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THE ANTI-PLAQUE EFFICACY OF LISTERINE® USED IN COMBINATION WITH
TOOTHBRUSHING IN ORTHODONTIC PATIENTS

A Thesis submitted in partial fulfillment of the requirements for the degree of Master of
Science at Virginia Commonwealth University

by

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Abstract

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The bactericidal efficacy of Listerine®, the essential oil-containing mouthrinse, has long been recognized. The purpose of this study was to determine whether Listerine® mouthrinse, when added to the standard oral hygiene regimen, had an added benefit in reducing plaque and gingivitis development in orthodontic patients over a six-month period. 50 orthodontic patients from the Virginia Commonwealth University Department of Orthodontics were assigned either to the brushing + flossing (N= 25) or brushing + flossing + Listerine® (N = 25) group. At baseline (T1), measurements for the Ramfjord teeth were recorded for the gingival index, plaque index and bleeding index. Subsequent measurements were taken at 3 and 6 months (T2 and T3, respectively).

The response profiles for the BI, MGI, and PI over time were significantly different ($p < .001$) between the two groups. Patients who had Listerine® mouthrinse added to their daily oral hygiene regimen exhibited significantly lower BI, MGI, and PI scores at 3

months and 6 months than the patients who only brushed and flossed. This study suggests that the addition of Listerine® to the routine oral hygiene

CHAPTER 1

Introduction

During orthodontic treatment, the development of white spot lesions is almost inevitable when oral hygiene is poor.^{1,2} Decalcification is more commonly seen on the buccal surfaces of orthodontically treated teeth than untreated teeth.¹ This is due to prolonged plaque retention around the brackets which causes a decrease in pH when certain bacteria interact with sugars.² These incipient lesions can appear in as little as 2 to 3 weeks after plaque accumulation in bucco-gingival areas of the teeth.² The presence of white spot lesions may lead to patient dissatisfaction at the end of orthodontic treatment and necessitate cosmetic intervention by a dentist. If these lesions progress to decay, more extensive dental procedures may be needed.

Previous studies have shown that the level of bacteria is increased in the oral cavity after the bonding of orthodontic attachments.³⁻⁶ The presence of *S. mutans* and lactobacilli increases the risk for decalcification as these microorganisms are the main pathogens in dental caries.^{4,7}

The development of gingivitis and hyperplastic gingiva is also a well-recognized problem during orthodontic treatment with fixed appliances. Brown and Loe⁸ measured the prevalence, extent, severity and progression of periodontal disease in a sample of approximately 15,000 subjects. Based on the data collected from that study, it was estimated that gingivitis was present in more than half of the population in the United

States.⁸ It would be reasonable to speculate that the prevalence of gingivitis would be even higher in a predominantly adolescent population of orthodontic patients since it is more difficult to brush and floss in the presence of fixed appliances. In addition to the inadequate oral hygiene status that may lead to the early stages of periodontitis, the presence of orthodontic fixed appliances may cause an increase in the progression of gingival hyperplasia requiring intervention or even surgery in some cases.

One of the primary causative factors in the development of gingivitis is the insufficient removal of supragingival plaque.⁹ Toothbrushing along with flossing is the most common way to maintain good oral hygiene. While plaque can adequately be controlled by taking proper daily hygiene measures, it is well known that many individuals are not capable of maintaining a high standard of plaque control due to the lack of compliance. Inefficient brushing and flossing can lead to an accumulation of plaque, particularly in areas that are difficult to access. Many orthodontic patients, especially children and adolescents, fail to floss because they find this procedure time-consuming and tedious in the presence of orthodontic archwires.⁸ A common strategy to improve mechanical plaque removal is to incorporate a chemotherapeutic agent such as an antibacterial mouthrinse into the oral hygiene regimen.¹⁰

The role of therapeutic rinses in the prevention and treatment of periodontal diseases has been long recognized.¹¹ Various antiseptics have been used in mouthrinse formulations, including bisbiguanides, essential oils, quaternary ammoniums and others.¹² Prominent clinical benefits of using these antiseptic mouthrinses include reductions in plaque or gingivitis attributable to the immediate or sustained antimicrobial activity.

