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Review Article

The Effect of Natural Based Toothpaste (Parodontax®) On Plaque and Gingivitis: A Review

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Abstract

Aims: The aim of the present study was to critically review the available published literature regarding the use of Parodontax® herbal toothpaste formulations and to determine whether there was supportive evidence for the safety and clinical efficacy of Parodontax® toothpaste formulations for the reduction in plaque growth and on gingival inflammation. Methods: A manual and electronic literature search (MEDLINE and Cochrane Central Register of Controlled Trials) was performed up to February 2015, for randomised controlled trials (RCT) presenting clinical, microbiological, immunological, and patient-centred data for the efficacy of Parodontax® in controlling both plaque and gingival inflammation. Results: From 111 titles and abstracts, 104 were excluded and from the full text articles screened, seven randomized controlled trials were selected. Two of the included randomized controlled trials reported that Parodontax® toothpastes were similar in efficacy to the control dentifrices in effectively reducing both plaque and gingival inflammation in patients with gingivitis based on the assessment criteria of clinical, microbiological, and patient-centred treatment outcomes. Four of the included studies reported a significant effect of Parodontax® however there was a lack of clarity in the reporting of measures e.g., appropriate randomisation, calibration, blinding, and the outcomes assessed, and as such, the quality of both reporting and methodology may have been flawed with a high risk of bias. Conclusion: The results from the published literature regarding the safety and clinical effectiveness of Parodontax® toothpaste would indicate that while the toothpaste has some short-term effects on both plaque and gingival inflammation, further studies are required to determine its effectiveness as an anti-gingivitis agent over six months.

Introduction

Rudolph & Focke first reported on the efficacy of Parodontax for the treatment of gingivitis and its effect was attributed to the cleaning ability of the sodium bicarbonate as well as the effect of the astringents of the herbal ingredients [1]. Parodontax® has recently received more attention in both the published literature and media compared to other herbal dental products. The commercial product (in both toothpaste and mouth rinse forms) consists of sodium bicarbonate, sodium fluoride (1400 ppm), and herbal ingredients such as Echinacea, camomile, sage, rhatany, myrrh, and peppermint [2]. These components have been reported to have several medicinal characteristics. For example, echinacea was considered to have an activating effect on leukocytes and in stimulating the immune system. It has also been reported that camomile is an anti-inflammatory extract. In addition, sage has been reported to have antiseptic effects, whereas both myrrh and rhatany are astringents [3]. Peppermint oil has been reported to have antiseptic, anti-inflammatory, and analgesics effects [4-5]. However it has been suggested that the combination of these ingredients had a better effect than the individual effect of each ingredient [6]. Imfeld [7] reported that Parodontax has a pH neutralizing activity; which was confirmed using a plaque telemetry method [8]. The action (mechanism) of sodium bicarbonate in removing plaque from the oral environment was previously unclear, however a recent study by Pratten *et al.* [9] using a biofilm model reported that sodium bicarbonate was able to disrupt the mature plaque in the dental plaque biofilm. These investigators postulated that this action was related to

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the efficacy of sodium bicarbonate to disrupt the exopolysaccharide matrix structure in the biofilm. A further interesting observation from this *in vitro* study was that there was no evidence of any antimicrobial activity by sodium bicarbonate. In the published literature, however there has been some disagreement as to the efficiency of Parodontax® and herbal based products in general [10]. For example, several studies have reported that Parodontax® was able to significantly reduce both plaque and gingivitis [11-12]. However other studies have reported that there were no added benefits compared to the control toothpastes [6, 8, 13]. A recent study by Triratana *et al.* [14] reported a randomized, double-blind, parallel-group study of 135 participants over six-months comparing a Colgate Total Toothpaste with a Parodontax® toothpaste demonstrated that Colgate Total Toothpaste was significantly more effective in both reducing plaque and gingivitis after 3 and 6 months of product use respectively.

Materials and Methods

Aims and Objectives

The aim of the present study was to critically review the available published literature regarding the use of Parodontax® herbal toothpaste formulations and to determine whether there was supportive evidence for the safety and efficacy of Parodontax® toothpaste formulations for the reduction in plaque growth and any effects on gingival inflammation (Gingivitis).

Methodology

The search methodology used for the current review was a modified version of the Cochrane systematic review by Leach & Thoms [15] and Tatikonda *et al.,* [16].

