Removing dental calculus using a pill.

Berth Mattsson and Sune Wikner

Introduction.
Plaque is a necessity for formation of dental calculus and for development of caries. However, all plaques do not develop calculus, probably due to some protective mechanism in saliva and/or the periodontal exsudate. There is not sufficient knowledge on the character of such a protective mechanism. The composition of diet might influence it.

The purpose of this study was to investigate if a daily swallowing of a pill (ProDen PlaqueOff ®) had any influence on human dental calculus and plaque.

Material and methods.
The pill consisted of herbs that have been commercially available all over Europe for more than 30 years. It contains a large number of nutrients and may be regarded as a dietary supplement.

The material consisted of 30 adult patients who used to be calculus formers and who had oral calculus present at baseline. They got free samples of the pill and agreed to consume two pills a day during two months.

One dentist recorded the extension of supragingival calculus and plaque on teeth 26, 31 and 11 (Greene and Wermillion index) at baseline and after two months. The results were recorded as plaque index (PLA) and calculus index (CAI).

Statistical method:
The differences between values recorded at baseline and two months later were statistically evaluated by analysis of variance.

Results.
The tables and figures 1-2 demonstrate that the extension of both plaque and calculus was strongly and significantly reduced on all examined teeth.

As shown in figure 3 the effect of the pill on calculus differed between individuals. In 16 persons the calculus disappeared or the extension of it was reduced. In 12 persons, only little reduction was recorded but the calculus was extremely soft and easy to remove, even by the patient. No effect was recorded in two cases. The differing effect is most likely due to different levels of mineralization.

At the two month examination some of the patients who still had calculus accepted to increase from two to four pills a day for another eight weeks. This experiment is still running but it is evident that they are loosing calculus more rapidly now. Thus it seems that the effect is dose dependent.
In other cases the calculus was removed by the dentist two months after baseline and the patients continued to eat the pill. Formation of new calculus was either nil or considerably slower compared to previous years. The pill had a pronounced effect on plaque formation (figure 2). Consumption during two months reduced plaque by 71-87 per cent. According to table 2 the difference before and after consumption was highly significant on all three examined teeth. Most likely that effect can be achieved already after a few days consumption of the pill.

**Table 1.** Extension of dental calculus on teeth no 26, 31 and 11 in 30 persons before and after two months consumption of Plaque-Off ®

<table>
<thead>
<tr>
<th>Tooth no 26</th>
<th>CAI</th>
<th>SD</th>
<th>Diff</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>At baseline</td>
<td>0,96</td>
<td>0,527</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After two months</td>
<td>0,57</td>
<td>0,503</td>
<td>41%</td>
<td>&lt;0,0021</td>
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<table>
<thead>
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<th>CAI</th>
<th>SD</th>
<th>Diff</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>At baseline</td>
<td>1,13</td>
<td>0,571</td>
<td>30%</td>
<td>&lt;0,011</td>
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<tr>
<td>After two months</td>
<td>0,76</td>
<td>0,504</td>
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<table>
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<th>Tooth no 11</th>
<th>CAI</th>
<th>SD</th>
<th>Diff</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>At baseline</td>
<td>0,41</td>
<td>0,568</td>
<td>68%</td>
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<td>After two months</td>
<td>0,14</td>
<td>0,350</td>
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**Table 2.** Extension of plaque on teeth no 26, 31 and 11 in 30 persons before and after two months consumption of Plaque-Off.

<table>
<thead>
<tr>
<th>Tooth no 26</th>
<th>PLI</th>
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<th>P</th>
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<tbody>
<tr>
<td>At baseline</td>
<td>0,85</td>
<td>0,456</td>
<td>87%</td>
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<td>After two months</td>
<td>0,11</td>
<td>0,362</td>
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</table>

<table>
<thead>
<tr>
<th>Tooth no 31</th>
<th>PLI</th>
<th>SD</th>
<th>Diff</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>At baseline</td>
<td>0,70</td>
<td>0,535</td>
<td>86%</td>
<td>&lt;0,0001</td>
</tr>
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<td>After two months</td>
<td>0,10</td>
<td>0,305</td>
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</table>

<table>
<thead>
<tr>
<th>Tooth no 11</th>
<th>PLI</th>
<th>SD</th>
<th>Diff</th>
<th>P</th>
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<tbody>
<tr>
<td>At baseline</td>
<td>0,48</td>
<td>0,580</td>
<td>71%</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>After two months</td>
<td>0,15</td>
<td>0,362</td>
<td></td>
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</tr>
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</table>
Discussion.

