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Full Length Research Paper

The effect of a self-bonding polymer on plaque and gingivitis over six months: A pilot study

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The purpose of this study was to evaluate the effect of self-bonding polymer (SBP) (KISSCARE® Concentrated Gel, KISS-COTE Inc., Tampa, FL, USA) in relation to plaque attachment and subsequent gingival inflammation. This randomized blinded clinical study followed a split-mouth design and examined prospectively 15 participants over a 6-month period. The average plaque index (PI) and average gingival index (GI) were measured for the control and SBP groups at baseline (week 0) and again after 2, 4, 12, and 24 weeks. Within the SBP groups, mean PI and GI at baseline, respectively, were compared to the same measures at the follow-up visits. Additionally, the control and SBP groups were compared in terms of the change in PI and GI from baseline to each of the follow-up points. For most part, the average PI and the average GI improved in both the control and SBP groups. The improvement in GI was statistically significant in both groups at weeks 2 and 4, while the improvement in PI was statistically significant at all follow-up visits. Among the areas to which polymer was applied, the average PI was statistically significantly lower than baseline at all follow-up visits. The SBP group showed significantly greater decrease in GI values when compared with the control group at week 2 (P<0.005). The overall potential benefit of SBP was too small to be clinically substantial as it may be compounded by an increase in subjects' attention to their oral hygiene during the clinical study.

Key words: Self-bonding polymer, gingival index, plaque index.

INTRODUCTION

Application of self-bonding polymers (SBP) has shown to be an effective method of surface coating in reducing staining of restorative resins (Park et al., 2006, 2008). The efficacy of SBP application was especially pronounced in the absence of brushing procedures. In addition to color stability, microbial attachment is unquestionably one of the most important clinical requirements of restorative materials. It plays a significant role in achieving ultimate clinical success in terms of preventing caries and periodontal disease.

The oral flora harbors a wide range of bacterial species responsible for a multitude of infections in the oral cavity. In cases of caries and periodontal disease, the initial attachment of critical microorganisms to the tooth surface is an essential prerequisite for infection. Complex bacterial compositions comprise dental plaque, which accumulates readily on the tooth surface. Dental plaque formation is initiated by the enamel salivary pellicle followed by adherence of bacteria to the pellicle. Colonization of critical indigenous species on tooth surface is an essential step in the occurrence and development of caries and periodontal disease (Rosan and Lamont, 2000; Liljemark and Bloomquist, 1996; Marsh and Bradshaw, 1995). Despite numerous efforts in promoting preventive dental care, dental caries is still the most common disease of children in the United States

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(Roackwille, 2000). Recurrent caries is the leading cause of short and long-term failure of dental restorations. Periodontal diseases have been associated with systemic diseases providing evidence of relationship between oral and systemic systems (Roackwille, 2000; Grossi and Genco, 1998). Research supports the link between specific microbial compositions of supra- and subgingival plaque and the occurrence of periodontitis (Ximenez-Fyvie et al., 2000a, b; Socransky et al., 1993; Löe et al., 1965). These oral infections can have profound systemic and local effects if left untreated.

In a previous study, the efficacy of SBP in reducing extrinsic stains was evaluated in an *in vitro* model (Park et al., 2006). This research showed that the SBP group exhibited significantly less discoloration as compared to both the control and sealer groups ($P<0.05$). Application of SBP has shown to be a highly effective method of surface-coating to reduce staining of restorative resins, especially in groups with poor oral hygiene procedures (Park et al., 2006). Therefore, it is also important to verify the effect that the surface coating material will have on plaque attachment and gingival health when it is applied.

Studies have indicated that color stability of resin restorations is influenced by different finishing treatments of the material surfaces (Gross and Moser, 1977; Shintani et al., 1985; Yap et al., 1997). The surface finishing affects the overall surface roughness attributing to staining and plaque accumulation, which could result in discoloration and secondary caries requiring replacement of restorations (Jefferies, 1998; Weitman and Eames, 1975). Therefore, it is important to elucidate the effect of SBP application in accumulation of dental plaque. This SBP, which is made of a pure poly(dimethylsiloxane), provides a mono-molecular layer of an inert protective coating that could potentially discourage microbial attachment and growth. It is an extremely thin coating, which changes the surface chemistry of the surface to which it is applied, but provides no mechanical protection (Park et al., 2006, 2008).

