INTRODUCTION

A wide range of parameters to assess the effect of chemotherapeutic agents exists in the literature and is used in clinical studies (see part I). In general, there is no recommendation which parameters should be applied and therefore parameter selection is often based on similar studies reported previously, on the preferences and experiences of the investigators, or on a specific research question to be answered (1). The variety of parameters will even increase further in future years when new technologies evolve (2).

It was not the aim of this paper to compare the test treatments with the respective controls, and therefore to repeat data that have been investigated in numerous studies on the effect of mouthrinses before. Instead, the idea was to select and assess the most often used parameters for this type of clinical studies. The results were comparable and in line with previous studies.

MATERIALS AND METHODS

The overall study design and details concerning parameters, treatments, and participants were described in part I (Lorenz et al.). In order to assess plaque, gingivitis, bacterial shifts in the oral cavity, and side effects, parameters most often found in the scientific literature were selected: Plaque indices PI (3), M-QHI (4) modified by Turesky et al. (5), plaque area PlA (6), bacterial vitality BV (7), gingival crevicular fluid (GCF) (8), colony forming units (CFU) (9), and the discoloration index DI (11). The parameters were applied in four study designs: eight-hour substantivity studies, four-day plaque re-growth studies, 21-day experimental gingivitis studies, and six-month home-use studies. Pearson correlation coefficients were computed. The highest correlations were found between PI and M-QHI and between GI and M-GI (p<0.01) in all corresponding studies and treatment groups. Few middle correlations existed between BOP and the other gingival indices. Neither GI nor M-GI correlated with GCF nor did BV with plaque indices. Inconsistent correlations were obtained between PlA and plaque indices and between PI and GI. It is concluded, that primary parameters for these designs should be one plaque index and/or one gingivitis index to monitor plaque and gingivitis. The other parameters did not yield additional information about the study outcome.

RESULTS

The numbers of participants who have accomplished each design and the participants’ demographic characteristics are
At baseline, participants were equally distributed to the test groups due to stratification (age, gender, sex). In summary, the results of all studies (designs I to IV) concerning the test and control groups were in line with those presented in the literature.

**Table 1.** Sample size, gender and mean age of participants for designs I to IV in populations α (GI<0.8) and β (GI≥0.8).

<table>
<thead>
<tr>
<th>Design</th>
<th>Sample size (male/female)</th>
<th>Placebo</th>
<th>ASF</th>
<th>CHX 0.06%</th>
<th>CHX 0.12%</th>
<th>CHX 0.20%</th>
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<tbody>
<tr>
<td>I</td>
<td></td>
<td>α</td>
<td>β</td>
<td>α</td>
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<td>16 (6/10)</td>
<td>16 (6/10)</td>
<td>16 (6/10)</td>
<td>16 (6/10)</td>
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<td>II</td>
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<td>14 (1/13)</td>
<td>14 (1/13)</td>
<td>14 (1/13)</td>
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<table>
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ASF- amine fluoride/stannous fluoride; CHX- chlorhexidine digluconate; N.A. not applicable.

**Table 2.** Plaque re-growth study. Comparisons between plaque indices PlI (3) and M-QHI (5), PlI and plaque area (modified after [6]), and M-QHI and plaque area in population α (GI<0.8) at day 4; R: Pearson correlation coefficients and significance levels two sided **p<0.01; * p<0.05.

<table>
<thead>
<tr>
<th>Population α (R)</th>
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<th>CHX 0.06%</th>
<th>CHX 0.20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D 4</td>
<td>PlI – M-QHI</td>
<td>0.736 **</td>
<td>0.397</td>
<td>0.256</td>
</tr>
<tr>
<td></td>
<td>ASF</td>
<td>0.821 **</td>
<td>0.524 **</td>
<td>0.716 **</td>
</tr>
<tr>
<td>0.06% CHX</td>
<td>0.777 **</td>
<td>0.005</td>
<td>0.209</td>
<td></td>
</tr>
<tr>
<td>0.12% CHX</td>
<td>0.849 **</td>
<td>0.087</td>
<td>0.164</td>
<td></td>
</tr>
<tr>
<td>0.20% CHX</td>
<td>0.864 **</td>
<td>0.078</td>
<td>-0.005</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population β (R)</th>
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<th>CHX 0.06%</th>
<th>CHX 0.20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D 4</td>
<td>PlI – M-QHI</td>
<td>0.602 **</td>
<td>0.114</td>
<td>0.473</td>
</tr>
<tr>
<td></td>
<td>ASF</td>
<td>0.806 **</td>
<td>0.497</td>
<td>0.640 **</td>
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<tr>
<td>0.06% CHX</td>
<td>0.880 **</td>
<td>0.750 **</td>
<td>0.864 **</td>
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</tr>
<tr>
<td>0.12% CHX</td>
<td>0.879 **</td>
<td>0.071</td>
<td>0.313</td>
<td></td>
</tr>
<tr>
<td>0.20% CHX</td>
<td>0.787 **</td>
<td>0.214</td>
<td>0.458</td>
<td></td>
</tr>
</tbody>
</table>