This study indicates that consumption of this herb may eventually eliminate existing plaque and calculus.

It is emphasized that the data accounted for in table 3 to some extent are based on the dentists subjective judgement. E.g no criterion for the hardness of the calculus or the force that was necessary for its removal had been decided before the start of the study. However, the observation that the calculus was easy to remove and/or soft may be important for the future understanding of the involved mechanisms. Such criteria should be included in future studies.

One patient told that his calculus could be removed with a wooden toothpick already after one weeks consumption of two pills a day. In other cases two months were not enough but when the dose was increased from two to four pills the calculus started to diminish even in those. Thus, some persons may need a higher dose and a longer treatment time than others. Our recommendation is to start by eating two pills daily during two weeks. If no effect is observed the dose should be increased to four pills to be eaten until the calculus is gone.

The recorded reduction of existing calculus is consistent with the observed plaque reduction and the observation that new calculus formation was unusual during the consumption period.

Since the pill seems to reduce plaque to quite an extent it should protect people from caries in the long run as well. Future studies will reveal if that assumption comes true.

Conclusion.

Daily consumption of the Plaque-Off pill may reduce the extension of plaque and of calculus in adults having calculus, but also prevent formation of new plaque and calculus.
Extension of calculus on 3 teeth in 30 persons after 2 months consumption of Plaque-Off

![Graph showing extension of calculus on 3 teeth in 30 persons after 2 months consumption of Plaque-Off.]

Extension of plaque on 3 tooth surfaces in 30 persons after 2 months consumption of Plaque-Off

![Graph showing extension of plaque on 3 tooth surfaces in 30 persons after 2 months consumption of Plaque-Off.]

Quality of dental calculus before and after 2 months consumption of Plaque-Off in 30 adults.

![Graph showing quality of dental calculus before and after 2 months consumption of Plaque-Off in 30 adults.]

In more than 50% the tartar disappeared completely.

Even in these person’s tartar disappeared when the dosage was increased.
The systemic effect of a food additive on dental plaque and calculus

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Short title: A food additive and dental deposits

Abstract

A food additive containing the brown algae Ascophyllum nodosum SW1313 was used in an eight-week clinical trial with the purpose to explore its possible effect on reducing supragingival plaque and calculus. 105 subjects were randomly assigned to one of three groups, each containing 35 subjects at baseline. Two groups received tablets of either a low (125mg) or a higher (250mg) concentration of the algae. A third group (control) received placebo tablets. Significant reduction in plaque levels compared to control were observed after eight weeks in both the low concentration (49%) and the high concentration (66%) algae groups (P = 0.002). Significant reductions in supragingival calculus levels were observed after four weeks (P = 0.037) improving after eight weeks (P = 0.000). The effect appeared to be dose-dependent. It is concluded that a food additive containing brown algae reduces the amounts of supragingival plaque and calculus in humans.

Key words
Dental calculus, dental plaque, food additive

Introduction

Several attempts have been made to prevent the formation of dental plaque and calculus by topically applied chemotherapeutic agents, e.g., by incorporating antiseptics in dentifrices and mouthwash. There is currently, however, limited knowledge about the possibility of interfering with plaque and calculus formation using agents via the systemic route. Naturally, it would be preferable to prevent the formation of plaque and calculus, instead of removing them once they are established.

One of the authors of the present study had observed that a patient who normally formed a lot of calculus had none a year after he had retired and moved from Sweden to another country. On examination, his oral hygiene regime had not changed, and neither, as far as could be ascertained, the quality of his dental care. His diet, however, had changed quite significantly. He had started eating a salad containing a particular fresh seaweed: Ascophyllum nodosum (AN). Pilot tests with tablets made from dried AN confirmed in other patients that calculus appeared to reduce, and, interestingly, the tablets were swallowed whole – neither chewed nor sucked (Mattson B & Wikner S, unpublished data). The results of these simple experiments suggested that the observed dissolution of calculus may have been caused by some salivary factor.
that was systemically influenced by the AN tablets. Ascophyllum nodosum is a brown seaweed which is confined to the North Atlantic basin. AN is used widely in the production of alginic acid and caregeenan; polysaccharides commonly used as food additives for thickening such as ice cream and other dairy products. It is also used as a feed additive in cattle and as a soil conditioner and fertilizer.