The bactericidal efficacy of Listerine®, the essential oil-containing mouthrinse used in this study, has long been recognized. In fact, as early as the turn of the century, W.D. Miller wrote in his classic monograph, *Microorganisms of the human mouth*, that “Listerine®” had proved to be a “very useful and active antiseptic.”¹³ In 1929, *The Lancet* published a report of an independent assessment of this essential-oil containing mouthrinse that demonstrated a significant bactericidal activity against a variety of microorganisms.¹⁴ It was also concluded that the use of Listerine® was both safe and effective.¹⁴ Numerous periodontal studies have confirmed the ability of the essential-oil mouthrinses to kill a broad spectrum of microorganisms both *in vitro* and *in vivo*.¹⁵⁻¹⁷ The clinical benefits associated with the bacteriocidal activity of Listerine® include prevention and reduction of supragingival plaque and gingivitis, decreased intrinsic oral malodor and a significant decrease in viable bacteria contained in aerosols that are generated during dental procedures.¹⁵⁻¹⁷

The use of mouthrinse may be short term as with chlorhexidine or long term as a part of a daily oral hygiene regimen as with Listerine®. There is considerable clinical trial evidence to show that oral hygiene status is significantly improved when therapeutic mouthrinses are added to daily oral hygiene measures (toothbrushing and flossing) compared to toothbrushing and flossing only.¹⁸

Compared to antibiotics, antiseptic mouthrinses are considered safe for routine use because of a low incidence of adverse events and small concern for resistance development.¹² Clinical oral soft tissue effects are reported to not differ from normal

controls.¹⁹ Common side effects of mouthrinses include temporary taste alterations, bitter taste, and burning sensation. Except for chlorhexidine, taste alteration is transient.²⁰

Recently, Charles and Bauroth^{21,22} reported that Listerine® antiseptic mouthrinse was as effective as flossing in reducing interproximal plaque and gingivitis in subjects who brushed twice a day. Data obtained from that study led the maker of Listerine® (Pfizer Inc.,) to use advertisements claiming that the mouthrinse was “as effective as flossing.” However, this statement became very controversial in the dental community and raised a significant concern among clinicians that it would mislead the public into the thought that rinsing with Listerine® alone could replace flossing. After losing a lawsuit brought by Johnson & Johnson (the maker of dental floss), Pfizer Inc. had to abandon these commercials. Nevertheless, it should be kept in mind that the use of mouthrinses such as Listerine® was proven to add benefits in maintaining appropriate oral hygiene.²³

The purpose of this study was to determine whether the use of Listerine® in addition to the standard oral hygiene regimen (toothbrushing and flossing) has an added benefit for orthodontic patients in maintaining proper oral health.

The null hypotheses of this study were:

- There is no difference in gingival health when Listerine® use is added to the daily oral hygiene regimen in orthodontic patients.
- There is no difference in plaque accumulation when Listerine® use is added to the daily oral hygiene regimen in orthodontic patients.

CHAPTER 2

Material and Methods

This prospective study included 50 patients recruited at Virginia Commonwealth University, School of Dentistry, Department of Orthodontics. Subjects chosen were in good health and without a medical or dental history that would otherwise affect the outcome of the study. All participants signed a consent form prior to the study and were informed that they would be given \$25 upon completion of the study. Approval from the Institutional Review Board at Virginia Commonwealth University was obtained to conduct the study.