ASF- amine fluoride/stannous fluoride; CHX- chlorhexidine digluconate; PlI- plaque index (3); M-QHI- plaque index (5); PlA- plaque area modified after (6).

**Table 3.** Experimental gingivitis study. Comparisons between parameters in population α (GI<0.8) at day 21; R: Pearson correlation coefficients and significance levels two sided **p<0.01; * p<0.05.

<table>
<thead>
<tr>
<th>Population α (R)</th>
<th>Placebo</th>
<th>ASF</th>
<th>CHX 0.06%</th>
<th>CHX 0.20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D 21</td>
<td>PlI – M-QHI</td>
<td>0.539</td>
<td>0.795</td>
<td>0.739</td>
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<tr>
<td></td>
<td>PlI – GI</td>
<td>0.608 **</td>
<td>0.475 **</td>
<td>0.163</td>
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<tr>
<td></td>
<td>ASF</td>
<td>0.611 **</td>
<td>0.405</td>
<td>0.182</td>
</tr>
<tr>
<td>0.06% CHX</td>
<td>0.777 **</td>
<td>0.005</td>
<td>0.209</td>
<td></td>
</tr>
<tr>
<td>0.12% CHX</td>
<td>0.849 **</td>
<td>0.087</td>
<td>0.164</td>
<td></td>
</tr>
<tr>
<td>0.20% CHX</td>
<td>0.864 **</td>
<td>0.078</td>
<td>-0.005</td>
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<table>
<thead>
<tr>
<th>Population β (R)</th>
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<th>CHX 0.06%</th>
<th>CHX 0.20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D 21</td>
<td>PlI – M-QHI</td>
<td>0.861</td>
<td>0.882</td>
<td>0.830</td>
</tr>
<tr>
<td></td>
<td>PlI – GI</td>
<td>-0.090</td>
<td>0.374</td>
<td>0.590 **</td>
</tr>
<tr>
<td></td>
<td>ASF</td>
<td>0.058</td>
<td>0.439 **</td>
<td>0.514 **</td>
</tr>
<tr>
<td>0.06% CHX</td>
<td>0.880 **</td>
<td>0.750 **</td>
<td>0.864 **</td>
<td></td>
</tr>
<tr>
<td>0.12% CHX</td>
<td>0.879 **</td>
<td>0.071</td>
<td>0.313</td>
<td></td>
</tr>
<tr>
<td>0.20% CHX</td>
<td>0.787 **</td>
<td>0.214</td>
<td>0.458</td>
<td></td>
</tr>
</tbody>
</table>

ASF- amine fluoride/stannous fluoride; CHX- chlorhexidine digluconate; PlI- plaque index (3); M-QHI plaque index (5); PlA- plaque area modified after (6).

**Table 4.** Experimental gingivitis study. Comparisons between parameters in population β (GI≥0.8) at day 21; R: Pearson correlation coefficients and significance levels two sided **p<0.01; * p<0.05.

<table>
<thead>
<tr>
<th>Population β (R)</th>
<th>Placebo</th>
<th>ASF</th>
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<th>CHX 0.20%</th>
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</thead>
<tbody>
<tr>
<td>D 21</td>
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<td>0.882</td>
<td>0.830</td>
</tr>
<tr>
<td></td>
<td>PlI – GI</td>
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<td>0.374</td>
<td>0.590 **</td>
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<td>0.750 **</td>
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</tr>
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<td>0.071</td>
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<td>0.787 **</td>
<td>0.214</td>
<td>0.458</td>
<td></td>
</tr>
</tbody>
</table>

ASF- amine fluoride/stannous fluoride; CHX- chlorhexidine digluconate; PlI- plaque index (3); M-QHI plaque index (5); PlA- plaque area modified after (6).