AN contains a large number of nutrients (Table 1) but several of them in concentrations (1) which seem to be too low to have any significant effect on human metabolism e.g. the protein and most vitamins and minerals. Nutrients that prevail in the highest concentrations are alginic acid, phenol, fucoidan, mannitol, laminaran and sulphated fucoidan. Also the concentrations of vitamin D and iodine are high considering recommended daily allowances (RDA). AN also contains several minerals and trace elements which are vital to enzymes or hormones e.g. magnesium, manganese, zinc, cobalt, chromium and selenium. Those may be important to human metabolism in spite of low concentrations.

Plaque and dental calculus are widespread in adults. A study in 9689 Americans, 30 years of age and older, reported supragingival calculus in 91.8 per cent (2). A British study reported visible plaque in 72 per cent of adults and calculus deposits in 73 per cent (3). It is agreed that calculus does not exert a detrimental effect on the gingiva but facilitates plaque retention. Dental calculus is removed at the dental office in order to facilitate oral hygiene.

For a long time dental calculus was defined as calcified deposits adhering to the teeth. It was not until 1969 that Schröder (4) provided the definition which is regarded appropriate to day: mineralised dental plaque that is permeated with crystals of various calcium phosphates. Calculus consists initially of an organic matrix which becomes calcified when certain conditions prevail. These include a sufficiently high pH and a supersaturated saliva with respect to ions which participate in the calcification process e.g. calcium, phosphate and carbonate. Precipitation does not occur below pH 7 but may be heavy at higher, alkaline, values (5).

Calculus contains 83 per cent inorganic salts and the most common are calcium phosphate (75%) calcium carbonate (3%) and magnesium phosphate (4%). Others are calcium oxalate and ammonium magnesium phosphate (6). Apatite is the most abundant structure followed in order by brushite, whitlockite, octacalcium phosphate, monetite and calcite (7). A high number of other minerals (8) have been identified as well; sodium, potassium, aluminium, iron, copper, silicon, nickel, zinc just to mention a few. The composition of dental calculus may differ in persons from different geographical locations and from the same area and also within the deposit (7). No one has yet provided a theory of calculus formation that satisfactorily explains all the observed variations in calculus formation in human subjects. E.g. no theory has explained the presence of calculus in some persons having an excellent oral hygiene and its absence in others having a poor oral hygiene.

Besides mechanical elimination of plaque and calculus several chemical compounds have been used for topical application. E.g. mouthwashes containing triclosan and sodium lauryl sulphate produced a significant reduction in plaque formation (9). Topical treatment of dog’s teeth with 8-hydroxyquinoline
sulphate also retarded the formation of plaque (10). Other effective compounds against plaque are chlorhexidine and the essential oils in Listerine (11, 12). Polyphenols e.g. tannins are abundant in most herbs, bushes and trees and also in tea, coffee and wine. They are astringent and antiseptic and may prevent plaque formation. E.g. polyphenols in cacao beans have antiplaque activity in vitro and in vivo (13). Phenolic compounds in hop may inhibit growth of oral streptococci in vitro (14). Also cranberry has been suggested for plaque inhibition due to ability to interfere with aggregation and adhesion of S. mutans (15).

Topically applied compounds have also been suggested for prevention of calculus formation e.g. zinc (16-18), silica (19) and pyrophosphate (5, 20, 21). Also structural analogs of pyrophosphate e.g. bisphosphonates have been used for topical oral application in order to inhibit calculus formation (22). Hexametaphosphate used as a feed additive retards the growth of calculus on previously cleaned teeth in squirrel monkeys. However, no effect was observed on existing calculus that was left in situ (23). There are no reports on the systemic effect of the compounds accounted for above.

Several studies have reported influence on the deposit formation rate by altering the composition and consistency of the diet (24). However there is little evidence that the formation of calculus was systemically influenced in those studies. One problem is to distinguish between the topical effect during consumption and the systemic effect from nutrients absorbed from the intestine and then transported to saliva by the blood system. Similarly, due to the study design, the pilot tests (mentioned above) conducted prior to the present study do not prove that diet, rather than other factors, caused the apparent calculus reduction.

An Australian study indicates that diet might play a role for calculus formation. It reported that dental calculus scores were significantly higher in domestic cats than in feral cats (25). The assumption that AN may inhibit calculus formation, when used systemically, is contradictory to the opinion that dental calculus is merely a calcification product of bacterial plaque (26). That view is supported by the observation that calculus may form in the absence of bacterial plaque (27-29).

The purpose of this clinical study was to investigate the systemic effects of tablets made from AN on plaque and calculus formation in persons who had existing supragingival calculus at baseline.