At the beginning of the study, all of the volunteers were given instructions on how to brush and floss. All of the participants received an initial prophylaxis by the same dental hygienist. Subjects were divided into two groups: Listerine® group (N = 25) and control group (N = 25). Treatment groups were matched with respect to age. At this time (T1), baseline readings were recorded for the bleeding index (BI), modified gingival index (MGI), and plaque index (PI). BI was scored as described by Saxton and van der Ouderaa²⁴ upon probing the buccal sulcus of the Ramfjord teeth (upper right first molar, upper left central incisor, upper left first premolar, lower left first molar, lower right central incisor, lower right first premolar) as described: 0: absence of bleeding after 30 s, 1:

bleeding observed after 30s, 2: immediate bleeding. Gingivitis was scored according to the MGI on the buccal marginal gingiva of the Ramfjord teeth as follows: 0: absence of inflammation, 1: mild inflammation (either marginal or papillary gingival unit), 2: mild inflammation (entire marginal and papillary gingival unit), 3: moderate inflammation and 4: severe inflammation. Plaque area was scored according to the Turesky modification on the Quigley-Hein PI²⁵ on the buccal surface of Ramfjord teeth as described: 0: no plaque, 1: discontinuous band of plaque at the gingival margin, 2: up to 1 mm continuous band of plaque at the gingival margin, 3: band of plaque wider than 1 mm but less than 1/3 of the surface, 4: plaque covering 1/3 or more of the surface, but less than 2/3 of the surface and 5: plaque covering 2/3 or more of the surface. One measurement for each tooth was scored for all categories.

Both groups were instructed to brush and floss twice daily. Subjects in the rinse group were asked to rinse vigorously for 30 seconds twice daily with 20 ml of Cool Mint Listerine® in addition to their basic oral hygiene regimen (toothbrushing and flossing). All of the subjects in the mouthrinse group were monitored monthly for compliance by having them bring empty bottles from the previous month. All clinical measurements were performed by the same blinded examiner at 3 and 6 months (T2 and T3). Examiner repeatability with respect to plaque and gingivitis was evaluated on 5 subjects prior to the start of the study. Mean BI, MGI, and PI were compared statistically between the groups using repeated measures ANOVA. The significance level was set at $P \leq 0.05$.

CHAPTER 3
Results

Of the 50 volunteers who participated, 47 completed the 6 month-study. One subject was excluded because she initiated a systemic drug therapy that could have affected the results. Two subjects were excluded from the study because of lack of compliance. The remainder of the participants complied as requested. The demographics for the 47 subjects are presented in Table I. Overall, the mean age was 16.6 with a range of 9 to 64 years. The brushing+flossing+Listerine® group included 24 subjects (12 males, 12 females; mean age, 16.2; range 10-43). The brushing + flossing group included 23 subjects (8 males, 15 females; mean age, 17.0; range 9-64).

Table I. Demographic Variables

	<i>Brushing + Flossing + Listerine®</i>	<i>Brushing + Flossing</i>
	<i>(N = 24)</i>	<i>(N = 23)</i>
<i>Mean Age (± SD)</i>	16.2 (7.0)	17.0 (11.4)
<i>Gender</i>		
<i>Male</i>	12 (50%)	8 (34.8%)
<i>Female</i>	12 (50%)	15 (65.2%)
<i>Race</i>		
<i>Caucasian</i>	12 (50%)	17 (73.9%)
<i>African-American</i>	5 (20.8%)	4 (17.4%)
<i>Other</i>	7 (29.2%)	1 (4.3%)

Within each of the groups all of the index values for the brushing + flossing group increased significantly from the baseline period to the 3 month timepoint ($p < .05$). Although the measures for all indices continued to increase for the brushing + flossing group at the 6 month timepoint, the increases were not statistically significant. The brushing + flossing + Listerine® group possessed slightly higher index values at the 3 month and 6 month intervals than at baseline, but these values were not statistically significant.

Table II shows BI, MGI and PI scores for each oral hygiene regimen protocol for each of the three time points. The baseline measurements (T1) were not significantly different between the two groups ($P > 0.05$). At T2, subjects in the mouthrinse group had statistically significantly lower mean BI ($p < 0.001$), MGI ($P < 0.01$) and PI ($P < 0.001$) scores than the subjects in the brushing + flossing group. 6-month measurements showed that the mean BI, MGI and BI scores were statistically significantly different between the groups ($P < 0.001$).

