

Milleman J, Milleman K, Santos S, Mateo L, Morris A, Stewart B, Khayat H. 2021, Data on File.

Objectives: Evaluate the safety and plaque removal efficacy of a new children’s sonic toothbrush (BURSTkids™ SONIC TOOTHBRUSH) compared to a marketed children’s manual toothbrush (Sparkle Kids Toothbrush, Stage 2, OraLine Kids) and a standard fluoride dentifrice.

Methodology: This single use, examiner blinded, randomized, two-period, cross-over, IRB approved clinical study included 3 study visits with male and female children 5 to 8 years of age. See Figure 1 for details. The brushing regimens included: 1) brush for 2 minutes twice daily with Sparkle Kids Toothbrush, Stage 2, (OraLine Kids, [Sparkle Kids Toothbrush, Stage 2 | Kids Toothbrushes | OraLine Kids](#)) and a sodium fluoride toothpaste (control group); or 2) Brush for 2 minutes twice daily with BURSTkids™ SONIC TOOTHBRUSH and a sodium fluoride toothpaste. Subjects brushed at home with their first assigned toothbrush and fluoride toothpaste, under supervision of a parent or legal guardian, at least once daily for two minutes during a 1-week acclimation period. After refraining from oral hygiene for a 12–16-hour period, subjects returned to the clinical site where they were assessed for plaque using the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (PI). Subjects then brushed their teeth with their assigned toothbrush and toothpaste for 2 minutes and plaque levels were reassessed. Subjects were then given their second assigned toothbrush and the acclimation period and clinical site visit were repeated for the second crossover period. Qualified subjects had a mean pre-brushing PI score of ≥ 1.80 at all 3 study visits.

A questionnaire assessing the potential of the sonic power toothbrush in promoting a positive toothbrushing experience was administered to the subject and their parent/legal guardian at the end of the study (Visit 3). Data were summarized based on percent responses on the top two boxes.

Differences between pre-and post-brushing scores were analyzed for each toothbrush and between toothbrush groups for whole mouth plaque and proximal and gingival margin sites, using baseline adjusted ANCOVA.

Results: Both toothbrushes significantly reduced whole mouth, gumline and proximal plaque levels (BURSTkids™ SONIC TOOTHBRUSH: $p < 0.001$ for whole mouth, gumline, and proximal; manual toothbrush: $p < 0.01$ for whole mouth, gumline, and proximal).

Compared to a manual toothbrush (Sparkle Kids Toothbrush (Stage 2), OraLine Kids, brushing twice daily with BURSTkids™ SONIC TOOTHBRUSH in the “power mode”:

- Removed 19.2% of plaque.
- Was significantly more effective in removing plaque from hard-to-reach areas:
 - Between the teeth, BURSTkids™ SONIC TOOTHBRUSH removed 17.2% more plaque.

- Along the gumline, BURSTkids™ SONIC TOOTHBRUSH removed 22.4% more plaque.
- Brushing with BURSTkids™ SONIC TOOTHBRUSH* provided significantly greater reductions in plaque compared to a manual toothbrush:
 - Provided 26x greater plaque removal (based on whole mouth plaque scores).
 - Provide 24x greater plaque removal between the teeth
 - Removed 30.7x greater amount of plaque along the gumline
- The end of study questionnaire, consisting of 11 questions completed by children and their parents/legal guardian after the post-brushing plaque assessment demonstrated:
 - >96% of parents reported the BURSTkids™ SONIC TOOTHBRUSH was easy for their child to use and the built-in timer helped their child brush their teeth for the recommended 2 minutes.
 - >90% of parents reported the BURSTkids™ SONIC TOOTHBRUSH helped their child take responsibility for brushing their own teeth,
 - their child preferred the BURSTkids™ SONIC TOOTHBRUSH to their existing toothbrush,
 - their child enjoyed brushing their teeth with BURSTkids™ SONIC TOOTHBRUSH. See Figure 3.

Conclusions: BURSTkids™ SONIC TOOTHBRUSH was superior in reducing plaque compared to a marketed children’s manual toothbrush (Sparkle Kids Toothbrush, Stage 2) in a population of 32 children with primary and mixed dentition. There were no adverse events reported in this study, thus, the BURSTkids™ SONIC TOOTHBRUSH is safe and gentle when used as directed. Overall, the results of this study highlight the benefits of incorporating a power toothbrush into a child’s home care routine in reducing plaque compared to brushing with a manual toothbrush.