Selection Criteria

Types of Study: This review included all full text, blinded evaluation implemented types of studies, randomized controlled trials (RCT) or quasi-RCT conducted *in vivo* to assess the efficacy of Parodontax® toothpaste (Sodium Bicarbonate containing Herbal toothpaste) on either plaque growth and gingivitis. The duration of the included studies was at least 4 weeks in duration.

Types of Subjects

Inclusion and Exclusion Criteria

The subjects included in the relevant studies were dentate, healthy adults (of at least 18 years of age) with a dental-plaque induced gingivitis. The described intervention included a natural based toothpaste (Parodontax®) compared to a placebo/positive control in Randomized Clinical Trials (RCT) or studies that were quasi-RCT designed studies. All studies had to be in English, studies other than those in English or in abstract form were excluded. Subjects with established chronic periodontitis, diabetes related gingivitis, drug induced gingivitis, leukaemia-associated gingivitis, and non-plaque related gingival lesions or experimentally induced gingivitis were excluded. Studies were excluded if the sample in the original study was not described in detail or if the subjects included into the study had received periodontal treatment within the period of the trial or if the participants were undertaking anti-inflammatory treatment due to medical problems. The number of participant dropouts and reason(s) for the dropout should also be included in the published study.

Types of interventions

For the purpose of the present review, only studies including Parodontax® toothpaste formulations were considered. Studies that evaluated other herbal products using Parodontax® in either a mouthwash or adjunctive solution as a local delivery system were not considered. Studies that included the adjunctive use of a Parodontax mouthwash following using a Parodontax® toothpaste were also not considered. Comparator groups included those groups using a placebo, recognized positive control and other herbal products.

The ideal negative control group would entail the usage of a toothpaste of the same composition as the test product, minus the active ingredient however due to the nature of the composition of the Parodontax® toothpaste which included sodium bicarbonate and several different herbal ingredients, studies were also considered for inclusion if the sodium bicarbonate was replaced by calcium carbonate or equivalent abrasive in the other groups.

Types of Outcome Measurement

Primary outcomes

i. Severity of gingivitis (determined using appropriate indices such as the Gingival Index or Modified Gingival Index) [17-18].
ii. Severity of gingival bleeding (determined using appropriate indices such as the Sulcus Bleeding Index or Gingival Bleeding Index) [19-20].
iii. Incidence and types of adverse events.

Secondary outcomes

Severity of dental plaque (determined using appropriate indices such as the Loe-Silness Index or Quigley-Hein Plaque Index) [21-22].

Other Relevant Criteria

i. Investigator calibration on the assessment of the indices assessed in

the study.

ii. Statistical analysis.

iii. Randomization of the participants into different groups to be clearly described, together with the appropriate concealment of participant group allocation to both investigators and subjects.

iv. Consideration of any 'drop outs' recorded in the studies.

Search Strategy

The search strategy included using electronic databases (e.g., PUBMED) and hand searching up to 28th, February 2015. Hand searching included examining the relevant published or incomplete journals in English. The searching keywords in PUBMED were a combination of MeSH and free text terms e.g., Sodium Bicarbonate toothpaste, Parodontax®, plaque, gingivitis. An additional search strategy using Sodium Bicarbonate and Baking Soda as MeSH terms with variations e.g., herbal, herbal ingredients and Parodontax® yield up to 85 articles of interest. The combined MeSH term(s) that yielded the most relevant papers was Sodium Bicarbonate and Parodontax®, which yielded 17 papers for further analysis. The electronic search followed by hand searching relevant to the topic and researching for un-published related data. Hand searching journals included: Journal of Periodontal Research, Journal of Clinical Dentistry, Journal of Clinical Periodontology, Oral Diseases, International Journal of Dental Hygiene, Periodontology 2000, Journal of Public Health and Dentistry and other related journal not in the Dental area. The search was up to 28th February 2015 with no restrictions on the article status. Finally, the references of related articles were scanned for analysis. Additional website searches (e.g., Google) were also conducted.

Statistical Analysis

The statistical reporting of the analysis in the included studies was compared and figures and tables were constructed from the data of the included studies for comparison purposes. Due to the heterogeneity inherent in the studies no meta-analysis was performed on the available data.

