patients received a professional dental cleaning, oral hygiene methods were reviewed, and photographs were taken to capture a baseline assessment of the decalcification index (DI). Subjects were instructed to bring the tube of toothpaste to each monthly appointment, at which time old toothpaste was collected, new toothpaste was dispensed, and oral hygiene instructions were reinforced. Toothpaste was also weighed after collection as a means to measure patient compliance.

At the 3- and 6-month follow-up appointments, pictures were taken, and the following clinical procedures were carried out in the maxillary and mandibular anterior teeth:

1) *Measurement of decalcification*: the DI used in the study was a modified version of the WSL index developed by Gorelick et al.[9]. The modified decalcification index scores individual teeth as follows: (0) no white spot lesion present, (1) visible white spots without surface interruption (mild decalcification), (2) visible white spot lesion having a roughened surface but not requiring a restoration (moderate decalcification), (3) visible white spot lesion with surface interruption (severe decalcification), and (4) cavitation. DI scoring was done with the photographs taken at the beginning of the study serving as documentation. The same camera settings were used throughout the study.
2) *Measurement of gingivitis*: we used the modified gingival index (GI), defined by Lobene et al. [15], as follows: (0) normal (no inflammation), (1) mild inflammation (slight change in color, little change in texture) of any portion of the gingival unit, (2) mild inflammation of the entire gingival unit, (3) moderate inflammation (moderate glazing, redness, edema, and/or hypertrophy) of the entire gingival unit, and (4) severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding or ulceration) of the gingival unit.
3) *Measurement of plaque*: the plaque index (PI) used in this study was the Turesky modification of the Quigley-Hein index [16]. Scoring used for this index is on a zero to five scale and is defined as (0) no plaque; (1) separate flecks or discontinuous bands of plaque at the gingival margin; (2) thin (up to 1 mm), continuous band of plaque at the gingival margin; (3) band of plaque wider than 1 mm but less than one third of the tooth surface; (4) plaque covering between one third and two thirds of the tooth surface; and (5) plaque covering more than two thirds of the tooth surface.
4) *Plaque bacterial counts*: relative *Streptococcus mutans* and *Lactobacillus* levels were measured in saliva using a commercial caries risk test (CRT-Bacteria, Ivoclar, Vivadent, Amherst, NY).

Inter-examiner reliability was assessed between two investigators (AEC and DAH) by scoring the indices of five randomly selected patients and time points from the study sample. Two-sample *t*-tests were used to test for differences between treatment groups, while paired tests were used to examine changes over time within treatment groups. Non-parametric tests were also used (Wilcoxon rank-sum and Wilcoxon signed-rank, respectively). While we expected outcome variables to be normally distributed, differences between parametric and non-parametric testing would alert us to cases where this may not be true. Results did not vary; thus, only the parametric results will be presented. A P value less than 0.05 was considered statistically significant. Chi-square tests, Fisher exact test, two sample *t*-tests, and Wilcoxon rank-sum tests were used to analyze any significant differences in regard to sex, race, age, and time in treatment between the control and experimental groups.

Results

Statistical analysis showed that the groups were similar regarding a number of variables at baseline, including age, time in treatment, DI, GI, and PI scores (Table 1). They also did not differ significantly with respect to sex ($P = 0.54$, chi-square test) or race ($P = 0.72$, Fisher exact test). No clinical trends or statistically significant difference between the control group (Crest®) and experimental group (ReNew™) was noted throughout the 6-month follow-up for PI (Fig. 1, Table 2). There was a trend toward improvement in white spot lesions (DI score) found in subjects using Crest® at the 3-month time point, which was statistically significant ($P = 0.0403$) (Fig. 2, Table 2). Likewise, the ReNew™ group showed a trend toward improvement in gingival health at the 3-month time point; however, no statistically significant difference was detected (Fig. 3, Table 2). These improvements were not sustained throughout the study since no statistically significant differences were detected between the control and treatment groups at the 6-month time point for all three indices (DI, GI, and PI).

We also examined change from baseline to 3 and 6 months, comparing the two groups. No statistically significant differences were detected. Within-group comparisons detected significant changes from baseline to

Table 1 Baseline comparison between groups

	ReNew™	Crest®	*P* value (*t*-test)
Mean DI score	0.33	0.33	0.27
Mean GI score	2.14	2.15	0.95
Mean PI score	3.04	3.41	0.27
Mean age	15.6	15.3	0.63
Tx time	1.5	1.2	0.23

P value was set at 0.05. No significant difference between groups at baseline were detected using two-sample *t*-test