Table II. Mean (SD) BI, MGI and PI scores for each regimen at baseline (T1), 3 months (T2), and 6 months (T3).

	<i>Brushing + Flossing + Listerine®</i> (N = 24)	<i>Brushing + Flossing</i> (N=23)	<i>Significance Between Groups</i>
<i>Bleeding Index</i>			
<i>Baseline</i>	0.174 (0.271)	0.297 (0.405)	
<i>3 Months</i>	0.146 (0.266)	0.877 (0.589) [†]	***
<i>6 Months</i>	0.278 (0.471)	1.094 (0.703) [†]	***
<i>Marginal Gingival Index</i>			
<i>Baseline</i>	0.799 (0.453)	0.891 (0.587)	
<i>3 Months</i>	0.847 (0.602)	1.572 (0.977) [†]	**
<i>6 Months</i>	0.951 (0.595)	1.957 (1.079) [†]	***
<i>Plaque Index</i>			
<i>Baseline</i>	0.799 (0.586)	0.826 (0.589)	
<i>3 Months</i>	0.924 (0.639)	1.775 (0.934) [†]	***
<i>6 Months</i>	1.014 (0.698)	2.167 (1.168) [†]	***

Significant within groups, [†]P<0.05

Significant between groups, **P<0.01, ***P<0.001

Figure 1 presents the treatment response for the BI over the course of the 6 month study period for the brushing + flossing group compared to the brushing + flossing + Listerine® group. At 3 months, the brushing + flossing + Listerine® group had a slight decrease in BI scores, while the brushing + flossing group increased significantly (p<0.001). Both groups had an increase in BI scores from baseline to six months, however the brushing + flossing group had a significantly higher BI scores at 3 months and 6 months than the brushing + flossing + Listerine® group (P<0.001).