Method of the Review (Data Collection and Analysis)

MS obtained copies of all the relevant studies that where available following a review of the abstracts and titles. All titles that appeared to meet the selection criteria as well as those that may not have been adequately assessed in abstract form were retrieved and investigated in the full text version. Those studies that failed to meet the inclusion criteria were excluded and the reasons for exclusion reported in the results section. Those studies that met the inclusion criteria were reported in the results section. A Data Extraction Form was constructed outlining the Included and Excluded studies. MS and WT determined the eligibility of the papers and data extraction and independently analysed a selected number of studies. Any differences to the inclusion or exclusion of articles accepted/rejected were resolved following discussion between the two reviewers and DGG.

Quality Assessment of the Included Studies

The methodological quality of the included studies was assessed according to the criteria of the treatment allocation. of treatment allocation as described in the Cochrane Handbook for Systematic Reviews of Interventions. The acceptance and rejection criteria for the inclusion of relevant studies was discussed should two of the three reviewers (MS and DGG) prior to the collection of papers. Any disagreements were resolved by discussion.

Allocation of Risk of Bias in the Included Studies

The risk of bias in each of the included studies was assessed by MS and one of the other reviewers (WT/DG) using the criteria described in the Cochrane Handbook for Systematic Reviews of Interventions. [23].

Results

Overall Description of the Included and Excluded Studies

The initial screening for this review revealed 111 potentially relevant studies 85 studies were identified following the electronic databases (PUBMED) search. Hand searching articles from the published literature accounted for 26 articles. Unpublished articles were identified by searching both the electronic databases or by hand searching. After the initial screening of 111 articles, 31 articles (duplication [n=21]; sodium bicarbonate related [n=10]) were excluded. Therefore, 80 studies were as regarded relevant to the study. Following the evaluation of the studies, 73 studies were excluded (Figure 1) [1-5, 7,9-10, 13-16, 24-84] and seven studies [6, 8, 11-12, 85-87] were considered initially suitable for inclusion (see Table 1). The reasons for exclusion were as follows: 1) review papers (n=11) [3-4, 10, 15, 24-27, 32, 38, 50], 2) papers in a language other than English (9) [1, 7, 55-56, 62, 68, 80-82], 3) publication identified outside the present study's timeline (n=1) [14], 4) abstract only (n=1) [84]; 5) clinical studies not satisfying the inclusion criteria (24) [13, 16, 40, 45, 51-52, 57-59, 61, 63-67, 69-71, 73, 75-79], 6) animal studies (2) [54, 74] and 7) *in vitro* studies (including antimicrobial) (25) [2, 5, 9, 28-31, 33-37, 39, 41-44, 46-49, 53, 60, 72, 83]. The selection procedure is illustrated in Figure 1. Generally, the initial inclusion criterion was to include articles that had a study design of RCTs, quasi RCT, cohort studies or case-control studies. In addition, only *in vivo* studies were selected.

Analysis of included studies

Study Design

The included studies in this review were only from Randomised Controlled Clinical Trials (RCT). The control [test] toothpastes were ei-

ther positive (Active/Parodontax®) OR negative [control] (Placebo/not Parodontax®). All included studies were double-blind (Table 1).

Study Population

Most of the included studies were mainly conducted in Dental hospitals. However, the Al-Kholani study [85] was conducted in a private clinic in Yemen. In all the studies the participants were reported to be medically in good health, and dentate. Concerning the gender distribution, most of the studies failed to report on the gender distribution (Table 2). The total numbers of participants (n=392) from the included studies were as follows 1) for Parodontax® toothpaste (n=165 participants) and 2) for the control toothpaste (n=227 participants).

Age Range of Participants

In the included studies all the participants were reported to be adults (at least 18 years of age). There was a difference in the age range distribution(s) in the included studies. (See Table 2)

Randomisation and Allocation Concealment

All the included studies were randomised double-blinded clinical trials although in several studies the degree of concealment was unclear. For example, both the Saxer *et al.* [8] and Yankell *et al.* [12] studies failed to report any details of the allocation concealment procedure. However, the Saxer *et al.* [87] study reported that the subjects were randomly allocated to the different groups in a continuously numbered manner. Yankell & Emling [11] reported that their study was