**Table 5.** Experimental gingivitis study. Comparisons between parameters in population β (GI≥0.8) at day 21; R: Pearson correlation coefficients and significance levels two sided **p<0.01; * p<0.05.

<table>
<thead>
<tr>
<th>Population β (R)</th>
<th>Placebo</th>
<th>ASF</th>
<th>CHX 0.06%</th>
<th>CHX 0.20%</th>
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<tbody>
<tr>
<td>D 21</td>
<td>PlI – M-QHI</td>
<td>0.861</td>
<td>0.882</td>
<td>0.830</td>
</tr>
<tr>
<td></td>
<td>PlI – GI</td>
<td>-0.090</td>
<td>0.374</td>
<td>0.590 **</td>
</tr>
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<td></td>
<td>ASF</td>
<td>0.058</td>
<td>0.439 **</td>
<td>0.514 **</td>
</tr>
<tr>
<td>0.06% CHX</td>
<td>0.880 **</td>
<td>0.750 **</td>
<td>0.864 **</td>
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<td>0.12% CHX</td>
<td>0.879 **</td>
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<td>0.20% CHX</td>
<td>0.787 **</td>
<td>0.214</td>
<td>0.458</td>
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</tbody>
</table>

ASF- amine fluoride/stannous fluoride; CHX- chlorhexidine digluconate; PlI- plaque index (3); M-QHI plaque index (5); PlA- plaque area modified after (6).

Design I - eight-hour substantivity study

In Design I, bacterial vitality of plaque was the only plaque parameter studied. Therefore, no correlations could be calculated.

Summarized in Table 1.
Table 6. Home-use study. Comparisons between plaque and gingivitis parameters at month 6 (M 6); population α (GI<0.8); Pearson correlation coefficients and significance levels two sided

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>ASF</th>
<th>CHX 0.06%</th>
<th>CHX 0.12%</th>
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<tbody>
<tr>
<td>PI - M-QHI</td>
<td>0.86†</td>
<td>0.86†</td>
<td>0.67†</td>
<td>0.63†</td>
</tr>
<tr>
<td>PI - GI</td>
<td>0.42†</td>
<td>0.49†</td>
<td>0.36†</td>
<td>0.45†</td>
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<tr>
<td>GI - M-GI</td>
<td>0.85†</td>
<td>0.86†</td>
<td>0.59†</td>
<td>0.90†</td>
</tr>
<tr>
<td>GI - BOP</td>
<td>0.52†</td>
<td>0.79†</td>
<td>0.52†</td>
<td>0.42†</td>
</tr>
<tr>
<td>GI - GCF</td>
<td>0.32†</td>
<td>0.23†</td>
<td>0.14†</td>
<td>0.26†</td>
</tr>
<tr>
<td>M-GI - BOP</td>
<td>0.38†</td>
<td>0.78†</td>
<td>0.39†</td>
<td>0.38†</td>
</tr>
<tr>
<td>M-GI - GCF</td>
<td>0.32†</td>
<td>0.21†</td>
<td>0.02†</td>
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</tbody>
</table>

Table 7. Home-use study. Comparisons between plaque and gingivitis parameters at month 6 (M 6); population β (GI≥0.8); Pearson correlation coefficients and significance levels two sided

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo</th>
<th>ASF</th>
<th>CHX 0.06%</th>
<th>CHX 0.12%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI - M-QHI</td>
<td>0.78†</td>
<td>0.76†</td>
<td>0.83†</td>
<td>0.92†</td>
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<tr>
<td>PI - GI</td>
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<td>0.52†</td>
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<td>0.41†</td>
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<tr>
<td>GI - M-GI</td>
<td>0.97†</td>
<td>0.91†</td>
<td>0.93†</td>
<td>0.94†</td>
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<tr>
<td>GI - BOP</td>
<td>0.80†</td>
<td>0.70†</td>
<td>0.69†</td>
<td>0.81†</td>
</tr>
<tr>
<td>GI - GCF</td>
<td>0.087</td>
<td>0.72†</td>
<td>0.21†</td>
<td>-0.007</td>
</tr>
<tr>
<td>M-GI - BOP</td>
<td>0.76†</td>
<td>0.61†</td>
<td>0.70†</td>
<td>0.78†</td>
</tr>
<tr>
<td>M-GI - GCF</td>
<td>0.12†</td>
<td>0.62†</td>
<td>0.29†</td>
<td>-0.05†</td>
</tr>
</tbody>
</table>

Design II - four-day plaque re-growth study

Statistically significant high correlations were detected between the plaque indices PI and M-QHI in populations α and β at day four (Tables 2, 3). Only a few statistically significant correlations were found between plaque area and the two clinical indices PI and M-QHI. For this design, the gingivitis parameters GI, M-GI, BOP, GCF were only recorded as secondary parameters. No changes in inflammation were noticed during the four days.