**Material and methods**

150 subjects were recruited after an advertisement was placed in a local paper in Stockholm, Sweden. After a primary screening, 105 subjects were admitted after meeting the inclusion criterion of visible deposits of supragingival calculus. Persons with advance periodontal disease were excluded. Participants were randomly assigned to one of three groups, each containing 35 subjects at baseline. The clinical examination comprised the assessments of plaque and calculus on three tooth surfaces per person. The assessment of plaque was based on the lingual surface of 26, and the buccal surfaces of 11 and 31. Supragingival
calculus was assessed on the buccal, lingual and lingual surfaces, respectively, of the same teeth. The extension of plaque as well as calculus was assessed using Green and Vermillion’s Oral Health Index Short Form (30). In this system score 0 indicated absence of plaque or calculus, score 1 that one third or less of the gingival part of the tooth surface was covered, score 2 that two thirds were covered, and score 3 that more than two thirds were covered. Plaque and calculus scores, respectively, were summarised across surfaces and given per subject. A preselected tooth, when missing, was replaced by 27, 41 and 21, respectively.

The food supplement selected was the brown algae _Ascophyllum nodosum_ SW1313. Tablets (ProDen PlaqueOff™) containing dried and pulverised AN were used in this trial, and in order to minimise any perioral absorption the tablets were wax-coated.

Tablets of two different concentrations of dried algae were tested: 125mg and 250mg. Two groups received tablets of either the low or the high concentration and a third group (control) received placebo tablets. Participants were instructed to take two tablets a day for four weeks when a second dental examination was made. The subjects were clearly instructed that the tablets should be swallowed whole.

Following the four-week examination, participants were instructed to take three tablets a day for a further four weeks. Eight weeks after baseline a final dental examination was conducted. Subsequent to the final examination, any remaining plaque and calculus were removed. The trial was performed double blind. Participants were asked to maintain their normal oral hygiene regimes during the course of the trial.

**Statistics**

The distributions of individuals with reference to plaque and calculus were normal at baseline. Differences between groups were tested by means of 1-factor ANOVA and, for comparisons over time, repeated measures ANOVA. Statistical significance was accepted at $P<0.05$.

**Results**

14 persons dropped out during the course of the trial, leaving a total of 89 participants (85%), 47 women and 42 men, to be accounted for. The mean age was 45 years (range 23-68 years) and there were no significant differences between groups. Adverse events were rare. One person complained about abdominal pain.

The mean levels of plaque and calculus at baseline and during the course of the trial are presented in Tables 2 and 3, respectively. There were no statistically significant differences between groups at baseline. After four weeks, slight reductions of plaque were observed in all groups. There were, however, no significant differences between groups. Further reductions were observed at eight weeks in both the low concentration alga (LA) and the high concentration alga (HA) groups but not in the placebo group (Table 2). The reductions compared to baseline were 49% and 66% in LA and HA groups, respectively, compared to just 20% in the placebo group. The differences between groups
were statistically significant \((P = 0.002)\). Post hoc comparisons testing revealed a significant difference between HA and placebo groups (Scheffé \(P = 0.002\)) but not between LA and placebo groups or LA and HA groups.

The changes in plaque levels over time are illustrated in Figure 1. Repeated measures ANOVA disclosed a significant plaque reduction effect over time associated with substance use. Although differences between groups regarding change were small during the first 4 week period, there were significant differences between LA and placebo groups and between HA and placebo groups during the second 4 week period \((P = 0.038\) and \(P = 0.015\), respectively). For the total duration of the trial, the differences in plaque reduction between LA and placebo groups as well as between HA and placebo groups were statistically significant \((P = 0.015\) and \(P = 0.001\), respectively).

There were no statistically significant differences with reference to calculus extension between groups at baseline. After four weeks, however, a statistically significant reduction associated with the test substance was observed \((P = 0.037)\). Further reductions were observed after eight weeks in LA and HA groups but not in the placebo group. The differences between groups were statistically significant \((P = 0.000)\). Post hoc comparisons testing suggested significant differences between HA and placebo groups as well as between LA and placebo groups (Scheffé \(P = 0.000\) and \(P = 0.004\), respectively). The difference between LA and HA groups was almost significant \((P = 0.080)\). The changes in calculus levels over time are illustrated in Figure 2. Similar to plaque changes, a significant calculus reduction effect over time associated with substance use was observed. The differences in calculus reduction between groups during the first 4 weeks were not significant. During the second 4 week period, however, a significant difference was seen between HA and placebo groups \((P = 0.029)\) and a trend towards a difference between LA and placebo groups \((P = 0.078)\). For the total eight-week period the calculus reductions in both LA and HA groups were statistically significant compared to placebo \((P = 0.015\) and \(P = 0.001\), respectively). The results remained as baseline plaque levels were introduced as a co-variable in the analyses.