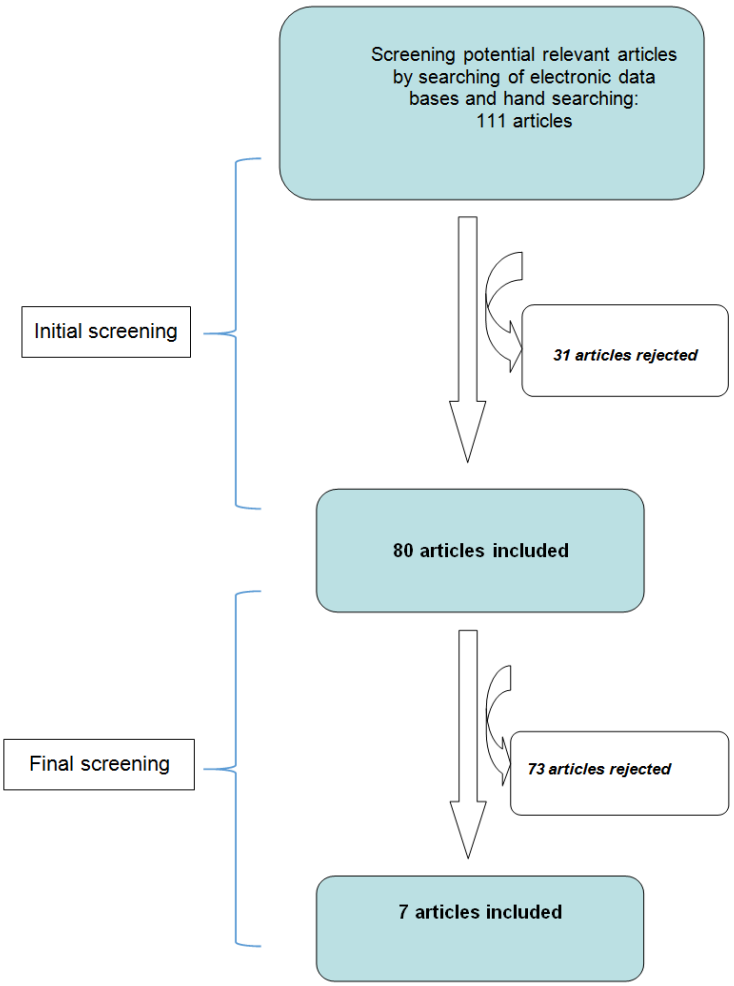

Figure 1: The flow diagram of the study selection process.

Table 2: Age range of the participants in the included studies.

Authors Name	Age range and mean age of participants (years)
Yankell & Emling [11]	No details provided
Al-Kholan [85]	20-40 years age range
Ozaki *et al.* [86]	Mean 33.19 ± 13.56
Yankell & Mullally *et al.* [12]	18-65 years age range
Saxer *et al.* [8]	Control group mean 31.0
	Parodontax® group mean 30.3
Saxer *et al.* [87]	No details provided
Yankell *et al.* [12]	18-65 years age range

Table 3: The statistical tests used for analysis in the included studies

Study	Statistical Test
Yankell & Emling [11]	ANOVA, Analysis of Covariance, Chi square analysis, post hoc Tukey analysis
Al-Kholani [85]	Statistica 6.0 for Windows; Statsoft Inc., Tulsa, OK) and Student's t-test was used to com- pare the difference between groups. Results were tested for significance at the P < 0.05 level.
Ozaki *et al.* [86]	SPSS 11.0 for windows (Mann-Whitney U test, Wilcoxon test, student's t test, chi-square test) all tests employed a level of significance of =0.05
Mullally *et al.* [6]	T-test P<0.05
Saxer *et al.* [8]	Analysis of covariance with the minimum acceptable level of significance set at p <0.05
Saxer *et al.* [87]	2-way variance analysis (adjusted by Greenhouse-Geisser) with significant set at p<0.001
Yankell *et al.* [12]	Group means, standard deviation, and statistical comparisons. The analysis of variance, the analysis of variance for repeated measures and the analysis of covariance

double blinded and that the assessors did not know which product the subjects were using. Furthermore, it was reported in the study that the tubes were delivered to the subjects in plain white tubes with a single colour code. Ozaki *et al.* [86] reported that the random allocation sequence was completed by one of the authors who used a random-number table and the random allocation sequence was concealed from the main assessor. Mullally *et al.* [6] also reported that the study was double blinded and that the toothpastes were packed in identical tubes and were given to the participants by an independent observer who maintained a sealed code breaker.

Consideration of Withdrawals and Dropouts

No details were provided in four of the studies (Yankell & Emling [11], Al-Kholani [85], Mullally *et al.* [6], Saxer *et al.* [87] although it appeared from the articles that all subjects completed the study. Of the other three remaining studies, Ozaki *et al.* [86]recorded six dropouts (e.g., too busy to complete the study (4) did not complete the study but received prophylaxis [2]); Saxer *et al.* [8] reported that seven subjects dropped out (4 due to the dislike of the taste of the toothpaste and 3 for non-product related reasons); Yankel *et al.* [12] also reported that seven subjects dropped out of the study but according to the investigators these drop-outs were not product related.