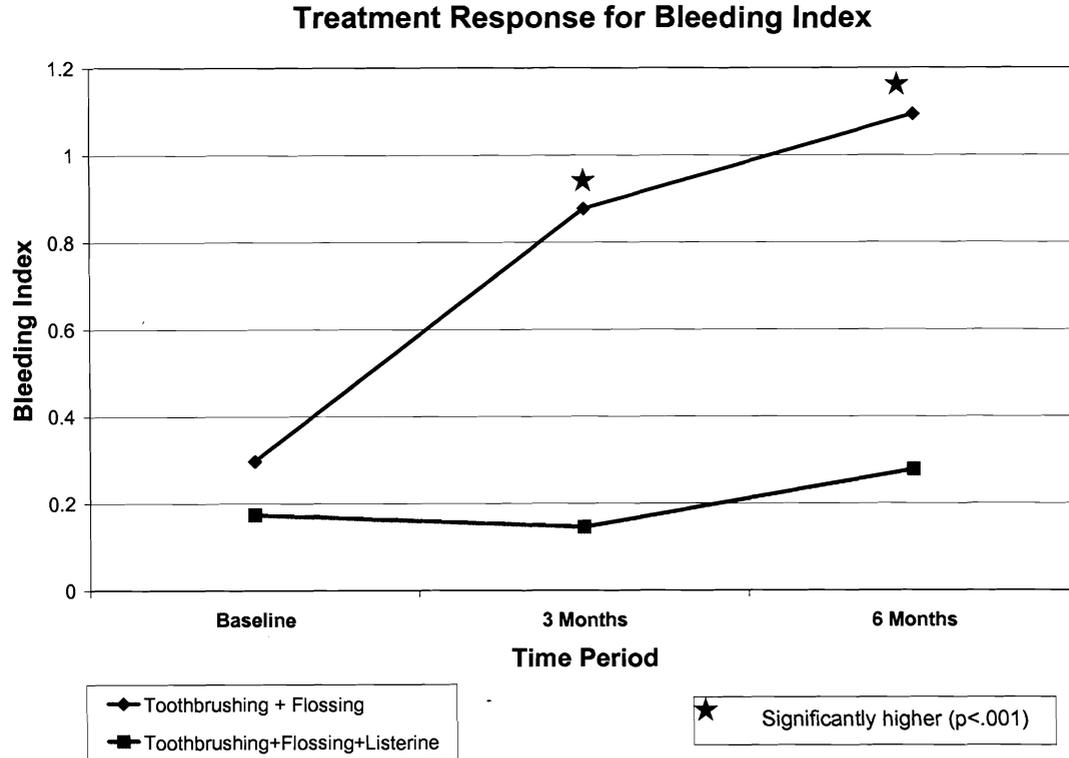


Figure 1. Treatment response for Bleeding Index

Figure 2 presents the treatment response for the MGI over the course of the six month study for the brushing + flossing group compared to the brushing + flossing + Listerine® group. Both groups had an increase in MGI scores from baseline to 6 months. However the brushing + flossing group had significantly higher MGI scores at 3 months ($p < 0.01$) and 6 months ($p < 0.001$) than the brushing + flossing + Listerine® group.

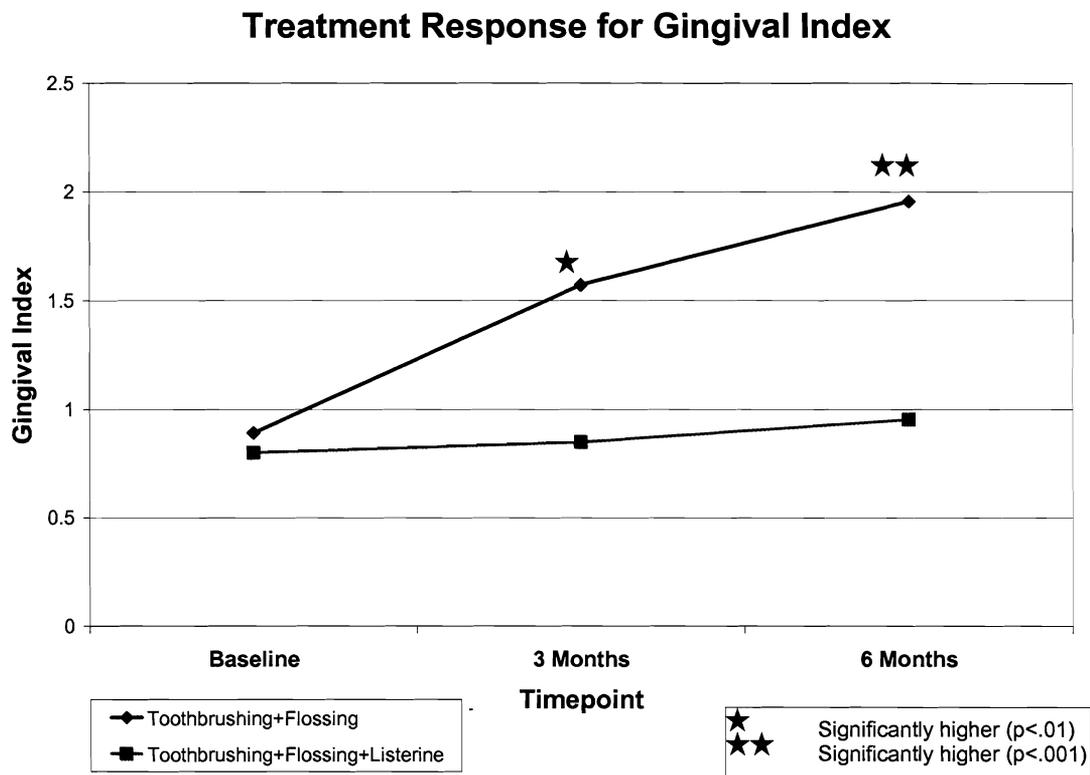


Figure 2. Treatment response for Marginal Gingival Index

Figure 3 presents the treatment response for the plaque index over the course of the 6 month study for the brushing + flossing group compared to the brushing + flossing + Listerine® group. Both groups had an increase in PI scores from baseline to 6 months. However, the brushing + flossing group had significantly higher PI scores at 3 months and 6 months than the brushing + flossing + Listerine® group ($p < 0.001$).

