Summary of clinical experience

- Product development rationale
- Advanced laboratory testing
- Plaque removal efficacy
- Long-term safety and efficacy
The Oral-B® CrossAction® toothbrush is the result of unprecedented scientific research with one clear objective: to design a toothbrush that helps patients do a better job brushing. The results of this extensive laboratory and clinical evaluation are consistent and conclusive in demonstrating that CrossAction provides significantly better cleaning performance than all other toothbrushes tested.

This Clinical Summary reviews the groundbreaking performance than all other toothbrushes tested. The results of this extensive laboratory and clinical evaluations are consistent and conclusive in demonstrating that CrossAction provides significantly better cleaning ability.

With conventional vertical bristles, this phenomenon is limited because only a few bristles are correctly positioned at the interproximal junction when the brush changes direction. These observations led Oral-B researchers to recognize that if a brushhead was designed with its bristles already positioned at an angle toward the direction of travel, the entire brushing action could be made more effective.

Since behavior modification is difficult to achieve, improving toothbrush design to help people brush better may be the most direct route to improved oral hygiene.

Removing plaque using conventional technology

Studies show that most plaque accumulates on the approximal surfaces of molars and premolars—areas of the mouth that also experience the highest incidence of gum disease. Improving plaque removal at these sites is therefore a key part of improving overall oral health.

In recent years, several new toothbrush designs have been evaluated in both laboratory and clinical settings. While many of these brushes have demonstrated improvements in plaque removal that were statistically significant, the results were often marginal, inconsistent, and clinically small—especially for approximal plaque (results of which are often not recorded).

Breakthrough findings: bristle/tooth dynamics

To better understand how toothbrush bristles act on the tooth surface, especially in the approximal area, Oral-B researchers pioneered new laboratory methods of investigation. Their research showed that the point of greatest interproximal penetration occurs when the brushing direction changes. Bristles that sweep across the tooth surface in one direction angle back into the interproximal space, moving down and back up the adjoining approximal surface.

With conventional vertical bristles, this phenomenon is limited because only a few bristles are correctly positioned at the interproximal junction when the brush changes direction. These observations led Oral-B researchers to recognize that if a brushhead was designed with its bristles already positioned at an angle toward the direction of travel, the entire brushing action could be made more effective.

Breakthrough findings: bristle angle and arrangement

Early research showed that small angles up to 12° from vertical (0°) did not provide markedly greater interproximal penetration than conventional vertical bristles. However, as the researchers increased the bristle angle above 12°, they discovered that the bristles not only penetrated much deeper but also more frequently than before, enhancing the cleaning potential for approximal surfaces.

Oral-B researchers also discovered that altering the brush angle into the lateral, elliptical tufts reduced bristle-to-bristle interference, allowing greater coverage of the tooth surface, thereby maximizing their cleaning ability.

CrossAction design: features and benefits

Using this information, the CrossAction brushhead was developed with tufts of bristles angled at 16° in both directions to provide a brushing action that penetrates, lifts, and sweeps plaque away on the forward and backward strokes.

Putting CrossAction® to the test

Oral-B researchers developed two advanced laboratory tests that would be critical in developing and evaluating products that help people brush better. These tests were used to optimize the brushhead configuration and to compare CrossAction with more than 80 leading toothbrushes from around the world.

Transparent Tooth Penetration Test

Objective

To measure frequency and duration of bristle penetration into the interproximal space.

Methods

A robotic brushing arm was calibrated to provide a brushing action and force similar to that of a typical adult, moved a test brush over a simulated jaw section while being recorded through a transparent tooth with a high-speed video camera (Figure 1). After each test, the tape was replayed in slow motion and bristle penetration was calculated using a computerized digital image analysis process. Each toothbrush model was tested ten times (with a new brush each time), after which an average score for the brush was calculated.

Results

Evaluation of angled vs straight bristles

CrossAction with angled bristles provided 15.5% greater average cleaning effectiveness than an identical brushhead with vertical bristles.

Evaluation of competitor brushes

As with interproximal penetration, the cleaning effectiveness of the CrossAction was found to be significantly superior to each of the 80+ toothbrushes tested.

