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Salivary pH level and bacterial plaque evaluation in orthodontic patients treated with Recaldent[®] products

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Abstract: Dental caries and resulting tooth decay can produce a multifactorial destructive process with a very high incidence. Cariogenic bacteria attack enamel with acids that produce subsurface lesions, thereby weakening the enamel and allowing bacterial progression into the dentin. The formation of dental decay, because of demineralization of the tooth structure, can be prevented or delayed by increasing the rate of the tooth's remineralization and replacement relative to the tooth's rate of demineralization. This rebuilding of enamel may be accelerated by the addition of amorphous calcium phosphate (ACP) with the aid of casein phosphopeptide (CPP) (Recaldent[®] molecule). In this study, the role of CPP in stabilizing and releasing ACP on the tooth surface has been investigated to better understand its efficacy in the prevention of tooth demineralization in orthodontic patients. Twenty-five patients who wore fixed orthodontic appliances were enrolled in this clinical trial. It was explained to the patients that CPP-ACP would be used for 3 weeks and then suspended for an additional 3 weeks. Salivary pH evaluation, plaque pH evaluation and oral hygiene index (OHI) were performed at T0, T1 and T2. Results showed an increase in OHI level and an increase of the salivary pH (76% of the patients). Instead of plaque pH level that showed trivial results, only 48% of the patients showed a bacterial plaque pH increase. In conclusion, this study has not provided unequivocal evidence for the protective properties of Recaldent[®] molecule. Long-term studies are necessary to better understand the role of this molecule.

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Introduction

The destructive nature of the dental caries process on hard tissues in the oral cavity is well documented, but its cause is still not fully known or properly understood.

The most commonly acknowledged factors determining dental caries are bacterial plaque, dental anatomy, diet and poor oral hygiene. Most of the studies over the last two decades have provided evidence in favour of a positive association between good oral hygiene and lower caries prevalence. Moreover, today additional considerations influence the rate of dental caries: fluoride exposure, salivary flow and buffering capacity. Dental caries, an infectious disease resulting in tooth decay and eventual tooth loss, has a very high prevalence afflicting an estimated 90% of the world's population at least once in their lifetime. It may be assumed that in the prefluoride era, only 'perfect' oral hygiene was sufficient to inhibit the onset of caries. The use of fluoride, in its various forms, as a caries-preventive agent for both the individual and the community is a fundamental agent in the fight against tooth decay. Moreover, in orthodontic patients, the increased prevalence of enamel decalcification during fixed appliance therapy is partly because of the irregular surfaces of brackets, bands, wires and other attachments, which create areas for plaque build up. This causes tooth cleaning to be more difficult, and the hardware limits naturally occurring self-cleansing mechanisms, such as saliva and the movement of the oral musculature and tongue (1). These conditions, in turn, promote lower plaque pH in the presence of fermentable carbohydrates, accelerate the rate of plaque accumulation and plaque maturation, and favour the colonization of aciduric bacteria such as *Streptococcus mutans* and *Lactobacilli*. Early enamel cavities appear as white spot lesions and develop as a result of the presence of dietary carbohydrates and a saliva-modified bacterial infection (2).

Research into caries prevention is continually being carried out. A breakthrough came in 1980 when Reynolds, from the University of Melbourne, researched the anti-cavity properties of some products made of casein (3). He noted the key role that casein phosphopeptide (CPP) plays in stabilizing and localizing amorphous calcium phosphate (ACP) on the tooth surface. He also found that CPP can rebuild subsurface areas of enamel defects, including white spot lesions from dental cavities, because of its remineralizing properties. The CPP-ACP molecule acts in dual manner, by providing a source of calcium and phosphate, while also supplying a soluble format