Data Analysis

No further analyses were performed on the mean differences from 0-24 weeks for any other measurement outcomes for the purposes of meta-analysis (see Table 3).

Previous history of gingivitis and other dental conditions reported at baseline

Gingival inflammation and plaque accumulation was reported at baseline by investigators using the Plaque index (PI) and Gingival Index (GI)[17-22]. No prophylaxis was undertaken prior to the commencement of the studies. All the participants were medically fit and well, none were taking any antibiotics or anti-inflammatory therapy. None of the participants reported any issues of sensitivity or oral mucosal tissue reaction to the toothpaste ingredients.

Types of Treatment Intervention

In all the included studies a daily home use of Parodontax® toothpastes vs. control(s) was the only type of treatment intervention. All the participants in the included studies were advised to brush at least twice a day with their allocated toothpaste.

The Clinical Methodology Used To Assess The Gingival Tissues

The most commonly reported methodology for assessing gingival inflammation and plaque growth was 1) Gingival Index (GI) and 2) Plaque Index (PI)[17-22](Table 1). No third molars were included in their assessment. In addition, all the studies reported on the safety of the toothpaste e.g. any adverse effect that may have occurred during the duration of the study.

Table1: Summary of the Study characteristics of the included studies

Study	Methods	Participants	Interventions	Outcomes	Results
Yankell & Emling [11]	2 months parallel, double blind, randomised	Approximately 60 (no exact figures provided no drop outs recorded	Parodontax® vs. Crest Tartar control (Control) vs. placebo toothpaste in the table with abrasivity levels similar to Parodontax ® (control)	Plaque Index (QH), Gingival Index (LS) BOP (Polson). Stain Index (Yankell *et al)*	• There a significant difference favouring Parodontax® vs. placebo and Parodontax® vs. Crest in reducing gingivitis • Parodontax® significantly reduced BOP • Parodontax® caused a significant in reduction stains vs. Crest and placebo
Al-Kholan [85]	42 days	48 (20-40 years) No gender mean age	Volunteers with chronic marginal gingivitis were randomly divided into three groups. Groups 1 and 2 received herbal extract dentifrices. Group 3 used a conventional dentifrice	PHP, API, GI, SBI	• Regular application of herbal extract dentifrices during 42 days provided a significant reduction in dental plaque accumulation and in some signs of gingival inflammation such as gingival bleeding. • No significant differences of GI and SBI indices values between the herbal test groups • Final indices values in both herbal test groups were significantly ($P < 0.001$) lower compared to those at baseline and those after 42 days in the conventional group.
Ozaki *et al.* [86]	4 weeks randomised double-blind	48 (20M 28F) 33.19 +13.57	Parodontax® vs. Colgate total		• Both were effective in reducing PI and GI but no significant difference between the groups.
Mullally *et al.* [6]	6 weeks	70 36M 34F (Range 18-65)	Parodontax® vs. Colgate	PI, GCF, GI, BI,	• No significant reduction in plaque accumulation. • Slightly greater reduction in GI in the group who used Parodontax® but was not significant • No significant differences between the two groups.
Saxer *et al*. [8]	4 weeks	22 No age range/Gender on the next line adults mean 31 and 30.3 years control/ Parodontax®	Parodontax® vs. marketed fluoride containing dentifrice as a control	BI and Number of no-bleeding sites	• There was a significant reduction in bleeding in the group using Parodontax® • Number of no-bleeding sites was significantly higher in the group using Parodontax®
Saxer *et al*. [87]	12 weeks	53/ 60 completed all 3 exams 46 completed	Parodontax® vs. non-marketed new toothpaste containing herbal ingredients and calcium hydrogen phosphate as an abrasive	PI, GI, BOP	• The reduction in gingivitis from baseline to 12 weeks was significant at $p<0.001$ • There was no significant difference between the the control and Parodontax® group on PI • There was a significant decline in bleeding on probing from baseline to the end of the study $p<0.001$