There is a need in restorative dentistry for a novel, conservative treatment approach to develop advanced biomaterials and restorative techniques. An ideal restorative material should satisfy color stability through preventing discoloration and help reduce the adhesion of dental plaque to teeth, periodontium, and restorative materials. This study hypothesized that understanding the characteristics of the SBP and its application may help reduce the adhesion of plaque on tooth surfaces. The aim of this study was to investigate the effect of a self-bonding polymer on plaque attachment and subsequent gingival inflammation during the course of six months.

MATERIALS AND METHODS

Study population

A total of seventeen human subjects were recruited, but two participants failed to follow through with recall visits and were eliminated from the clinical pilot study. Fifteen (7 women) subjects were included in the final analysis. Recruitment of subjects took place at the Harvard School of Dental Medicine, Faculty Group Practice. Exclusion criteria included subjects with complete edentulism in any arch. Existing restorative restorations, such as amalgams, resins, crowns, and bridges, were not exclusion criteria. All included subjects ranged from 20 to 46 years of age and reported no significant medical history, such as heart disease, diabetes, immune deficiencies, etc. None of the female subjects was pregnant for the duration of the study. There were no specific inclusion criteria to subject selection related to gender, ethnic background, medication, smoking, etc., however, 3 patients reported a history of smoking. Due to the small sample size, this variable was not calculated in the pilot study. All subjects were able to tolerate dental treatment and were competent to provide basic self-care, including oral hygiene practices. The project was explained to all subjects, and each person signed an informed consent form prior to enrollment. The project was approved by the Harvard Medical School Committee on Human Subjects.

Application of SBP

Subjects received an oral prophylaxis (cleaning and prophy), after which the KISSCARE® Concentrated Gel (KISS-COTE Inc., Tampa, FL, USA) was applied according to manufacturer's instructions in one quadrant of the maxillary arch and another quadrant of the mandibular arch on the opposite side. The test quadrants were randomly selected. The remaining two quadrants served as controls. This split-mouth design was chosen to control for individual- and time-dependent factors. For each quadrant, 1 to 2 drops of the KISSCARE® Concentrated Gel was applied on a prophy cup using a slow-speed hand piece to spread the material completely over the tooth surfaces. Any excess material was wiped off with gauze. Only light pressure was required to assure that the surface was thoroughly wetted with the material. One operator was responsible for the application of the material for the study. Subjects were given oral hygiene instructions and advised to brush their teeth twice daily (morning and evening) for 2 min with an American Dental Association approved dentifrice and soft-bristled toothbrush.

Measurements

Baseline measurements of plaque index (PI) and gingival index (GI) scores were made at the day of application. The PI and GI were measured again at 2, 4, 12, and 24 weeks. One operator was responsible for the measurements for consistency. The PI was measured using the Turesky Plaque Index System to access the amount of plaque on the facial and lingual surfaces of all of the teeth after using a disclosing agent (Turesky et al., 1970; Mandel, 1974). For each split-mouth treatment area, an average PI score was calculated.

For the measurement of GI, four gingival units (the distofacial papilla, facial margin, mesiofacial papilla and entire lingual gingival margin) were scored according to the Loe-Silness Gingival Index System (Löe and Silness, 1963; Löe, 1967). All of the scores were totaled and divided by the number of teeth examined, providing the average GI score per split-mouth treatment area. The GI can be used to differentiate severity of clinical gingivitis (0.1 to 1.0: mild gingivitis, 1.1 to 2.0: moderate gingivitis, and 2.1 to 3.0: severe gingivitis) (Löe, 1967).