Conclusions

These laboratory results prove that the unique CrissCross™ bristles of CrossAction provide significantly greater interproximal penetration and plaque removal than conventional toothbrushes.

Furthermore, the laboratory model presented here was also shown to accurately predict the clinical outcome obtained in 16 independent clinical studies reported in the rest of this summary booklet. The 14 different leading toothbrushes tested represented 12 multilevel toothbrush designs as well as 2 flat trim toothbrushes.

These results provide the most extensive direct evidence ever reported, demonstrating the clinical relevance of a laboratory model and fully corroborating the significantly greater performance provided by CrossAction.
The purpose of toothbrushing is to remove plaque and food debris from the teeth. Toothbrushes perform this function through the direct mechanical action that occurs during brushing. The amount of plaque removed during a single brushing provides, therefore, a direct assessment of a toothbrush’s cleaning ability.

Laboratory studies indicated that the Oral-B® CrossAction® design significantly enhances plaque removal, especially with respect to the proximal surfaces. To confirm these laboratory findings, the CrossAction was assessed in independent head-to-head, single-brushing clinical trials.

Methods

Seven independent, crossover, examiner blind, clinical studies—each involving approximately 100 healthy subjects—compared a single brushing with CrossAction to a randomly assigned alternative brush. Plaque was assessed before and after a single brushing with the first brush, and two weeks later the procedure was repeated with the second brush. In order to duplicate normal, at-home oral hygiene practices, the participants were not instructed in brushing techniques, were not supervised, and brushed for one minute. Plaque scores were evaluated using the Proximal/Marginal Plaque Index (PMI).

Results

All toothbrushes in the seven studies significantly reduced levels of plaque from baseline values and were found to be safe. However, CrossAction was significantly (P<0.05) more effective than all of the comparison brushes for whole mouth plaque scores, as well as for plaque scores at the gingival margin and proximal surfaces (Figure 3).

Overall, mean percentage plaque removal for CrossAction was 46.4% for the whole mouth, 53.9% for the gingival margin, and 43.3% for proximal surfaces.

Conclusions

The results of the 14 single-brushing studies (involving 4,860 subject examinations) carried out at two different centers using two different plaque score systems, clearly demonstrate that the novel design of CrossAction resulted in improved efficacy, leading to significantly greater plaque reduction, in each of the 14 comparisons, the greatest advantage was seen at the proximal surfaces, confirming that the bristle arrangement of CrossAction does enhance interproximal penetration as demonstrated in laboratory studies.

The study design employed in these investigations was developed to ensure that, as far as possible, the results obtained would reflect the use of the toothbrush as part of normal home oral hygiene procedures. For this reason, no specific oral hygiene instruction was offered except a brushing time of one minute, which more accurately reflects an average brushing cycle. Subsequently, CrossAction would be expected to provide the same advantages observed in these investigations during an individual’s normal routine.

Finally, confidence in these results is also enhanced by their consistency, namely, a significantly increased level of plaque removal with CrossAction across 14 independent clinical trials—more trials than have been recorded for any other manual toothbrush.

A comparative clinical investigation of a novel toothbrush designed to enhance plaque removal efficacy


Objective

To compare the plaque removal efficacy of CrossAction with seven leading manual toothbrushes: Mentadent® Oral Care, Oral-B Indicator®, Reach® Advanced Design, Colgate® Total®, Colgate Plus®, Dr Best InterDent (Aquafresh Flex Direct®), and Colgate Wave® (Colgate Sensation).

Figure 3: Oral-B CrossAction removed

<table>
<thead>
<tr>
<th>Whole mouth plaque</th>
<th>Gingival margin plaque</th>
<th>Proximal plaque</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.4%</td>
<td>12.1%</td>
<td>17.7%</td>
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<tr>
<td>20.6%</td>
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</tbody>
</table>

More than Mentadent Oral Care

More than Oral-B Indicator

More than Reach Advanced Design

More than Colgate Total

More than Colgate Plus

More than Dr Best InterDent (Aquafresh Flex Direct)

More than Colgate Wave (Colgate Sensation)

An advanced toothbrush with improved plaque removal efficacy


Objective

To compare the plaque removal efficacy of CrossAction® with seven leading manual toothbrushes: Oral-B® Advantage®, Crest® DeepSweep®, Crest Complete®, Crest Extender, Reach UltraClean®, Mentadent® Adaptor (Mentadent Surround®), and Aquafresh® Flex Tip.