Design III - 21-day experimental gingivitis study

Correlation coefficients and statistical significance levels for all parameters in populations α and β are depicted in Tables 4 and 5. The plaque indices, PI and M-QHI, correlated in all groups and in both populations α and β. Correlations ranged between middle and high but were all statistically significant on the <1% level. No correlations existed between bacterial vitality and the clinical plaque indices.

Among the gingivitis parameters, the clinical indices GI and M-GI were the only parameters that showed very high and statistically significant correlations in all groups regardless the study population. Few correlations were found between BOP and the gingivitis indices. Neither GI nor M-GI correlated with GCF. This was true for both population α and population β. Some correlations existed between plaque and gingivitis indices.

Design IV - six-month home-use study

Pearson correlation coefficients are depicted in Tables 6 and 7. PI and M-QHI correlated in all groups of populations α and β at the end of the six-month study period (middle and high correlations). High and very high correlations also existed between GI and M-GI. GI and BOP highly correlated in population β, while middle correlations existed in population α. Weaker but still high correlations were calculated for the comparison between M-GI and BOP in population β but only one statistically significantly high correlation was found in population α. When gingival indices were compared with GCF, no correlations were present in any population. Between plaque and gingivitis indices correlations were not consistently found.

DISCUSSION

Parameter selection has always been a matter of discussion and varies considerably between the different studies. All studies on oral chemo-prophylactic agents have applied clinical indices as primary and secondary variables to describe the outcome. On the other hand, indices are seen to be highly subjective parameters that in addition are time and labor consuming when used (12). Therefore, there was always a search for more easily applied and more objective parameters. The present studies have applied several parameters that had been both objective and subjective. However, the outcome shows that best results were achieved when clinical indices had been used. Comparisons in all designs among the applied parameters have shown that consistent correlations only existed among the plaque indices and among the gingivitis indices. Parameters like GCF, CFU, or BV did not provide better or more reliable information.

Plaque parameters

Plaque area measurements were thought be more objective and therefore more precise than the indices because they are permanent records that can be evaluated by different persons without the pressure that derives from the actual study procedure (13). This could not be supported by the present studies (designs II and III) in terms of correlations that existed to the indices. A possible explanation for this disagreement could be that the present method was modified from a previous description (14). These authors measured plaque area at four upper and four lower incisors while in the present studies only one tooth (the upper right central incisor) was selected for area estimations. The "one tooth" approach was chosen because the photography could be then taken in a 90° angle to the tooth surface so that the whole vestibular area could be evaluated as accurately as possible. Due to their anatomy and position in the dental arch, other teeth like second incisors, canines or premolars are more difficult and imprecise to evaluate. The "one tooth" planimetric analysis can statistically discriminate between moultrine groups but did not result in statistically significant correlations between indices and area. This problem is discussed controversially in the literature. Comparable results were found in a study on chlorhexidine mouthrinse and tablets (15). While the plaque index could more precisely differentiate between the groups, plaque area analysis did not reveal as many significant differences. Superiority of the index compared to the area was shown by Addy et al. (16) who evaluated the results of 15 plaque re-growth studies performed on healthy volunteers. In two thirds of these studies the plaque index showed a greater discriminatory power compared to plaque area measurements (Shaw and Murray stain index (17)
modified by Addy et al. (18), while the other one third showed a lower discriminatory power. Planimetric evaluation in these studies was performed on the upper and lower incisors, canines, and premolars. The authors discussed the reduced number of selected teeth compared to the full-mouth index approach in order to explain the lower discriminatory power of the plaque area assessment in most of the studies. In contrast, Quirynen et al. (19) found that planimetric area measurements were superior to five other plaque indices. These authors included three randomly selected teeth per subject while comparing undisturbed plaque growth over a period of 96 hours on patients who had healthy and inflamed gingiva. It can be summarized, that planimetric analysis is a possible approach to assess the teeth's plaque coverage and to differentiate between plaque inhibition by several agents. It has the advantage of being a permanent record that can repeatedly be re-evaluated. In terms of costs and time effort the plaque area assessment particular on multiple teeth seems to be disadvantageous compared to an index when applied in clinical studies on mouthrinses. The results of the present study support the superiority of the indices over plaque area.