for delivery of these essential minerals to the tooth surface. As a result, the CPP-ACP molecule was named Recaldent® (GC USA, Alsip, IL 60803) and it was inserted into the products used in clinical trials (Tooth Mousse, MI Paste; GC America). Recaldent® (CPP-ACP) is made from casein, a natural protein extracted from milk. The protective properties of milk and its derivatives are well known, but how they act on the tooth surface had previously been unknown. Recent studies have localized the molecule responsible for the protective properties of casein, namely, CPP (4). This molecule is able to bind and transport phosphate and calcium ions in the form known as ACP into the tooth (Fig. 1). Calcium phosphate is not usually soluble and, if combined with CPP, has a crystalline form which facilitates the delivery of calcium and phosphate ions available in CPP-ACP. Moreover, when applied to the tooth surface, the CPP is able to bind not only onto the enamel surface but also on the biofilm and soft tissues, thus localizing bio-available calcium and phosphate (5). The nanoclusters of ACP in CPP-ACP release calcium and phosphate ions, under low oral pH conditions, in a unique soluble form (CaHPO_3) which is then transported into the tooth structure and enables enamel and dentin regeneration (6, 7). This in turn, combined with other beneficial substances, can help fight tooth demineralization and thus restore the pH equilibrium of the mouth. In conclusion, the topical appliance of Recaldent® can consolidate the professional work of dentists and dental hygienists (8). For this study, 25 patients who wore fixed and mobile orthodontic appliances were selected. The aim of this study was to evaluate the longevity of Recaldent's molecules inside the oral cavity, by measuring the salivary pH variation, the bacterial plaque pH variation and the level of bacterial plaque.

Tooth mousse

GC Tooth Mousse (MI Paste) is a water-based, sugar-free, topical cream containing Recaldent® CPP-ACP (CPP-ACP). When CPP-ACP is applied to the tooth surface, it binds to the biofilms, plaque, bacteria, hydroxyapatite and surrounding soft tissue localizing bio-available calcium and phosphate (9, 10). Saliva will also enhance the effectiveness of CPP-ACP, and the flavour of the tooth mousse will help to stimulate saliva flow. As a general rule, the longer CPP-ACP is maintained in the mouth, the more effective the end result will be (11).

Tooth Mousse (MI Paste) composition: PH: 7.8; CPP-ACP: 10%; Ca content: 13 mg g^{-1} ; P content: 5.6 mg g^{-1} .

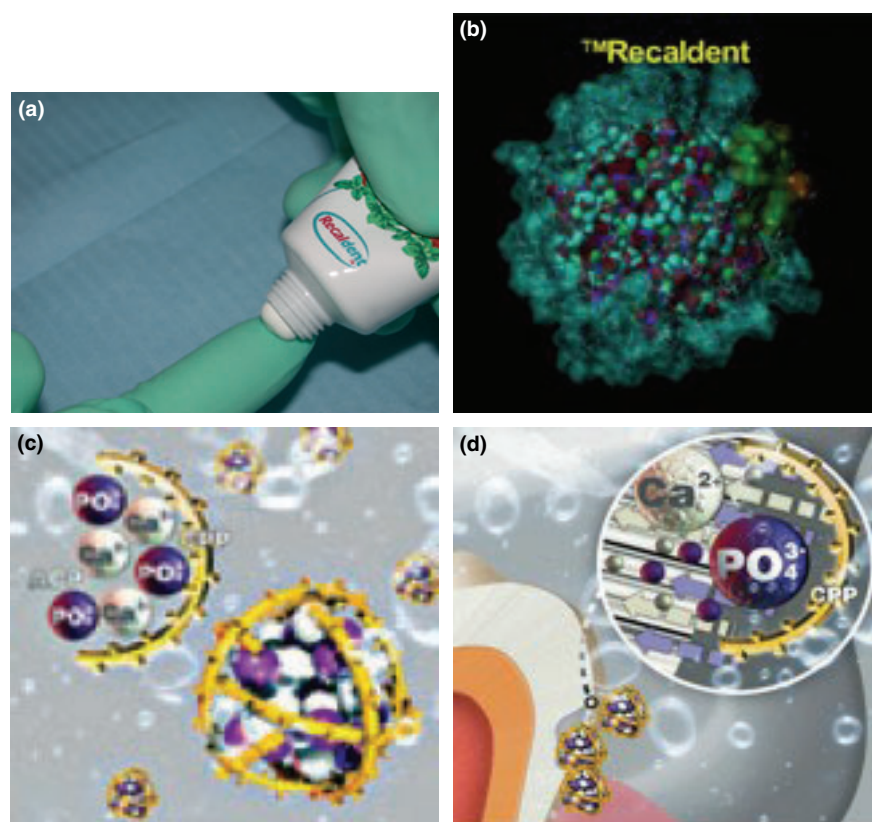


Fig. 1. Recaldent Tooth Mousse (MI Paste) (a, b); CPP-ACP action on the enamel surface (c, d). TABLE 'clinical application of tooth mousse' eliminated.

Material and methods

Clinical study

Twenty-five patients with orthodontic appliances and who consented to participate in the study were enrolled in this clinical study. It was explained to the patients that Tooth Mousse (MI Paste) would be used for 3 weeks and then suspended for further 3 weeks.

