____ Sex: _____

PLAQUE INDEX / GINGIVAL INDEX MEASUREMENTS

		Tooth Number											
		16	15	14	13	12	11	21	22	23	24	25	26
Plaque Index	Gingival												
	Mesial												
	Distal												
	Occlusal												
Gingival Index	Mesial												
	Middle												
	Distal												
		46	45	44	43	42	41	31	32	33	34	35	36
Plaque Index	Gingival												
	Mesial												
	Distal												
	Occlusal												
Gingival Index	Mesial												
	Middle												
	Distal												

For participants. Please circle the answer that apply.

- | | | | |
|-----------------------------------|---------------------------|-------------------|----------------------------|
| 1. How often do you brush a day? | <i>once or less</i> | <i>twice</i> | <i>3x or more</i> |
| 2. How long do you take to brush? | <i>Less than a minute</i> | <i>1-2minutes</i> | <i>more than 2 minutes</i> |

This is the end of the questionnaire. Thank you very much.

2.7.8 T₁ outcome measurement form.

Patient Unique Identifier #: _____

Date: __/__/__

PLAQUE INDEX / GINGIVAL INDEX MEASUREMENTS

		Tooth Number											
		16	15	14	13	12	11	21	22	23	24	25	26
Plaque Index	Gingival												
	Mesial												
	Distal												
	Occlusal												
Gingival Index	Mesial												
	Middle												
	Distal												
		46	45	44	43	42	41	31	32	33	34	35	36
Plaque Index	Gingival												
	Mesial												
	Distal												
	Occlusal												
Gingival Index	Mesial												
	Middle												
	Distal												

Participants' reported brushing technique.
Compliance.Mod Bass
HighMod Ortho
MediumOthers (specify)
Low