Methods

Seven independent, crossover, examiner blind, clinical studies—each involving approximately 75 healthy subjects—compared a single brushing with CrossAction to a randomly assigned alternative brush. Plaque was assessed before and after a single brushing with the first brush, and one week later the procedure was repeated with the second brush. In order to duplicate normal, at-home oral hygiene practices, the participants were not instructed in brushing techniques, were not supervised, and brushed for one minute. Plaque scores were evaluated using the Rustogi Modified Navy Plaque Index (RMNPI).

Results

While each of the toothbrushes provided significant reductions in plaque scores after a single brushing, CrossAction removed significantly greater amounts of whole mouth, gingival margin, and approximal plaque (P<0.0001) than each of the compared toothbrushes (Figure 4).

Figure 4: Oral-B CrossAction removed

<table>
<thead>
<tr>
<th>Whole mouth plaque</th>
<th>Gingival margin plaque</th>
<th>Approximal plaque</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.0%</td>
<td>36.8%</td>
<td>26.2%</td>
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<td>92.3%</td>
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</tr>
<tr>
<td>46.2%</td>
<td>76.0%</td>
<td>53.7%</td>
</tr>
</tbody>
</table>

More than Oral-B Advantage

More than Crest DeepSweep

More than Crest Complete

More than Crest Extender

More than Reach UltraClean

More than Mentadent Adaptor (Mentadent Surround)

More than Aquafresh Flex Tip

†P<0.001 for all sites evaluated

*P<0.05 for all sites evaluated

Conclusions
Two long-term clinical trials were undertaken to establish that the greater plaque removal efficacy of CrossAction® also provides better long-term benefits for gingival health. The clinical trials compared CrossAction with two of the toothbrushes previously investigated in the single-use studies.

A 3-month comparative investigation of the safety and efficacy of a new toothbrush: Results from two independent clinical studies


Objective
To compare the long-term safety and efficacy of CrossAction with the Dr Best InterDent toothbrush (also known as AquaFresh Flex Direct®) and the Crest® DeepSweep® toothbrush in two independent, parallel-group, examiner-blind clinical studies.

Methods
Each study involved approximately 100 healthy subjects who were instructed to brush with their assigned toothbrush twice a day. No instructions in brushing techniques or in brushing times were given. At six weeks and 12 weeks, participants were assessed for oral tissue status, plaque, and gingival health. Plaque scores were evaluated using RMNPI. Gingivitis was evaluated using the Modified Gingival Index (MGI).

Results
In both studies, CrossAction® was significantly more effective in reducing both plaque and gingivitis over 12 weeks than the alternative toothbrush.

Conclusions
The results comparing CrossAction with Dr Best InterDent showed that mean whole mouth MGI reductions recorded for both brushes were statistically significant (P≤0.0001). However, the MGI reduction for the CrossAction group was greater at both six and 12 weeks, being highly significant at 12 weeks (P≤0.0001) (Figure 7).

In the second study, a similar advantage in favor of CrossAction was observed, with the CrossAction group demonstrating significantly greater reductions in gingivitis (P≤0.0001) compared with Crest DeepSweep at both six and 12 weeks (Figure 8).

Gingival condition
The results from the two comparative studies confirm that CrossAction is both safe and highly effective. No evidence of hard or soft tissue trauma was found in either study. Furthermore, the benefits observed in terms of long-term plaque reduction were translated into improved gingival health, reflecting the already established link between reduced plaque levels and gingivitis.

Percentage reductions in plaque levels achieved with CrossAction were similar across both studies, with the greatest reduction from baseline being at approximal surfaces. It is of particular importance that CrossAction removes significantly more plaque from the interdental area where gingivitis is most prevalent.

The consistent findings across all laboratory, single-use, and 3-month clinical studies confirm the greater efficacy of CrossAction.