**Discussion**

This is the first study to demonstrate that a food supplement containing the brown algae Ascohyllum nodosum SW1313 (ProDen PlaqueOff), taken daily, significantly reduces the amount of established supragingival plaque and calculus in humans. Given that the tablets were wax-coated and swallowed, it would appear that the effect of plaque and calculus resulted from systemic absorption of algal components, not a purely local effect.

The higher concentration of the algae had a greater effect than the lower one, suggesting a dose-dependent response. This is further substantiated by the observation that a greater reduction was seen in the second clinical phase when the dose was increased from two to three tablets daily.
The results are consistent with those of a pilot study (unpublished) in 30 persons, conducted over 16 weeks and where four tablets were taken daily. The reduction in plaque and calculus was 86% and 87%, respectively. The reduction of plaque in the placebo group at the four-week examination reflected an improvement in oral hygiene during the first part of the study, making difficult any firm conclusion about the true reducing effect of the active agent during the first four weeks. However, at the eight-week examination the plaque level of the placebo group remained unchanged whereas the levels observed in the verume groups continued to decrease.

Three mechanisms may account for the reduction in plaque accumulation observed. Among the many components of AN, three have previously been shown to affect plaque accumulation when used topically: phenols (11-14), iodine (31) and sulphate (9, 10). The assumption that the high content of the sulphate containing fucoidan in AN is a probable reason to the plaque reduction is in line with the results of previous studies. They demonstrated that funoran had a strong desorption activity against mutans streptococci pre-absorbed to saliva-coated hydroxyl apatite. Furanon like fucoidan is a sulphated polysaccharide but is extracted from a red seaweed. In rats funoran reduced the colonization of S. cricetus and the caries scores compared to a control group (32). Added to chewing gums funoran reduced plaque formation in man (33). It is assumed that the sulphate groups of funoran interfered with bacterial adhesion to proteins of the pellicle in those studies. However, the administration of the active agent used in those studies precludes the possibility to judge if the effect was systemic or local.

Prevention of calculus formation has been demonstrated after topical application of zinc (16-18), silica (19) and pyrophosphates (5, 20, 21). AN contains rather high concentrations of all these except pyrophosphate. However the sulphate in AN is a structural analog of pyrophosphate (34, 35) and may often replace it.

About 35 per cent of AN dry weight consists of highly acid sulphate esters and the absorption and mobilisation of these compounds may contribute to an increased sulfation of acid salivary components such as glycosaminoglycans (GAGs). The acidic nature of these components exhibit calcium-binding properties, which in turn would reduce the concentration of calcium available for precipitation (34-37). Although AN was taken by the subjects as a food supplement and a direct topical effect is ruled out, one or more of these simple molecules may be secreted in the saliva following absorption.

The observed dissolution of calculus is more difficult to relate to current knowledge of the dental science. However, in urological studies sulphated compounds have been used in order to prevent or eliminate urinary stones (38-40) in vitro and in vivo in animals and man. The mechanism is believed to result from acidification of the urine.

Hydroxyapatite is generally resistant to demineralisation but acids produced by oral bacteria can dissolve it. The critical pH for dissolution of hydroxyapatite in dental enamel is pH5.5 in persons with high salivary calcium and phosphate concentrations (41). Apatite is the most abundant structure but calculus precipitations may also contain brushite, whitlockite, octacalcium phosphate, moneitite and calcite, all having a higher solubility than hydroxyapatite (43).
A theoretical explanation to the observed dissolution of calculus is an acidification of salivary pH due to an increased GAG concentration caused by AN consumption. That would be a similar mechanisms as when acidification of urine dissolves the kind of renal stones (45) which have a similar composition as dental calculus. The lowering of pH from 6.5 to 5.75 increased the dissolution rate by 35 per cent in that study. It is reasonable to believe that certain parts of calculus may dissolve at a higher pH values than hydroxyl apatite (pH 5.5) due to the presence of more soluble calcium phosphates and carbonates in calculus.

Maybe the simplest explanation to the dissolution of calculus is acids from microorganisms in plaque. The bacterial composition of dental plaque should be the same as in plaque covering dental calculus. Thus after consumption of fermentable carbohydrates a pH drop should occur on the calculus surface having the same magnitude as on the enamel surface. Consequently one may expect that a pH drop in plaque covering calculus will dissolve calculus and particularly if parts of the calculus contain calcium precipitations that dissolve at a higher pH than hydroxyl apatite in dental enamel. Due to that difference the dissolution of calculus will start earlier during a pH drop and stop later during recovery of pH to normal values. The significance of oral microorganisms for the dissolution of dental calculus is supported by previous observations that rinsing with the antibacterial solution Chlorhexidine increased the formation of calculus (44, 45).