(Yankell *et al*. [12]	6 months	128 (18=65 years)	Parodontax® carbonate placebo using ADA guidelines	GI using the method of Loe & Silness BOP using Abrams, Caton and Palson methodology PI (QH) Tooth staining using the colour matching method developed by Yankell *et al.* Cell counts (microbiological) Safety	• No significant difference between the 2 groups in GI after 3 and 6 months • Plaque areas counts in Parodontax® group were significantly less at 3 and 6 months • BOP was significantly lower for Parodontax® compared to placebo • No significant difference between 2 groups in stain index • No significant difference in any of the microbiological parameters monitored between the 2 groups

Calibration and Examiner Training

Three of studies reported on the calibration and examiner training. For example, both the Saxer and co-worker studies [8, 87] reported that the examiner had been previously calibrated for the study. No explanation of the details of calibration and examiner training however, was recorded. In the Ozaki *et al.* study [86], the authors reported that the main assessor, who was calibrated, completed the measurements. The calibration of the assessor involved five participants and included two measurements sessions which were completed with a one-hour interval. The intra-examiner calibration was in 80% agreement.

Measurement of Compliance

Some of the investigators in the included studies reported patient compliance, for example, Saxer and co-workers studies [8, 87], Al-Kholani [85], Yankell and co-workers studies [11-12] did not report on the participants' compliance (Table 3.10). In the Mullally *et al.* study [6], the authors measured the compliance and assessed this by providing the participants with a diary to record brushing at home. The participants were also asked to return the tubes at the end of the study. In the Ozaki *et al.* study [86], the authors reported that they checked the participants' compliance by asking them to return the tubes at the end of the study to determine the amount of the toothpaste used during the study.

Discussion

Currently there has been a renewed interest in using natural or herbal based products such as a sodium bicarbonate based Parodontax® formulation as part of a patient's oral hygiene regime at home. It was evident from a review of the published literature that both herbal toothpaste and mouth rinse (including sodium bicarbonate or calcium carbonate based) formulations to a large segment of the general public. For example, Maldupa *et al.* [90] reported that herbal toothpastes were globally accessible as 'over- the-counter' oral hygiene products and promoted as both natural and safe, together with claims of effectiveness in terms of superiority or equivalence to conventional toothpastes for the control of plaque and gingivitis. However, the anti-gingivitis and anti-plaque claims of these natural ingredients of herbal toothpastes may be challenged if they have not been through the robustness of a well-controlled RCT of six months duration. The present review attempted to search the available published literature, up to 28th February 2015, to evaluate acceptable studies (based on the inclusion/exclusion criteria), on the use of Parodontax® herbal toothpastes (compared with conventional toothpastes) in the control of gingival inflammation and plaque accumulation in patients with gingivitis. Ideally the present review would have included only six-month studies to determine the efficacy of Parodontax® using recognised assessment indices as recommended by both regulatory and professional bodies for an acceptance of a product as an anti-gingivitis agent [91-92]. However, following an initial assessment of the study titles for the present review it was evident that there were limited studies of this nature and therefore it was decided to accept short term studies of a minimum of 4-weeks duration. In the present review only one six month study was included and the evidence of effciacy in the some of the other studies studies appears to be weak. A study by Triratana *et al.* [14] (previously reported in abstract form [84]) indicated that in a randomized, double-blind, parallel-group study of 135 participants over six-months comparing a Colgate Total Toothpaste with a Parodontax® toothpaste demonstrated that the Colgate Total Toothpaste was significantly more effective in reducing both plaque and gingivitis after 3 and 6 months product use respectively.

According to Saxer *et al.* [8, 87] the first published paper (in German) relating to the use of Parodontax for the treatment of gingivitis was in 1937 [1]. The initial evidence for the product, however was based on results presented at a symposium in 1988 and subsequently published in the Journal of Clinical Dentistry. Most of these reports were based on *in vitro*, animal, microbiological and clinical studies of mainly