Similarly, the qualitative plaque parameter "bacterial vitality" did not reveal additional information. No correlations existed to plaque indices. Even when it takes only a few seconds to collect the plaque sample from the patient's tooth, the vital fluorescence technique is labor intensive. It requires instant processing of the plaque sample, precise staining, and quick evaluation. If this is impossible due to the high numbers of study participants and therefore high numbers of plaque samples to be investigated within a given time frame, then the quality of assessment seems to be impaired. While the method revealed good results in other studies (6, 14, 20, 21), the studies included less participants that obviously allowed a more proper analysis. When both plaque indices (PII, M-QHI) can be applied equally concerning the study outcome, which index should be preferred then? Experiences from these investigations suggest the PII is faster to assess because there is no need for disclosing the plaque before it is scored. In addition, PII can be scored at in-between visits during an experimental gingivitis study. However, to discriminate between score 0 and score 1, plaque has to be removed while this is not the case with the M-QHI. Because of the disclosure requirement for M-QHI, this index can be only assessed at baseline and at study termination.

**Gingivitis parameters**

Gingivitis can be judged by either quantitative clinical indices that are based on a combination of inflammation symptoms like gingival color, contour, bleeding, or extent of gingival involvement (22), or on bleeding as a single variable (23). In many clinical studies more than one gingivitis variable was applied (24-29). As stated in the ADA guidelines for the assessment of gingivitis, application of both a non-invasive index and an index that purely relies on bleeding or a comprehensive index that includes the bleeding component is recommended for long term studies (30).

The results of the present investigation indicate that both the invasive gingival index (8) and the non-invasive index (9) can be used alternatively. Since the histological analysis being the golden standard for inflammation (31), obviously it is not applicable in mouthrinse studies on humans. Therefore, a substitute correlate was looked for that can describe the inflammation status with a comparable precision. Bleeding on probing seemed to be a both easily to assess and objective parameter. A study by Greenstein et al. (32) showed that histological signs of inflammation and BOP correlated. In contrast, since the bleeding symptom was included in the parameter list, authors reported about different approaches to elicit the bleeding that again influence the results (33) and therefore questioned the objectiveness and reliability of BOP (34). Investigators often experience that clearly visually inflamed sites in gingivitis patients do not bleed after provocation. In plaque induced gingivitis, bleeding varied when BOP was elicited at different time points (from one hour to 24 hours after the first provocation) (35). Accordingly in the present study, superiority of BOP over the non-invasive index could not be proven. Correlations to GI or M-GI were only observed in the long-term study in population β. The assumption that invasive indices are considered to be more objective than non-invasive indices (22), could not be confirmed by this study. Furthermore, when the bleeding component is included in the index like in the GI, it does not give additional information compared to the non-invasive index (M-GI) in terms of a more precise outcome between different treatments. This is in accordance with other studies on mouthrinses that applied either the GI or the M-GI and led to similar results (27, 29, 36-38). Another study found correlations between M-GI and other gingivitis indices as well (39). Since correlations exist between both indices, they can be equally applied keeping in mind the advantages and disadvantages of invasive vs. non-invasive indices (12, 40). The following disadvantages of the invasive approach should be considered: Provocation of gingival bleeding can cause gingival trauma and can be followed by increased bleeding (41). Plaque will be destroyed in some extent. Bleeding sites can be obscured by blood oozing from previously probed areas to adjacent tooth surfaces (9, 42, 43). Concerns have arisen that bacteremia following invasive procedures can represent a risk for certain persons. A calibration of examiners or assessment of the reliability of single examiners using the same site is not feasible (44). In accordance with the present results the use of the non-invasive M-GI seems to be preferable.

**CONCLUSIONS**

Clinical indices on plaque and gingivitis were the best correlating parameters in all study designs. Therefore, utilization of one index for plaque assessment (PII) and one index for gingivitis assessment (M-GI) is recommended for studies on oral chemo- prophylactics to monitor plaque and gingivitis. All other parameters tested (GCF, CFU, BV, and other indices) can be used as secondary parameters but do not yield additional information about the study outcome.

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