Statistical analysis

Descriptive statistics were calculated for the study sample. The PI and GI were measured for the treatment and control split-mouth

Figure 1

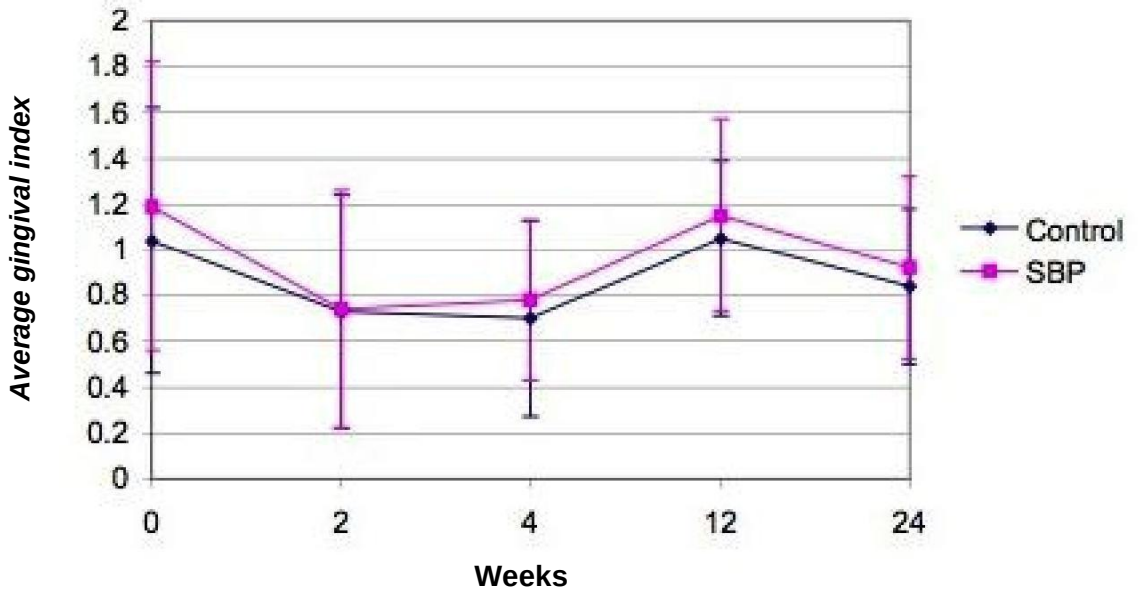

Figure 2

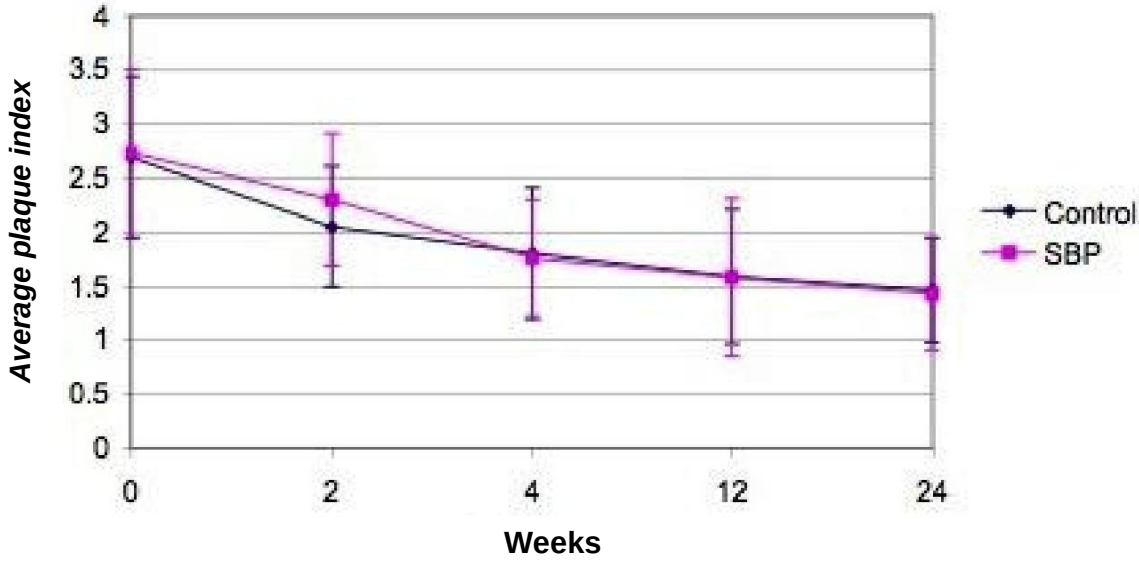

Figure 2. Mean average plaque index (PI) by week and treatment.

treatment areas at baseline (week 0) and follow up visits at 2, 4, 12, and 24 weeks. Plots of the mean GI and PI by group were constructed. To determine the effect of treatment on change on the GI and the PI, respectively, two sets of comparisons were performed. First, within category of treatment, each follow-up visit measure was compared to the baseline measure using a paired t-test. Second, the difference in each index at each of the follow-up visits as compared to baseline was calculated, and these differences were compared between the SBP split-mouth halves and the control split-mouth halves using a paired t-test.

