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The plaque and gingivitis reducing effect of a chlorhexidine and aluminium lactate containing dentifrice (Lacalut aktiv®) over a period of 6 months

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Abstract

Aim: The aim of the study was to determine the plaque and gingivitis reducing effect of a dentifrice containing chlorhexidine and aluminium lactate compared with a control toothpaste during the course of 6 months.

Material and Methods: This randomized, double-blind study looked prospectively at participants over a 6-month period. Plaque, gingivitis, calculus formation and tooth staining were assessed in 59 participants, who were divided into parallel groups. The participants used either a chlorhexidine and aluminium lactate-containing toothpaste (test group) or a minus active control toothpaste (control group). Parameters were assessed at baseline and again after 1, 3 and 6 months.

Results: After 6 months of product use, both groups had less gingivitis compared with the baseline evaluation ($p < 0.001$). At this time point, the test group showed a statistically significant lower gingival index values compared with the control group ($p = 0.001$). No statistically significant differences between either the groups or time points were detected with regard to plaque index and the development of calculus and staining.

Conclusion: Although there was a statistically significant difference at 6 months between test and control groups, this difference was too small to be considered clinically meaningful.

Key words: aluminium lactate; chlorhexidine; clinical trial; dentifrice; extrinsic stain; gingivitis; plaque

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As tooth brushing is the most common oral hygiene method in Europe, dentifrices are the most ideal vehicle for the daily delivery of antibacterial agents (Frandsen 1985). These chemotherapeutic agents should provide a preventive effect against caries and gingivitis. Chlorhexidine (CHX) is a cationic antiseptic with action against a wide array of bacteria including Gram-positive and Gram-negative bacteria, dermatophytes and some lipophylic viruses (Denton 1991). CHX acts on the bacterial cell membrane by changing its structure. As a result, osmotic equilibrium is lost, the membrane extrudes, vesicles are formed and the cytoplasm precipitates (Davies 1973, Brecx & Theilade 1984). CHX is poorly absorbed by the gastrointestinal tract and, therefore, displays very low toxicity. The superiority of this agent as opposed to other chemical agents derives from its increased persistence (substantivity), which in turn prolongs its anti-bacterial action (Kornman 1986).

In the past, the use of CHX in dentifrices gained little attention because of its possible interaction with anionic ingredients contained in toothpaste (such as sodium lauryl sulphate, SLS) and competition for oral retention sites (Dolles & Gjermo 1980). Therefore,

Conflict of interest and source of funding statement

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there are only limited data evaluating the clinical efficacy of CHX dentifrices (Jenkins et al. 1993, Yates et al. 1993, Sanz et al. 1994).

Moreover, side effects such as staining of teeth, restorations and the tongue limit the long-term use of CHX to a concentration of 0.1–0.2% (Flötra et al. 1971). Sanz et al. (1994) documented the efficacy of a dentifrice containing 0.4% CHX/0.34% Zn^{2+} and reported statistically significant reduction in plaque and gingivitis for the CHX/Zn^{2+} combination with significantly less staining and calculus compared with a positive control rinse.

Aluminum lactate is a salt of lactic acid and has astringent, protein coagulative and weak haemostatic properties (Fiedler 1967). Protein coagulation leads to a superficial coagulation membrane, which in turn induces an astringent effect in deeper parts of the tissue (Goodman & Gilman 1955). It was also suggested that the coagulation membrane can protect the gingiva from exogenous irritations for a short period of time (Fiedler 1967). A side effect of the shrinkage and tightness of the tissue is the anti-inflammatory and analgesic property of the aluminium lactate. The most pronounced astringent effect of aluminium lactate is obtained at a concentration of 0.5% at the tissue (Grauber & Waegelein 1950). This astringency is then maintained for about 3–4 h (Wannenmacher 1964).

