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ABSTRACT

Objective: To evaluate the extrinsic stain removal efficacy of baking soda toothpaste (TheraBreath® Whitening) compared to sodium fluoride control (Crest® Cavity Protection).

Methodology: A double-blind, randomized, parallel-group, 6-week clinical study. Stain evaluation employed the Modified-Lobene Stain Index (MLSI). Subjects used their assigned toothpaste and toothbrush twice daily for two minutes, for six weeks. Stain evaluations were repeated after 7-, 14-, 28-, and 42-days use.

Statistical analysis was conducted on subjects who completed the study (TheraBreath, n=59; Crest, n=58). MLSI Intensity x MLSI Area = Total Stain scores; Intensity, Area, and Total Stain scores were each averaged by subject. The primary endpoints for the treatment comparisons were reductions in MLSI Total Stain scores (whole-mouth, mandibular, and maxillary teeth) from baseline to Days 7, 14, 28, and 42. The comparison of treatments employed an analysis of covariance (ANCOVA) model, with the associated baseline score as the covariable. All statistical tests of hypotheses were two-sided and employed a level of significance of $\alpha=0.05$.

Results: No statistically significant differences were observed between the products at baseline. TheraBreath toothpaste demonstrated significantly lower Total Stain scores for whole-mouth, maxillary, and mandibular teeth compared to Crest control ($p<0.0001$) on Days 7, 14, 24, and 42. The whole-mouth total stain scores for TheraBreath toothpaste were 34.5%, 48.4%, 55.9%, and 64.7% lower than Crest control on these respective days. Similar % reductions were seen for the mandibular and maxillary teeth. At each time point, TheraBreath toothpaste resulted in significant within-treatment reductions from baseline ($p<0.0001$) in Intensity, Area, and Total Stain scores for whole-mouth, as well as for mandibular teeth, and maxillary teeth.

Conclusion: TheraBreath® Whitening was statistically superior to Crest® Cavity Protection in reducing extrinsic stain after 7, 14, 28, and 42 days of toothpaste use.

METHODS

This IRB approved, randomized, stratified, single-center, double-blind, 2-cell parallel study used the Macpherson modification of the Lobene Stain Index (MLSI)¹ to assess the stain removal efficacy of two toothpastes over a 6-week period.

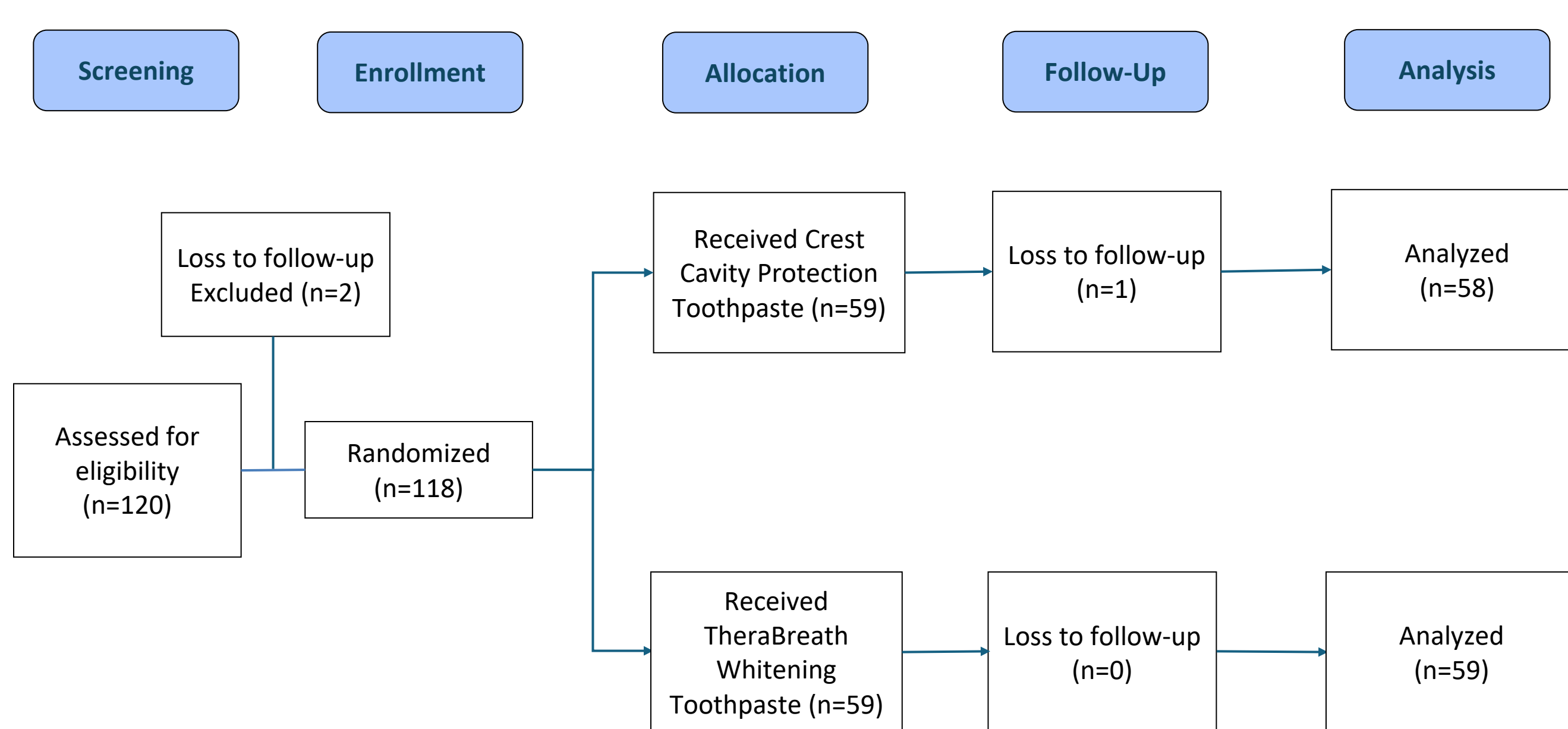
Key Inclusion Criteria:

- 18-65 years of age; Generally healthy adults
- At least 8 of 12 labial surfaces of the anterior teeth with a mean MLSI score ≥ 1.5 at baseline
- No oral pathology, explicit medical condition or treatment that could compromise the study
- No use of whitening products other than specified study products

Treatment Groups:

- Control Toothpaste: 0.243% NaF (Crest® Cavity Protection)
- Test toothpaste: 20% NaHCO₃ (baking soda) and 0.243% NaF (TheraBreath® Whitening)

Fig. 1 Consort Diagram Showing Overall Study Flow



Key Study Elements:

- Subjects were instructed to refrain from all oral hygiene for 12 hours and from eating or drinking for 4 hours prior to each study visit
- Subjects were stratified by mean baseline MLSI scores, smoking habits, and beverage consumption, and then randomized to ensure balanced treatment groups
- Oral soft and hard tissue (OSHT) examinations and baseline stain intensity and stain area assessments were performed
- Subjects completed an initial supervised brushing at the clinical site and brushed at home, with the assigned toothpaste and toothbrush (Oral-B Indicator) twice daily (morning and evening) for 2 minutes using a timer for the 6-week study duration
- Subjects returned to the clinical site on Days 7, 14, 28, and 42 for post-use evaluations

Clinical Scoring:

- All examinations done by the same trained and calibrated examiner
- Extrinsic stain scored using the MLSI 0–3 scale²



RESULTS

Statistics:

- Efficacy analyses used the per-protocol population (n=117); safety analyses used the intent-to-treat population (n=118)
- Total Stain scores were calculated as Stain Intensity x Stain Area, with Intensity, Area, and Total Stain scores averaged by subject
- Primary endpoints were MLSI Total Stain scores for whole-mouth, mandibular, and maxillary teeth at Days 7, 14, 28, and 42
- Secondary endpoints were MLSI Stain Intensity and Stain Area scores at the same time points
- Treatment comparisons for primary and secondary endpoints employed ANCOVA with treatment as a factor and baseline score as a covariate; all tests were two-sided ($\alpha=0.05$)

Demographics:

- There were no statistically significant differences in age or sex across treatment groups
- Crest® Cavity Protection (n=58): participants had a mean age of 46.9 ± 11.5 years (range 22–65); sex: 81% female, 19% male
- TheraBreath® Whitening (n=59): participants had a mean age of 46.0 ± 12.6 years (range 18–65); sex: 78% female, 22% male

Safety:

No adverse events were observed.

Efficacy:

- TheraBreath® Whitening exhibited statistically significantly lower whole-mouth MLSI Total Stain scores than Crest® Cavity Protection at all post treatment time points (Days 7–42; $p<0.0001$), with 65% lower at Day 42. See Fig. 2
- TheraBreath® Whitening exhibited statistically significantly lower whole-mouth MLSI Area and Intensity scores than Crest® Cavity Protection at all post treatment time points (Days 7–42; $p<0.0001$). See Table. 1