All analyses were conducted in Stata 8.2 (Stata Corp., College Station, Texas), and in all instances, alpha was set to 0.05.

RESULTS

The plots of average GI and PI values over time by groups are shown in Figures 1 and 2. In the SBP groups, the baseline average GI was 1.19, and the average PI was 2.73. In the control group, the baseline average GI was 1.04, and the baseline average PI was 2.69. The baseline and follow-up GI and PI measures, accounting for loss to follow-up, are shown in Tables 1 and 2, respectively. For most part, both the control and SBP areas

Table 1. Gingival index (GI) at week 0 and follow-up, by treatment.

Week	SBP			Control		
	Week 0	GI	P*	Week 0	GI	P*
2	1.17	0.74	0.0005	1.01	0.73	0.003
4	1.12	0.78	0.07	0.96	0.70	0.07
12	1.07	1.15	0.70	0.91	1.04	0.49
24	1.01	0.92	0.62	0.86	0.84	0.89

*Paired t-test.

Table 2. Plaque index (PI) at week 0 and follow-up, by treatment.

Week	SBP			Control		
	Week 0	PI	P*	Week 0	PI	P*
2	2.70	2.30	0.03	2.66	2.05	0.001
4	2.72	1.76	0.0008	2.68	1.80	0.002
12	2.75	1.56	0.0004	2.72	1.59	0.001
24	2.46	1.42	0.0003	2.57	1.46	<0.0001

*Paired t-test.

experienced improvements in average GI and PI values. Among the areas to which polymer was applied, the average PI was statistically significantly lower than baseline at all follow-up visits. For the SBP group, average GI was statistically significantly lower than baseline at week 2, while the improvements at weeks 4 and 24 were not statistically significant. At week 12, the GI was higher than at baseline, though this difference was not statistically significant.

For each individual, the differences between the baseline measures and those at each follow-up visits were calculated. The summary statistics of these differences are shown in Table 3. These statistics demonstrate improvement in both the PI and GI regardless of treatment group. The exception was the difference between week 12 and baseline GI, where both the SBP and control groups experienced an increase in the average GI values relative to the baseline values of 0.074 in the SBP group and 0.14 in the control group; these values were not statistically significantly different (paired t-test P-value=0.41). The SBP and control groups demonstrated a statistically significant difference only at week 2. The control group had a greater reduction in PI from baseline (-0.60) than the SBP group (-0.39) (P-value=0.02, paired t-test). By contrast, the control group had a smaller reduction in GI values from baseline (-0.29) than did the SBP group (-0.43) (P=0.004, paired t-test).

DISCUSSION

The results of the clinical pilot study showed a statistically significant decrease in PI scores for both the control group and the SBP group throughout the visits. These observations could be in accordance with the findings of other studies stating that frequent follow up visits and repeated oral hygiene instructions alone could improve the oral hygiene in patients without further interventions. A study measuring the effect of different treatment modalities in achieving a healthy microflora through differential counts indicated that improved oral hygiene was achieved from monthly recalls, with or without treatment (Zee et al., 2006). In another study, gingival health at baseline and dental knowledge were considered significant predictors of good oral health (Hugoson et al., 2007). Frequency of the follow up visits was more critical than any treatment intervention including professional tooth cleaning for the clinical result. Needleman et al. (2005) concluded that repeated oral hygiene instructions might have a similar effect as professional mechanical plaque removal.

At week 2, the control group experienced a small, but statistically significantly greater decrease in PI than the SBP group. Despite extremely careful effort to separate the treatment groups during clinical application, it is possible that excess polymer could have spread to the control sites inadvertently or the material could have remained intra-orally and could have adhered to the remaining surfaces through saliva. Under these circumstances, the effect of the SBP may be indistinguishable from the unaffected areas. Another interpretation of the result may be that general improved oral hygiene could have been attributed to the application of SBP in all tooth surfaces in both study groups, known as the Hawthorne effect (Kohli et al., 2009).