In a case series, Kämper (1942) observed a reduction of bleeding in the treatment of acute periodontal and gingival inflammation in patients with poor or no oral hygiene. The treatment consisted of professional tooth cleaning and administration of an aluminium lactate/CHX containing toothpaste (Lacalut®, Arcam, Hamburg, Germany). Keil (1969) reported on the clinical, histological and cytological results of treatment of acute and chronic gingivitis with Lacalut® medical dentifrice after removal of calculus. After only a few days, the acute forms showed definite improvement in their clinical condition. Histological and cytological examination of the cases confirmed the clinical findings. However, data concerning CHX toothpaste are rather sparse. Notably, no clinical long-term studies mentioning the toothpaste exist.

The aim of this study was to determine the plaque- and gingivitis-reducing effect of a dentifrice containing CHX and aluminium lactate compared with a placebo toothpaste during a 6-month clinical trial.

Material and Methods

Study population

A total of 60 (22 males and 38 females) subjects aged between 18 and 57 years participated in this study. The most important inclusion criterion was the presence of gingivitis (full-mouth gingiva index (GI) $\geqslant 1$ according to Löe & Silness 1963). Further inclusion criteria were the presence of a minimum of 20 teeth and the absence of a removable partial denture.

Subjects were excluded from the study if they were pregnant, if there was evidence of antibiotic use during the 4 weeks before the study, if the patients had to take anticoagulants, or if they were allergic to CHX, aluminium lactate or any of the other material present in the dentifrices.

Sample size

A level of significance of $\alpha = 0.05$ and a power $(1 - \beta)$ of 0.80 were set. A 20% reduction in GI with a 10% standard deviation was considered clinically relevant. For the given input values a minimum sample size of $n = 20$ was computed for the two sided null hypothesis H_0 by the software program ''statistics'' from the UCLA website (http://calculators.stat.ucla.edu/powercalc/).

Test products

The test product used in this study contained chlorhexidine digluconate (0.05%), aluminium lactate (0.8%) and 1400 p.p.m. fluoride (aluminium fluoride) as well as hydrated silica, silica and sodium lauryl sulphate. An identical dentifrice which contained 1400 p.p.m. fluoride (aluminium fluoride) but no chlorhexidine digluconate and aluminium lactate served as control. All products were filled in white, neutral tubes and supplied by Arcam, Homburg, Germany.

Study design

This randomized, double-blind study looked prospectively at participants over a 6-month period. Participants were placed in parallel groups and the study was performed in the Department of Operative Dentistry and Periodontology, Dental School and Hospital, Freiburg, Germany. The protocol for the study was reviewed and approved by the Medical Ethical Committee of the University of Freiburg and was in accordance with the Helsinki declaration. The study was conducted and monitored in accordance with the Guidelines for Good Clinical Practice. Before participation, the purpose and risks of the investigation were fully explained to all participants. Subjects were entered into the study only after having given written consent.

Table 1 shows the flow chart of the study. New toothbrushes (Lacalut®med toothbrush, Arcam, Germany) were made available to all subjects during the course of the study, but no preventive or therapeutic measures were undertaken during examinations. As the purpose of this investigation was to study the effect of CHX and aluminium lactate containing toothpaste, the investigator made special efforts to avoid any disruption of habits, home care practices or any other activity pertaining to the oral health status of the participants.

At Visit 1 (V1) a full-mouth (GI, Löe & Silness 1963) was obtained and participants who passed the inclusion criteria were randomly divided into a control group and test group. Subsequent to V1 a wash-out period of 2 to 4 weeks was carried out and both control and test groups received a standardized toothpaste (the same as the minus active control toothpaste) and Lacalut®med toothbrushes (both Arcam). At baseline (Visit 2, maximum 4 weeks after V1), the test group received the CHX and aluminium lactate containing toothpaste and the control group received the minus active control dentifrice.

At baseline, and after 1, 3 and 6 months of toothpaste use, different parameters were assessed as described in clinical assessments. Subjects were asked about any unfavourable side effects (e.g. allergy, staining, alteration of taste and burning sensations) at every visit.

Clinical assessments

Examinations throughout the study were performed by the same examiner (F. R.). The following parameters were used.

Primary parameters

GI as described by Löe & Silness (1963) was used on four sites of each Ramfjord tooth (16, 21, 24, 36, 41, 44, Ramfjord 1959) using the 0–3 scale.

