

A randomized, clinical evaluation of the safety and efficacy of a novel oral irrigator

Frascella J.A., et al., TKL Research Inc., Paramus, New Jersey, USA
Am. J. Dent. 2000: 13: 55-58

BRAUN

Oral-B

Objectives

The aims of this study were to evaluate the safety and efficacy of the Braun Oral-B OxyJet™ (MD15) Oral Irrigator when used as an adjunct to manual brushing, and to compare the effects on plaque, gingivitis and bleeding, to manual brushing alone.

Design

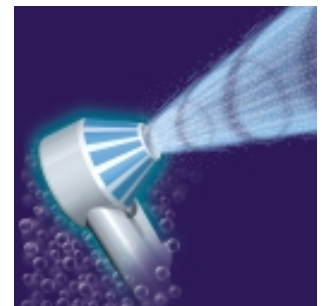
This was a randomised, parallel-group, examiner-blind clinical study.

Materials and Methods

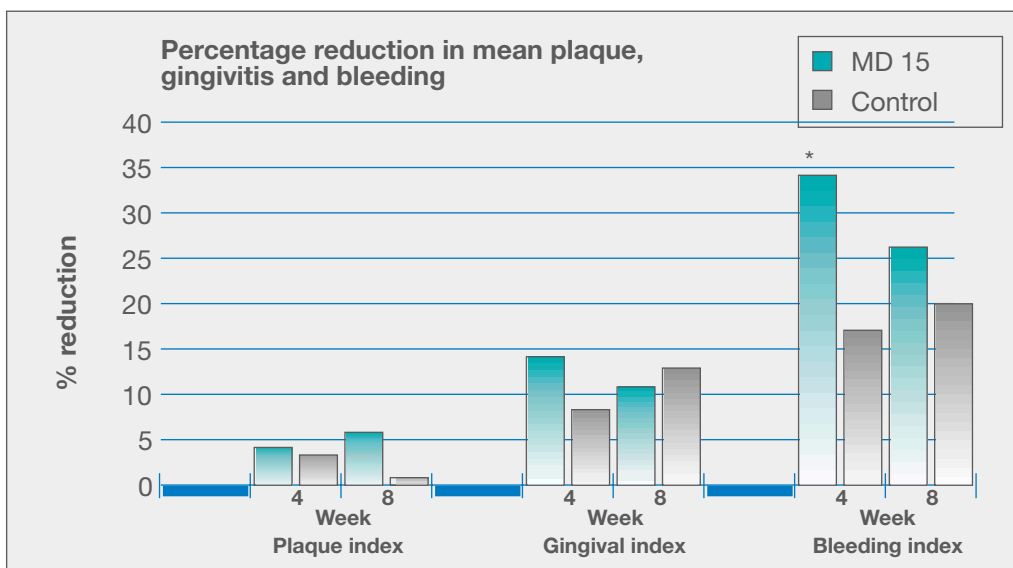
The study involved a total of 64 subjects with gingivitis (defined by bleeding at >30% of sites) randomly selected from a general population. Subjects eligible for the study were randomly assigned to use either a manual toothbrush alone or a manual brush with the additional use of the Braun Oral-B OxyJet (MD15) Oral Irrigator.

The MD15 is an oral irrigator that differs from conventional irrigators in that it incorporates approximately 5% of air into the water stream. The air is atomized at the exit of a push-on nozzle, producing stable microfine air bubbles with a diameter of between 1 and 50 µm.

After randomization to the two groups, subjects were asked to attend three study visits and were instructed not to use any oral hygiene procedure after midnight on the night previous to the visit. At baseline, subjects received a clinical examination, and were scored for plaque (Turesky modification of the Quigley-Hein index), gingivitis (modified gingival index) and bleeding (Angular Bleeding Index). Subjects were provided with a standard ADA approved manual toothbrush and Crest® Regular toothpaste. The MD15 + brushing group were instructed in the use of the device by a dental hygienist. All subjects were asked to brush twice daily in their usual manner. Subjects in the MD15 group were also requested to irrigate their supragingival areas with 600 ml water once per day, after brushing in the evening. Subjects returned to the test facility after 4 weeks and 8 weeks for safety and efficacy assessments.



Results



* Statistically significant difference between groups, p<0.05

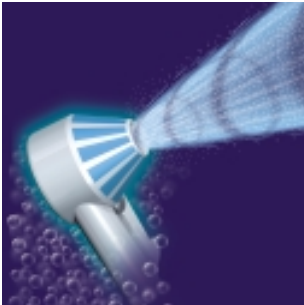
BRAUN

Oral-B

At week 8, 56 subjects remained in the study, 26 in the MD15 group and 30 in the manual toothbrushing group. Both brushing alone and brushing in combination with use of the MD15 were considered to be safe, and no treatment related adverse events were reported.

As shown in the figure, use of the MD15 in conjunction with manual toothbrushing resulted in a progressive reduction in plaque scores over the 8 weeks of the study. By week 4, the plaque index had decreased by a mean score of 0.11 and, at week 8, by 0.16. These reductions from baseline approached significance at week 4 and achieved significance at week 8 ($p=0.015$). In contrast, in the control group, the plaque score was reduced by only 0.07 at week 4 and by 0.02 at week 8. The difference between the two groups approached significance at week 8 ($p=0.065$).

The gingival index decreased significantly from baseline in both groups, the decrease being statistically significant at week 4 in the MD15 group and at week 8 in the control group (see figure). No statistically significant differences were observed between the two groups. The bleeding index was also significantly decreased in both groups over the course of the study, the reductions from baseline being significant at both 4 and 8 weeks. At week 4, there was a statistically significant difference between the groups in favour of the MD15 group ($p=0.023$).



Clinical comment

This clinical study compared the effect of using the Braun Oral-B Oxyjet (MD15) Oral Irrigator as an adjunct to manual toothbrushing, with toothbrushing alone. It confirmed the safety of the MD15, and showed that the combination of the MD15 and brushing resulted in a reduction in plaque and an improvement in gingival health. There was some evidence that the adjunctive use of the MD15 provided better plaque control and a greater reduction in the bleeding index.

Irrigation can be a useful additional method of oral hygiene, especially for those patients with orthodontic bands or implants, as it has the potential to remove debris from between the teeth where the toothbrush cannot reach. As a large proportion of the population do not regularly clean interdentally, irrigation must be considered of value as an adjunct to toothbrushing.