Future studies will be needed in order to explain the mechanisms behind the results of this study but one conclusion seems inevitable; the effects were caused by a systemic distribution of dietary nutrients. It may also be concluded from the present observations that daily consumption of tablets made of brown algae (ProDen PlaqueOff) reduces the amounts of dental plaque and calculus already after a few weeks. The rate of the reduction seems to be dose dependent.

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Acknowledgment: The study was supported by SweDenCare AB, Sweden.
Table 1. Average composition of the brown algae Ascophyllum Nodosum.

<table>
<thead>
<tr>
<th>Major components</th>
<th>%</th>
<th>Minor minerals</th>
<th>mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-free extractives</td>
<td>45-60</td>
<td>P</td>
<td>1500</td>
</tr>
<tr>
<td>Alginic acid</td>
<td>20-26</td>
<td>I</td>
<td>500-1200</td>
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<tr>
<td>Phenol</td>
<td>5-15</td>
<td>Fe</td>
<td>150-1000</td>
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<tr>
<td>Mannitol</td>
<td>5-8</td>
<td>Zn</td>
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<td>Laminaran</td>
<td>2-5</td>
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<tr>
<td>Fucoidan</td>
<td>10-15</td>
<td>Mn</td>
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</tr>
<tr>
<td>Crude fibre</td>
<td>8</td>
<td>Ba</td>
<td>15-50</td>
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<tr>
<td>Crude protein</td>
<td>5-10</td>
<td>Co</td>
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<table>
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<tr>
<th>Major minerals mg/kg</th>
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<td>S</td>
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<td>Cl</td>
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<td>Ni</td>
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<td>Na</td>
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<td>Mo</td>
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<tr>
<td>Lipid</td>
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<td></td>
</tr>
<tr>
<td>K</td>
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<td></td>
<td></td>
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<td>Ca</td>
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<tr>
<td>Mg</td>
<td>7000</td>
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<th>Vitamins mg/kg</th>
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<tr>
<td>C</td>
<td>500-2000</td>
<td>D</td>
<td>4</td>
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<tr>
<td>E</td>
<td>150-300</td>
<td>K</td>
<td>10</td>
</tr>
<tr>
<td>A(provit)</td>
<td>30-60</td>
<td>Thiamin</td>
<td>1-5</td>
</tr>
<tr>
<td>Niacin</td>
<td>10-30</td>
<td>Biothin</td>
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<tr>
<td>Riboflavin</td>
<td>5-10</td>
<td>Folacin</td>
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Table 2. Variation of plaque over time. Mean and standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>4 weeks</th>
<th>8 weeks</th>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Algae high</td>
<td>4.72</td>
<td>1.71</td>
<td>3.17</td>
</tr>
<tr>
<td>Algae low</td>
<td>5.01</td>
<td>1.70</td>
<td>3.90</td>
</tr>
<tr>
<td>Placebo</td>
<td>4.26</td>
<td>1.54</td>
<td>3.40</td>
</tr>
</tbody>
</table>

F = 1.6, P>0.05  F = 1.2, P>0.05  F = 6.8, P = 0.002

Table 3. Variation of supragingival calculus over time. Mean and standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>4 weeks</th>
<th>8 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Algae high</td>
<td>3.07</td>
<td>1.16</td>
<td>2.31</td>
</tr>
<tr>
<td>Algae low</td>
<td>3.33</td>
<td>1.69</td>
<td>2.89</td>
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<tr>
<td>Placebo</td>
<td>3.43</td>
<td>1.26</td>
<td>3.16</td>
</tr>
</tbody>
</table>

F = 0.6, P>0.05  F = 3.4, P = 0.037  F = 16.2, P = 0.000
References


Mean plaque score related to amount of seaweed and time

Mean calculus score related to amount of seaweed and time
Plaque Change over Time
2-way interaction
F (4,170)=3.98; p<.0041

Change in Calculus over Time
2-way interaction
F(4,170)=3.36; p<.0112

Trial manager: Marina Nordlund, registered dentist
04-02-2004

Introduction

The oral cavity always contains various bacteria which are "fed" and multiply from the remains of food that readily gather around the gums (gingiva) and between the teeth, forming a sticky coating of food and bacteria known as plaque. To say thanks for the delicious meal, these types of bacteria produce various inappropriate substances: acids which can lead to “cavities in the teeth” (caries) and loosening of the teeth (periodontitis).