Table 1. Flow chart of the study

Visit month	Visit 1 (screening)	Visit 2 baseline 1 month after V1	Visit 3 1 month after V2	Visit 4 3 months after V2	Visit 5 6 months after V2
1. Gingival index (GI)	•				
2. Randomization	•				
3. Distribution of the dentifrice for the standardization phase	•				
4. Distribution of the test dentifrice and the placebo toothpaste		•	•	•	
5. GI		•	•	•	•
6. Plaque index (PI)		•	•	•	•
7. Calculus index		•	•	•	•
8. Staining index		•	•	•	•
9. Drop-outs		•	•	•	•

Secondary parameters

Plaque Index (PI) was measured as described by Quigley & Hein (1962) and modified by Turesky et al. (1970). After staining of the plaque with an erythrosine-solution the PI was assessed at the Ramfjord teeth using the 0–5 scale.

Calculus Index according to Volpe et al. (1965)

VM index was used to assess supra gingival calculus accumulation. According to the method described by Volpe et al. (1965), lingual surfaces of the six lower anterior teeth (cuspid to cuspid) were examined.

Tooth staining

Tooth staining was measured by judging the colour and the intensity of the staining at the buccal surfaces of the anterior teeth of the upper and lower jaw. The colour was graded on a 0–5 scale (0 = no staining, 1 = yellow, 2 = slightly brown, 3 = brown, 4 = grey and 5 = black). In addition, each tooth was rated for intensity on a 0–4 scale (0 = no staining, 1 = weak, 2 = moderate, 3 = strong, 4 = very strong).

Randomization and supply of the products

All products were supplied in identical tubes (labelled only with a code number, the fluoride content and expiry date) by a laboratory assistant who was not involved in the study. The subjects were numbered according to the order of their appearance in the clinic. A computer-based randomization scheme generated before starting the study then allocated the (number of) subjects to the active or the control group. The code was kept in a sealed envelope and was disclosed when all examinations were finished.

Statistical analysis

The results were calculated with the use of the statistical package of social science/SPSS 12.01. Analyses were based on patient mean scores for the various clinical parameters of the different follow-up time points. First analysis of variance (ANOVA) was used to detect differences between the two groups as well as between the different time points. As data series were not normally distributed (tested with the Kolmogorow–Smirnow test), intra-group differences between baseline and various follow-up time points were determined using the Wilcoxon's-rank-sum test for independent variables. All statements of significance were based on $\alpha = 0.05$.

Results

All treatment groups were well balanced at the beginning of the study. A total of 59 patients finished the study, 30 in the test group and 29 in the control group. One patient of the control group did not finish the treatment period for reasons not associated with product use. No adverse events were reported by the participants.

Means and standard deviations of all parameters assessed at the different time points are shown in Table 2.

GI

The GI in the minus active control group decreased from baseline subsequently to the 6 months follow-up. Statistically significant differences could be detected after 1, 3 and 6 months of product use for the control product *versus* baseline ($p < 0.001$).

The test group showed a continuous decrease in GI values from baseline to the re-examination points at 1, 3 and 6 months, which were significantly better at all time points ($p < 0.001$) compared with the baseline.

While no significant differences between the two groups could be seen after 1 and 3 months, the test group revealed significantly lower values after the observation period of 6 months ($p = 0.001$).

PI

The control group showed similar mean values at baseline, 1, 3 and 6 months follow-up. There was no statistically significant difference between baseline and re-evaluation at different time points ($p > 0.05$).

The test group showed a continuous decrease of PI from the baseline to the 1, 3 and 6 month follow-up visits. However, no statistical significance was observed at any time point ($p > 0.05$).

PI compared between the minus active control and the test group also revealed no significant difference ($p > 0.05$).