The GI score exhibited a more complex pattern over time than the PI score. Both the control and SBP groups experienced a statistically significant improvement in average GI score at week 2, with results that bordered on statistical significance at week 4. As opposed to the effect seen in the PI, the polymer treated areas showed a statistically significant larger improvement in GI than did the control. However, at the 12th week visit, the GI scores slightly exceeded the baseline levels. This worse-ning was not statistically significant, and improvement relative to baseline was again seen at the 24th week visit. One reason for the worsening could have been the effect of a longer lapse in oral hygiene instructions during this period. Another point of interest is that the 12 week follow-up visits took place around and immediately after the winter holiday season, which has been linked to increased stress level (Phillips et al., 2004). Studies have shown that stress related to socioeconomic and various other conditions could pose as potential risk indicators for poor periodontal conditions and recommend intervention measures including stress reduction for preventing and treating periodontal disease (Spalj et al., 2008; Akhter et al., 2005). Johannsen et al. (2006) showed that women with stress-related depression and exhaustion had poor oral health leading to compromised periodontal health as compared to the control group in measures of more plaque

Table 3. Difference between week 0 and follow-up plaque (PI) and gingival (GI) indices, by treatment .

Week	PI Difference from week 0		P*	GI Difference from week 0		P*
	SBP	Control		SBP	Control	
2	-0.39	-0.60	0.02	-0.43	-0.29	0.004
4	-0.96	-0.88	0.30	-0.34	-0.26	0.44
12	-1.17	-1.13	0.84	0.074	0.14	0.41
24	-1.04	-1.11	0.37	-0.093	-0.02	0.44

*Paired t-test.

accumulation, GI and increased levels of IL-6 and cortisol in gingival crevicular fluid (Johannsen et al., 2006).

A limitation of this study is the loss to follow-up that occurred. The resultant reduction in sample size may have impacted the statistical power to make comparisons at the later follow-up visits. Despite this limitation, in the short term, these results demonstrate that the application of the polymer may even improve the PI and GI. This, in combination with the previous *in vitro* findings of reduced staining with polymer treatment, nominates the approach as a potentially useful complement to the existing treatment approaches for staining and plaque accumulation. The SBP could possibly reduce plaque accumulation, although the beneficial effect may be compounded by increased patient attention to oral hygiene.

The duration of the coating still needs to be explored to determine whether multiple applications are required and the optimal frequency of application. The time over which the treatment might continue to have a beneficial effect is not clearly defined. The wear resistance affected by daily tooth brushing with a dentifrice is another factor that needs to be explored further. As observed in our *in vitro* study, application of SBP was an effective method of surface coating in reducing staining of restorative resins, especially in groups without brushing procedures (Park et al., 2006). The overall efficacy of SBP could be more pronounced in patient population with poor oral hygiene.

To better understand the effect on PI, further investigations of the effect of the polymer on microbial adherence are required. Microbial adherence is an essential step in the formation of dental plaque leading to colonization and pathogenesis (Marsh, 2003). The early colonizers of the tooth surface attach through non-specific physiochemical interactions between microorganisms and host surface and the later colonizers bind to the existing organisms by adhesin-receptor mechanisms (Marsh, 2003; Busscher and van der Mei, 1997). Glycoproteins, mucins, and enzymes found in saliva are present in the pellicle covering the tooth surface and can be recognized by the early colonizers. The salivary components for specific binding by bacteria have been studied, such as acidic proline-rich proteins as the receptor for *Streptococcus gordonii* (Kolenbrander and London, 1993).

The patient population in the current pilot study did not have any significant medical complications leading to decreased salivary flow. Research has shown that decreased salivary flow is an important risk factor for root caries for the elderly (Almståhl et al., 1999). Application of the SBP in patients suffering from xerostomia, such as in Sjögren's syndrome, irradiation therapy, and medica-tion use for various medical conditions, may have a more profound benefit. The effect of saliva, pH, and the presence of a multitude of microorganisms that coexist within the oral environment and their possible effects on plaque attachment should be considered in future studies.

Conclusion

The SBP and control groups both displayed improvements in PI and GI scores. The potential clinical significance of self-bonding polymer on plaque and gingival health was marginal in this clinical study. The long-term benefit for its use as a complement to the existing treatment for preventing staining and plaque accumulation need to be further investigated.

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