The substances formed by the bacterial plaque (acids and bacterial toxins) can rapidly lead to inflamed gums (gingivitis), which has been established to constitute the first clinical sign of one of the common bacterial diseases of the oral cavity, namely loosening of the teeth, or periodontitis. This bacterial plaque can also be mineralised and form what we call tartar which gradually builds up and allows new bacteria to be retained and further plaque to be formed.

Although gingivitis is the first sign of periodontitis, this does not mean that all cases of gingivitis will develop into periodontitis. If the gingivitis is allowed to continue to develop on account of the balance between attack and defence tipping in favour of the attack or bacteria, however, the “suspension system” of the teeth – known in technical terms as the periodont – which attaches the teeth to the underlying bone, dissolves over time and breaks down = periodontitis. If tooth loosening is allowed to progress too far, the teeth may lose so much of the underlying bone that they cannot be saved. A recent Swedish dental health information campaign actually pointed out that more than half the population aged over 40 are heading for tooth loss as a consequence of periodontitis! There are a number of individual factors, such as the quantity of saliva and bacterial flora, plus their composition, which together determine how readily individuals fall victim to the sadly all too common diseases of the oral cavity known as periodontitis and caries.

In addition to a basic balanced diet, top oral health requires regular check-ups and treatment by the dental care team, and this team also has to provide information and guidance on how people themselves need to look after their teeth. For example, after “complete cleaning” including depuration (tartar removal) by a dental hygienist, well planned care by the individual is required in order to keep the mouth clean and fresh.

Apart from keeping the mouth clean by brushing the teeth and using other mechanical aids, new research has now shown that perorally swallowed and thus a systemically applied dietary supplement, PlaqueOff, which contains special maritime algae, can considerably reduce the formation of plaque and tartar.
The aim of this study is to contribute new research results relating to the effects of the seaweed preparation PlaqueOff (both before and after depuration) on plaque, tartar and gingival bleeding, and thus on periodontal status.

**Materials and methods**

An open clinical trial at Marina Nordlund’s dental clinic, Kungsholmen, Stockholm (this clinic has been run by Marina Nordlund since 1985). 22 volunteers, adults selected partly at random (15 men and 7 women aged 26-91, average age of 47) paying revision patients registered with the practice for a number of years, were called to the clinic to take part in the trials.

These people were informed that they would be asked to try out a maritime algae preparation, PlaqueOff, available as a dietary supplement in health food stores, for 10 weeks. PlaqueOff consists of a dried powder made from brown maritime algae, Ascophyllum Nodosum SW1313, and consists of approx. 52 % polysaccharides, 22 % minerals and trace elements, 6 % fibre, 6 % protein and 2 % omega-3 fatty acids. In addition, the preparation contains no colourings, preservatives, salt or sugar.

The trial subjects were informed that the purpose of the trial was to investigate whether the seaweed preparation has any positive effects on the formation of plaque and tartar. The trial subjects were told not to alter their oral hygiene habits. They were not told what would be examined and recorded, or which teeth.

The clinical trial included the recording of plaque, tartar and gingival bleeding in selected parts of the teeth (see below). The same data was recorded at the start of the trial, after 5 weeks, and after 10 weeks (the first part of the project ended at that point). The second part of the project is now in progress, new data being recorded after a further 10 weeks → A total of four sets of clinical data recorded, all carried out by the same clinical dentist.

The quantity of plaque and tartar was graded zero, 1, 2 or 3. If there was no plaque or tartar clinically visible, this was graded zero. A grade of 1 was given if there were coatings, i.e. plaque or tartar, over 1/3 or less of the gingival area of the tooth surface examined. A grade of 2 was given if there were coatings over 2/3, and a grade of 3 meant that more than two-thirds was covered with coatings. In addition, the dentist wrote information down if she discovered any other clear clinical change in the oral cavity.