Calculus and staining

Calculus and staining were already present in some individuals at the baseline examination, because no professional tooth cleaning was performed at the beginning of the observation. Values for the test and control group were stable throughout the 6-month observation period without a significant increase

Table 2. Means and standard deviations of clinical parameters at various follow up time points

Parameter	Time point	Lacalut® activ ($n = 30$ subjects)	Control group ($n = 29$ subjects)	p-value (between the groups)
Gingival index	Baseline	1.11 ± 0.22	1.19 ± 0.28	0.21, NS
	After 1 month	0.75 ± 0.26***	0.81 ± 0.35***	0.73, NS
	After 3 months	0.59 ± 0.25***	0.64 ± 0.28***	0.61, NS
	After 6 months	0.44 ± 0.27***	0.71 ± 0.45***	0.001***
Plaque index	Baseline	1.51 ± 0.41	1.46 ± 0.48	0.59, NS
	After 1 month	1.41 ± 0.54 NS	1.46 ± 0.63, NS	0.94, NS
	After 3 months	1.42 ± 0.49 NS	1.38 ± 0.48, NS	0.78, NS
	After 6 months	1.34 ± 0.61 NS	1.62 ± 0.64, NS	0.09, NS
Calculus index	Baseline	0.69 ± 1.18	1.27 ± 1.64	NS
	After 1 month	0.76 ± 1.26	1.40 ± 1.60	NS
	After 3 months	0.78 ± 1.19	1.44 ± 1.52	NS
	After 6 months	0.74 ± 1.14	1.38 ± 1.57	NS
Staining index colour	Baseline	0.23 ± 0.32	0.25 ± 0.32	NS
	After 1 month	0.23 ± 0.32	0.25 ± 0.32	NS
	After 3 months	0.23 ± 0.32	0.30 ± 0.36	NS
Intensity	After 6 months	0.24 ± 0.32	0.30 ± 0.36	NS
	Baseline	0.22 ± 0.30	0.28 ± 0.43	NS
	After 1 month	0.22 ± 0.30	0.28 ± 0.43	NS
	After 3 months	0.22 ± 0.30	0.32 ± 0.45	NS
	After 6 months	0.23 ± 0.31	0.32 ± 0.45	NS

***$p < 0.001$.
NS, not significant.

in calculus or staining (as measured by colour as well as intensity).

Discussion

This 6-month-long clinical trial was designed to study the efficacy of an aluminium lactate-CHX-based dentifrice. Although the statistical analysis showed a significant improvement of the GI using the test formulation compared with the minus active control toothpaste (0.27 index units corresponding to a 38% reduction), one can dispute, if this effect can be considered clinically significant.

The use of the control toothpaste also resulted in improvement in evaluated parameters. This phenomenon, also known as the Hawthorne effect, could be seen very often in studies which compared dentifrices in combination with toothbrushing due to a higher awareness of oral health care (for a review see Wickstrom & Bendix 2000). After 6 months, both GI and PI in the control group increased, which could possibly be explained by a decrease in motivation in the control group. As the Hawthorne effect disappeared, the anti-inflammatory property of the test dentifrice itself could be evaluated, explaining the significant differences between test and control group at 6 months but not at 3 months evaluation.

To the best of our knowledge, at the present time, there are no data from clinical long-term studies available evaluate this type of toothpaste formulation. Thus, no direct comparison of the present results to those of other studies can be made.

The reduction of the GI by 60% and PI by 11% after 6 months as compared with the baseline data of the test group, as well as the reduction of GI by 38% and of PI by 17% after 6 months compared with the baseline data of the control group, indicates that the test toothpaste with its two main ingredients CHX and aluminium lactate is effective in decreasing GI.

Various studies with different dentifrices failed to show significant differences between test and control toothpastes, although GI and PI were reduced compared with baseline values (Shapira et al. 1999, Winston et al. 2002). The observed reductions in the present study regarding GI (60%) and PI (11%) are higher than those found in other studies (22.2% reduction of GI and 18.7% of PI after 6 months reported by Mankodi et al. 2002; 16.2% of GI and 14.4% of PI after 3 months reported by Winston et al. 2002).