Fig. 2 Whole-Mouth Mean MLSI Total Stain Scores

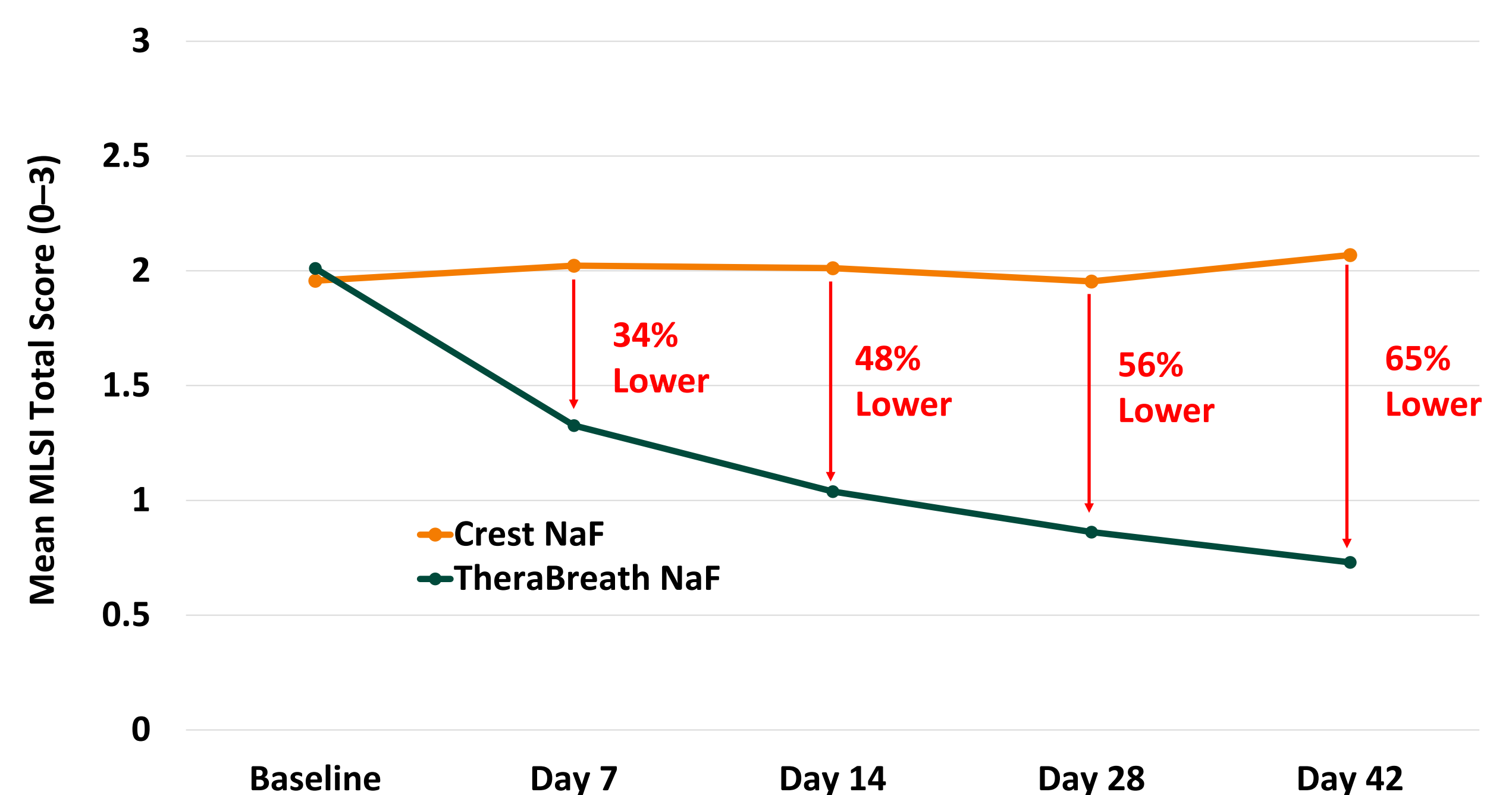


Table 1 Between Treatment Comparisons of MLSI Scores

Score	Day	Crest	TheraBreath	Difference	95% CI	p-value	%TB > Crest
Total Stain	7	2.02	1.33	0.69	(0.58, 0.81)	<0.0001	34.5%
	14	2.01	1.04	0.97	(0.85, 1.10)	<0.0001	48.4%
	28	1.95	0.86	1.09	(0.96, 1.22)	<0.0001	55.9%
	42	2.07	0.73	1.34	(1.21, 1.47)	<0.0001	64.7%
Area	7	1.08	0.80	0.28	(0.22, 0.34)	<0.0001	25.9%
	14	1.10	0.70	0.40	(0.34, 0.46)	<0.0001	36.2%
	28	1.07	0.62	0.45	(0.39, 0.51)	<0.0001	41.8%
	42	1.09	0.58	0.51	(0.45, 0.57)	<0.0001	46.8%
Intensity	7	0.96	0.65	0.32	(0.26, 0.37)	<0.0001	32.7%
	14	0.95	0.52	0.44	(0.38, 0.49)	<0.0001	45.5%
	28	0.91	0.43	0.48	(0.42, 0.54)	<0.0001	52.9%
	42	0.97	0.37	0.60	(0.55, 0.66)	<0.0001	61.9%

TB = TheraBreath® Whitening

CONCLUSIONS

TheraBreath® Whitening, a toothpaste containing sodium fluoride and baking soda, demonstrated statistically greater reductions in extrinsic stain compared with a sodium fluoride control toothpaste, with a 65% reduction in total stain observed at study end.

REFERENCES

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