The quantity of plaque was determined from the buccal surfaces of the incisors in the lower jaw (31, 32, 41 and 42), and the palatinal surfaces of the “sixes” in the upper jaw (16 and 26). The quantity of tartar was determined on the opposing surfaces of the same teeth, i.e. the lingual surfaces of the incisors in the lower jaw and the buccal surfaces of the “sixes” in the upper jaw. Gingival bleeding was recorded at the buccal, mesiobuccal, distobuccal and palatinal surfaces in the upper jaw (11-16 and 21-26). When recording gingival bleeding, a special periodontal deep measurement probe was used which was pushed into the gingival pocket. Bleeding within 10 seconds was recorded as a bleeding surface. This method is internationally established.
The first part of the project
All trial subjects were told to take two tablets of PlaqueOff a day (divided into two doses taken together with meals) throughout the entire first part, i.e. 10 weeks. When the first part of the project is completed, the results may, among other things, be compared with earlier similar projects carried out by dentists Sune Wikner and Bert Mattson, as well as Professor Jan Bergström and staff at the Karolinska Institute.

The second part of the project
Immediately after the third recording of plaque, tartar and gingival bleeding status, all the teeth of all the trial subjects were depurated (tartar and other coatings were removed using manual instruments and ultrasound). After that, half the trial group (random selection) continued with the PlaqueOff supplement for a further 10 weeks. The second half stopped taking the PlaqueOff supplement.

The project was brought to an end after two months with the last recording of data for all trial subjects. The results are expected to be able to provide a good view of how effectively PlaqueOff can prevent the recurrence of plaque and tartar and so also gingival bleeding.

Statistical methods
Statistical calculations have been carried out with a distribution-free test, Wilcoxon’s one-sample test*.

Results
The results show that plaque, tartar and gingival bleeding are reduced perceptibly after taking the seaweed preparation PlaqueOff for 10 weeks. All positive changes are statistically assured (p < 0.01 with the distribution-free Wilcoxon’s one-sample test).

In this trial, the reduction in plaque, tartar and gingival bleeding, and hence the improvement in periodontal status, is deemed to have mainly taken place over the first 5 weeks in which the supplement was administered.

Figure 1. Average quantities of plaque and tartar at various times in relation to the start of the trial.
If we “dress up the results in clinical terms” in a more readily accessible manner, we can state that seven trial subjects experienced considerably fewer surfaces with plaque, and none had more (if the difference in the number of surfaces is two or more, this is deemed to be a clinically relevant difference). With a corresponding judgement, seven have considerably fewer surfaces with tartar, and two had, in contrast, considerably more surfaces with tartar. Fifteen trial subjects experienced considerably reduced gingival bleeding and none had considerably more bleeding (here, a difference of four or more surfaces was deemed clinically relevant).

**Discussion**

The statistical calculations demonstrate that plaque, tartar and gingival bleeding have been reduced and that the periodontal status has hereby been improved in the trial subjects during the period when they were taking the PlaqueOff seaweed preparation supplement.

As this is a restricted open clinical trial, it is necessary to exercise caution before drawing too far-reaching conclusions regarding the significance of PlaqueOff to the positive effects (see below). However, the results are interesting when viewed in relation to the results of two other recent trials, of which one was a double blind, placebo controlled trial (Jan Bergström and staff, for publication). This trial was the first one to include gingival bleeding, which is the first sign of periodontitis. However, it is not surprising that gingival bleeding, and hence the degree of inflammation in the gingiva, were reduced when there was a reduction in the formation of plaque and tartar. Measurements did not demonstrate any statistically assured difference between five and ten weeks of taking the seaweed preparation supplement. The positive effects became apparent within five weeks and then stabilised. In the above mentioned trial by Prof. Jan Bergström and staff, the quantity of plaque and tartar was measured after four and eight weeks. In this trial, a further improvement was noted in the period between four and eight weeks, and the best results were found in a sub-group that increased its
intake of PlaqueOff. This indicates a dose-response link and emphasises the fact that one should place emphasis on the dosage issue in continued trials.

This open trial demonstrates actual clinical results and so various levels of improvement in the trial subjects. Like other open trials, however, one has to grapple with various “confounding factors”, as they are known, i.e. factors which cannot be included in the calculation model but which may nevertheless have been of significance with regard to the results. For example, it is not possible to entirely rule out the fact that the patients – who are aware that they are taking part in a trial and are being given a preparation either with or without their knowledge – may start to do a better job of their oral hygiene. Nor is it possible to know with any certainty whether they took all the seaweed tablets as correctly or regularly over the entire ten-week period. For example, were they less conscientious about taking the tablets over the last five weeks?

However, the results from this trial of PlaqueOff are in line with what has been demonstrated previously and indicate clinical improvement from the PlaqueOff seaweed preparation. Continued research is important. Not least because periodontitis from a global perspective is a major problem among the adult and, above all, the ageing population.

*The statistical calculations, which will be reproduced in their entirety in the coming publication, have been implemented by Jan Weiner, statistician at the Swedish Work Environment Authority.*