It has been suggested that aluminium lactate has astringent, coagulative, and weak haemostatic properties, possibly leading to less bleeding and tightness of the gingiva (Riethe et al. 1980). This could be confirmed by the subjective report of the volunteers. Twenty-five out of the 30 subjects of the test group noted a constricting effect and a well-groomed feeling of the gingiva after finishing the study. Owing to the fact that an effect on GI was seen but no effect was noticed on PI, it is possible that aluminium lactate, which itself has no antibacterial properties, is responsible for this slight improvement in GI.

However, as CHX is the most effective anti-plaque and anti-gingivitis agent (Brecx et al. 1992) it might be anticipated that the effect of CHX superseded the effect of aluminium lactate. However, it is also possible that other ingredients, particularly the anionic detergent sodium lauryl sulphate, could have reduced or even inactivated the cation CHX. In vitro as well as clinical data refer to an incompatibility with soaps and other anionic material by forming salts of low solubility (Barkvoll et al. 1988, 1989, Sweetman 2002). The staining and calculus data would support this conclusion.

However, according to a recently published review there are some reasons to believe that CHX and dentifrices are incompatible, but the evidence for this does not allow the drawing of any definitive conclusion (Kolahi & Soolari 2006). Moreover, (1) incompatibility is known to occur in aqueous solutions and (2) all studies deal with (SLS)-dentifrices alongside CHX rinsing, but not with both ingredients present together in a single toothpaste.

The study of Yates et al. (1993), which was based on home use and lasted 6 months, demonstrated that both CHX alone and CHX/fluoride formulations were more effective than the placebo in reducing plaque, gingival inflammation and bleeding. In a subsequent study, it was shown that CHX, as an ingredient of dentifrices, is able to reduce anaerobic counts in supragingival plaque (Maynard et al. 1993). Comparable clinical results concerning the effectiveness of CHX in toothpaste formulations were reported by others (Jenkins et al. 1993, Sanz et al. 1994).

Surprisingly, no side effects such as tooth staining as described by Flötra et al. (1971) could be seen in this study population. In contrast, some investigations using 1% CHX toothpaste reported significantly more tooth staining in the test groups compared with the control groups (Jenkins et al. 1993, Yates et al. 1993). Sanz et al. (1994) tested a 0.4% CHX containing toothpaste in conjunction with a placebo mouthrinse (experimental group), a placebo rinse and a gum care dentifrice

(control), and a 0.12% CHX rinse and a gum care dentifrice as a positive control (participants rinsed after tooth brushing). The authors reported significantly less staining and calculus when the experimental group was compared with the positive control group. It was suggested that these observations occurred because of the abrasive feature of the dentifrice. Thus, it seems that the abrasive character of dentifrices may partly overcome the negative effect of tooth staining while leading to a strong effect similar to that of a 0.12% rinse.

Although it is well documented that there is a strong correlation between the efficacy of CHX and its staining potential (Addy et al. 1989), it may also be anticipated that some other ingredients of such complex toothpastes could have partly inactivated CHX. Thus, the other ingredients may still be responsible for a significant effect (which was also seen with the control toothpaste used in the present study). In the present study, the test toothpaste contained only 0.05% CHX while the efficacy of this toothpaste as compared with the control was weak. Therefore, the non-occurrence of tooth staining may be explained by the abrasive effect of the toothpaste and a reduction in the effectiveness of CHX.

Within their limits, the present results indicate that (a) the twice daily application of the tested toothpaste formulation containing chlorhexidine and aluminium lactate as main ingredients showed statistically significant effectiveness in reducing gingival inflammation over a 6-month period and (b) no side effects such as tooth staining or mucosal alterations were observed during the entire study period of 6 months.

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Clinical Relevance

Scientific rationale for the study: New antibacterial products should be clinically tested for their efficacy even if they contain known antibacterial agents. The presence of CHX is no guarantee of efficacy and, therefore, should be tested in the complex product with all its ingredients.
Principal findings: The results suggest that the twice-daily application of the tested dentifrice, containing CHX and aluminium lactate as its main ingredients, was effective in reducing gingival inflammation.
Practical implications: There was a statistically significant difference after 6 months of product use between test and control groups, but this difference was very small.