short duration. Further information was also provided by the Manufacturer (Madaus GmbH, Koln, Germany) in a summary document but this does not appear to be currently available. There has, however been some disagreement as to the effectiveness of this formulation, for example, several investigators [6, 13, 86] reported that there was no significant effect compared to the results from the studies by Yankell & Emling [11], Ehlers *et al.* [62] who reported a significant effect in reducing gingival inflammation and plaque accumulation. The Saxer *et al*. study [8] also reported a significant reduction in bleeding on probing scores compared to the control group. However the study by Saxer *et al*. [87] reported a significant effect on GI but not on PI. A general observation from the results of the published studies would therefore suggest that while there was an effect on both plaque and gingivitis scores in these studies, the effect was more favourable for a reduction in the gingival scores rather than for plaque. One of the problems however in evaluating these results was the lack of homeogeneity in these studies particularly in the indices that were used to evalaute the products. For example, The Saxer *et al*. study [8] used the bleeding index of Ainamo and Bay [20] which was modified to evaluate the bleeding of the gingiva to assess the gingival inflammation of the participants at baseline and after 4 weeks. In addition, the numbers of non-bleeding sites were also measured. In the second study in 1995 [86], Plaque Index (PI), Gingival Index (GI), and Bleeding on Probing (BOP) were assessed. As a first stage in this study all the participants used a similar toothpaste for 4 weeks (wash-in period) then they were subsequently randomly allocated to two different groups (Parodontax® vs. Control) for 8 weeks. In the Yankell and co-workers studies [11-12] several measurements were attempted. For example, in the first study by Yankell & Emling [11], Plaque Index (PI), Gingival Index (GI), stains, and bleeding on probing were measured at baseline and after 8 weeks. In the second study by Yankell *et al.* [12], the investigators measured safety, tooth stain, gingivitis, plaque, microbiological, and bleeding assessment of the participants at the baseline, after 3, and after 6 months of using the Parodontax® or control toothpaste. In the Al-Kohlani study [85], several parameters were assessed including the Patient Hygiene Performance Index (PHP), dental plaque on approximal tooth surfaces using the Approximal Plaque Index (API), gingival inflammation using the Gingival Index (GI), and gingival sulcus bleeding using the Sulcular Bleeding Index (SBI) [19, 21-22, 88-89]. In the Mullally *et al.* study [6], several assessments were completed, such as the assessment of the condition of the oral mucosal surfaces, Gingival Crevicular Fluid (GCF), Gingival Index (GI) according to Loe & Silness [21], percentage (%) of sites which bled for each subject, percentage (%) of plaque in bacteria samples, and a Plaque Index (PI) using the Turesky *et al.* modification of the Quigley & Hein Plaque Index [22].

An overall assessment of the included studies also highlighted several issues that may have confounded the results of these studies. For example, one of the problems in reviewing the included studies was the lack of reported detail by the respective authors (e.g., appropriate randomization, calibration, blinding, number of dropouts, and outcomes assessed) and as a result, the quality of reporting was generally flawed with a high risk of bias [93-94]. For example, the sample size in the included studies was relatively small and none of the included studies apart from the Yankell *et al.* study [12] included baseline three and six-month clinical data. Furthermore, it is important to include the reasons why subjects drop-out from studies since missing data may impact on the results of the study. All included studies, however, reported on both safety and adverse event reporting. As previously discussed most of the studies were conducted over a short duration (maximum 24 weeks) with only one study satisfying the 6- month criteria for an anti-gingivitis agent [91-92]. It should also be noted that the minimum requirements for acceptance of a product as an anti-gingivitis agent was that, at least two independent six-month clinical studies, including microbiological monitoring to determine the safety and efficacy of a toothpaste product, should be conducted to support any claims of clinical efficacy. For example, the study by Ozaki *et al.,* [86] did not assess the effect of a Parodontax® toothpaste on plaque microbial count, which was an important component of the 1986 American Dental Association guidelines for the acceptance of chemotherapeutic products for the control of supragingival dental plaque and gingivitis [91], although the study by Mullally *et al.* [6] and Yankell *et al.* [12] did assess this measure. However, only a few of the included studies reported that there was a significant difference between Parodontax® and the control toothpaste in reducing plaque accumulation and gingival inflammation (gingivitis). For example, only Saxer *et al.* [8, 87] reported a significant difference in favour of Parodontax® in reducing gingivitis, all the other studies failed to demonstrate any statistical differences between Parodontax® and the control toothpaste. There are therefore several limitations as discussed in the present review which make it difficult to assess the efficacy of a Parodontax® toothpaste in reducing both plaque accumulation and gingival inflammation in patients with gingivitis. Of the studies reviewed for the present review it was evident that more well controlled RCTs over six months are required prior to a Parodontax® toothpaste being recognised as an effective anti-gingivitis agent.

Conclusion

The results from the published literature regarding the safety and clinical effectiveness of Parodontax® toothpaste would indicate that while the toothpaste has some short-term effects on both plaque and gingival inflammation, further studies are required to determine its effectiveness as an anti-gingivitis agent over six months.

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