Treatment Responses for Plaque Index

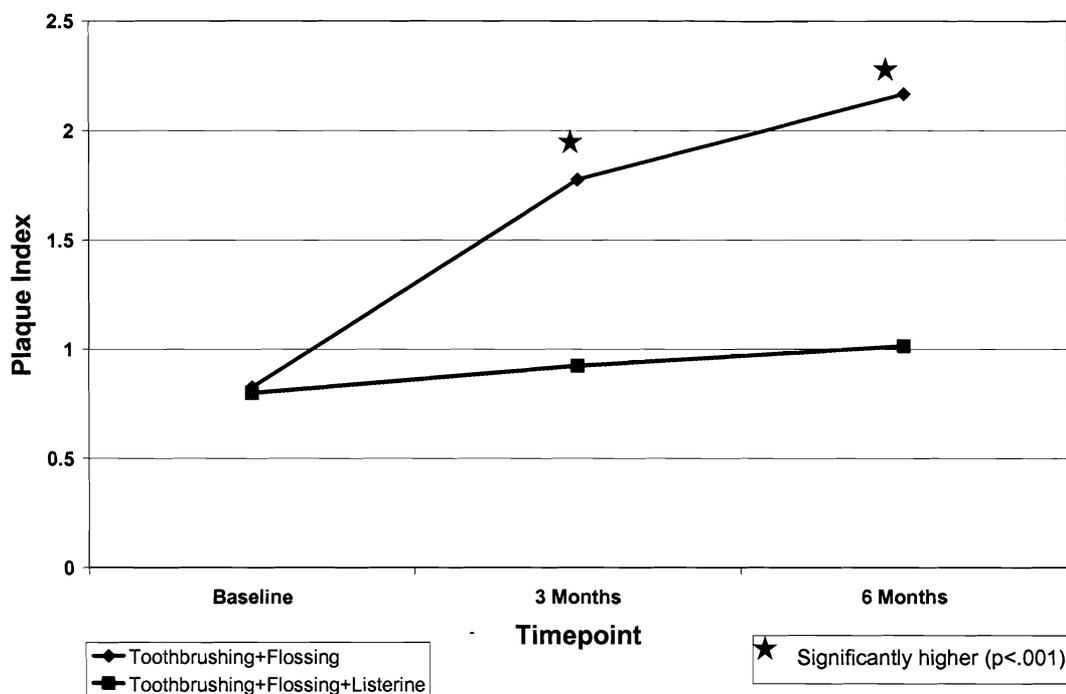


Figure 3. Treatment response for Plaque Index

The response profile for the brushing + flossing + Listerine® group was significantly different ($p < .001$) from the brushing + flossing group, with the brushing + flossing group responding with increases in all three indices at both the 3 month and 6 month intervals.

CHAPTER 4 Discussion

Plaque accumulation and subsequent gingivitis is common in orthodontic patients due to the challenge of controlling oral hygiene with the combination of brackets, bands, wires, and elastomeric ligatures present. Poor oral hygiene can eventually lead to the formation of white spot lesions, decay, and hyperplastic gingival tissue that may require intervention by a general dentist upon the completion of orthodontic treatment. There is considerable clinical trial evidence to show that oral hygiene status is significantly improved when therapeutic mouthrinses are added into the daily oral hygiene regimen (toothbrushing and flossing) compared to tooth brushing and flossing only.¹⁸ Although rinsing with Listerine® should not replace flossing, it could be an efficient adjunct to brushing in orthodontic patients who struggle to floss regularly in the presence of fixed appliances.