Figure 1. Study Design

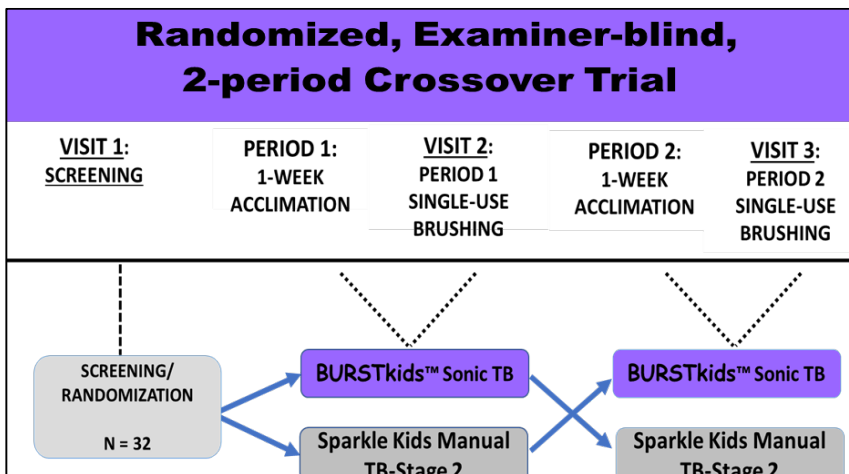
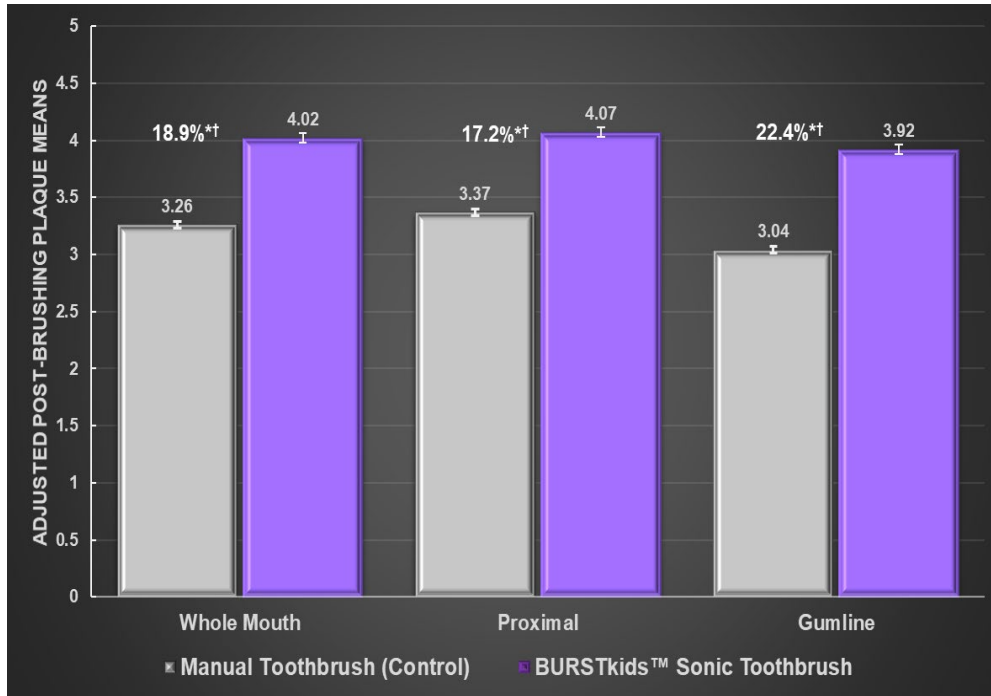


Figure 2. Percent Difference of Adjusted Post-Brushing Plaque Means (Whole-Mouth, Proximal, and Gumline)

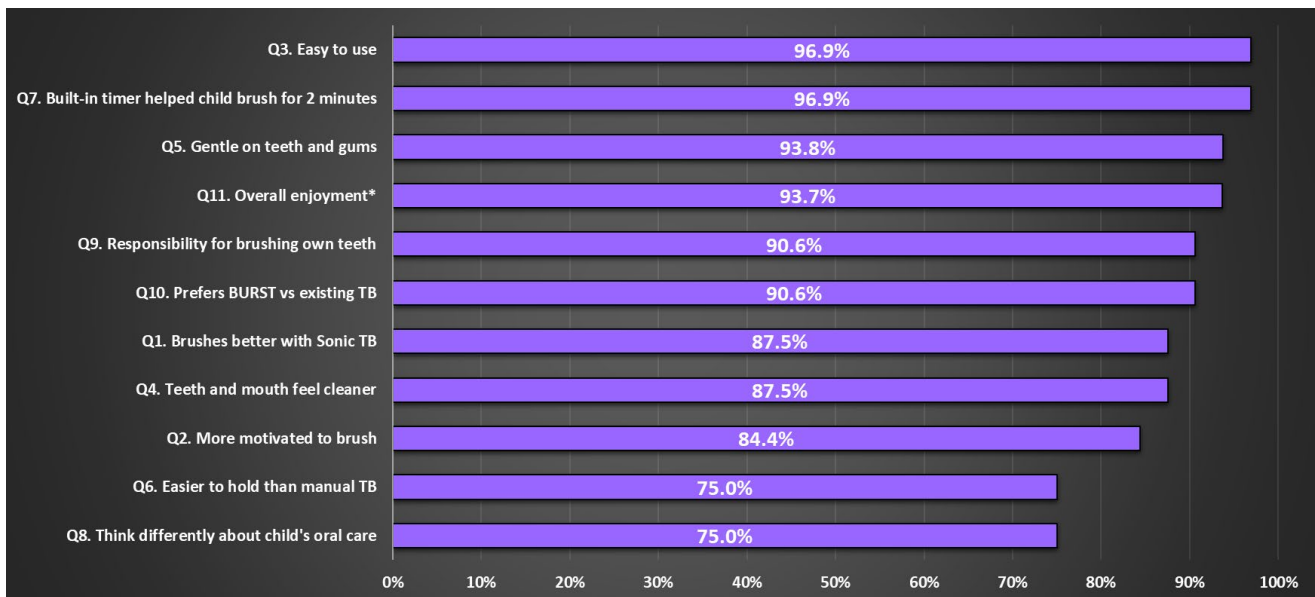


*Difference between the post-brushing means expressed as a percentage of the post-brushing mean for the Control Toothbrush Group.

†Significance of ANCOVA comparison of baseline-adjusted post-brushing means; $p < 0.001$.

†Significance of ANCOVA comparison of baseline-adjusted post-brushing means; $p < 0.001$.

Figure 3 End of Study Questionnaire: Top 2 Box Results



*Q11 scale: 1=not at all enjoyable and 5=extremely enjoyable