This study evaluated the effect of Listerine® mouthrinse in orthodontic patients when added to their routine oral hygiene regimen (brushing+flossing) over a 6 month period. It was demonstrated that the brushing + flossing + Listerine® group had superior oral hygiene to the brushing + flossing group after baseline measurements at all intervals for BI, MGI, and PI scores. The results were in agreement with previous studies that demonstrated the effectiveness of the oil-containing mouthrinse, Listerine®, in controlling plaque and gingivitis in numerous clinical trials on individuals who did not have orthodontic fixed appliances.

It is possible that the reduced plaque and gingivitis in the brush + floss + Listerine® group was attributable to “enhanced hygiene awareness” because of the added step of mouthrinsing. Patients who rinsed twice a day with Listerine® might have been motivated to care for their teeth more meticulously than the patients who just brushed and flossed. Studies on predicting patient compliance reported that cooperation levels varied considerably depending on the patient’s age and sex, perception of malocclusion, the influence of parents on the child, personality type and socioeconomic factors.³¹ While some studies suggested that young patients were more compliant than older ones, others found no correlation with age.³²⁻³⁵ Similarly, while some studies reported that girls were more adherent to orthodontic instructions than boys, others found no association between sex and compliance.^{32,36}

In the current study, patients in the two groups were matched by age. The brush + floss group had a higher proportion of females which may have biased the outcome in favor of better oral hygiene in that group. However, despite the greater proportion of males in the brush + floss + Listerine® group, that group still demonstrated significantly lower BI, MGI, and PI scores over time than the brush + floss group. Compliance with rinsing in the brushing + flossing + Listerine® group was monitored by having participants returning empty bottles on a monthly basis. The amount of empty bottles returned suggested that the patients were compliant with the given instructions.

In previous studies, the BI, MGI and PI scores were significantly lower at T2 compared to the values at T1. In the current study, there was a continuous increase in the BI, MGI and PI scores for both groups except the BI from baseline to 3 months in the

brush + floss + Listerine® group. This is to be expected as toothbrushing and flossing becomes more challenging in the presence of the orthodontic appliances.^{37,38} The results of the present investigation demonstrated that the use of Listerine® mouthrinse provided significant reductions in the amount of plaque and gingivitis compared to the control group. The use of Listerine® in addition to the standard oral hygiene regimen was found to be beneficial for orthodontic patients in maintaining proper oral health that could eliminate the formation of white spot lesions, decay and gingivitis.

CHAPTER 5

Conclusions

This study was conducted to establish a method for improving oral hygiene in orthodontic patients. The data collected in this study indicated that the addition of Listerine® to the daily oral hygiene regimen had an added benefit in reducing plaque and gingivitis development in orthodontic patients over a 6-month period. The confirmed reduction of plaque and gingivitis could lead to a lesser incidence of white spot formation though this study did not evaluate enamel demineralization. Daily rinsing with Listerine® is an easy and efficacious way of improving oral hygiene in orthodontic patients to help achieve a more esthetic and disease-free orthodontic treatment result. Based on the results of this study, it is recommended that orthodontists instruct their patients to rinse twice a day with 20 mL of Listerine® in addition to brushing and flossing.

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APPENDIX AVITA

Dr. Zachary Casagrande was born in Washington, D.C. on December 20th, 1977. He attended James Madison University in Harrisonburg, VA where he earned a Bachelor of Science degree in 1999. He then attended the Virginia Commonwealth School of Dentistry where he was awarded his Doctor of Dental Surgery degree in 2004. The following year he entered the Virginia Commonwealth University graduate orthodontics program and is anticipating receiving a Master of Science degree and a Certificate in Orthodontics in 2006. He plans to enter private practice as an orthodontist in Northern Virginia upon graduation.