The first evaluation was performed during the first appointment ($T = 0$). The following tests were carried out:

- 1 A salivary test (Saliva-Check™; GC Europe, Leuven, Belgium) was performed to provide a salivary pH evaluation (according to the manufacturer's instructions).
- 2 A plaque test (Plaque-Check™; GC Europe) was carried out to assess the pH of the bacterial plaque (according to the manufacturer's instructions).
- 3 The oral hygiene index (OHI) was ascertained to evaluate the patients' oral status.

The total follow-up period was 6 weeks and at each appointment, the parameters were re-evaluated.

During the first evaluation ($T = 0$), tests were performed and Tooth Mousse (MI Paste) was supplied for domestic use. During this visit, the patients were asked to use the paste twice a day for 3 weeks.

On the second visit, after 3 weeks ($T = 1$), the tests were repeated and the patients were asked to stop using Tooth Mousse for the following 3 weeks.

Finally, 6-week later, during the third visit ($T = 2$), the same tests were carried out and the Tooth Mousse's (MI Paste) protective effect was evaluated.

Results

All the patients included in this study were followed carefully for 6 weeks. The following parameters were evaluated for each of the 25 patients.

Evaluation of salivary pH

1 Sixteen patients (out of the total 25 patients) showed a pH level increase after the daily use of Tooth Mousse (MI Paste). In some cases, a change from the initial level of 6.6 (acid pH) to the final level of around 7.6 was observed. This pH increase restored the neutral environment of the oral cavity (Fig. 2).

2 Four patients showed a pH increase only 3 weeks after treatment, suggesting either that the use of Recaldent® provided no benefit or that its effect could only be seen after 6 weeks.

Fig. 2. 76% of the patients showed a salivary pH level increase.

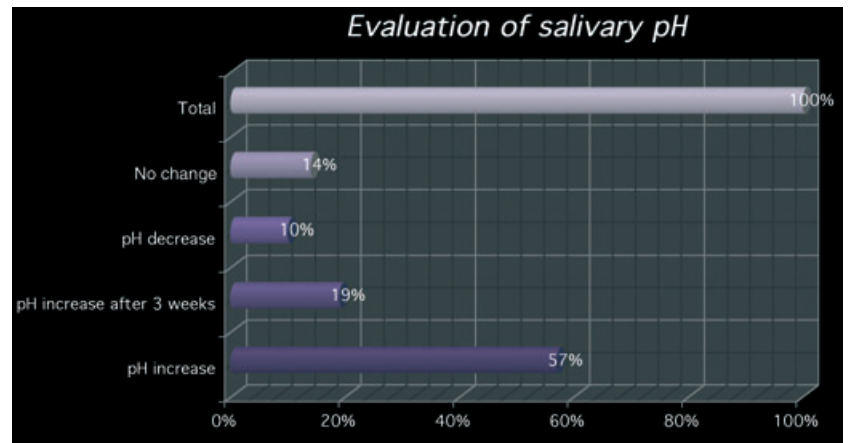


Fig. 3. 48% of the patients showed a bacterial plaque pH increase.

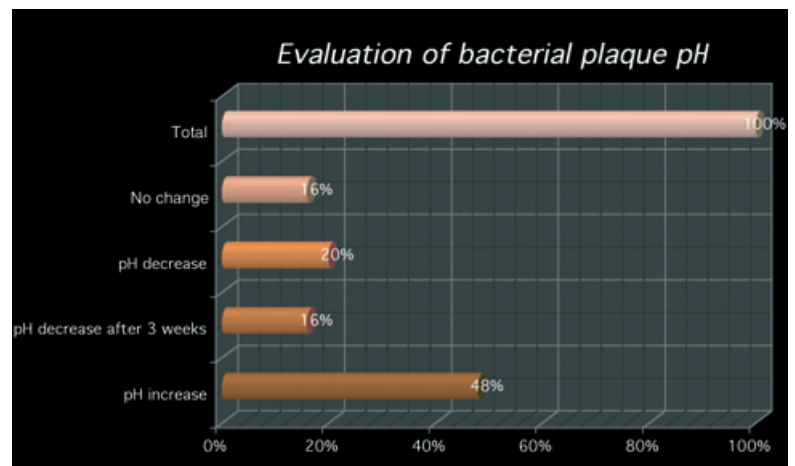
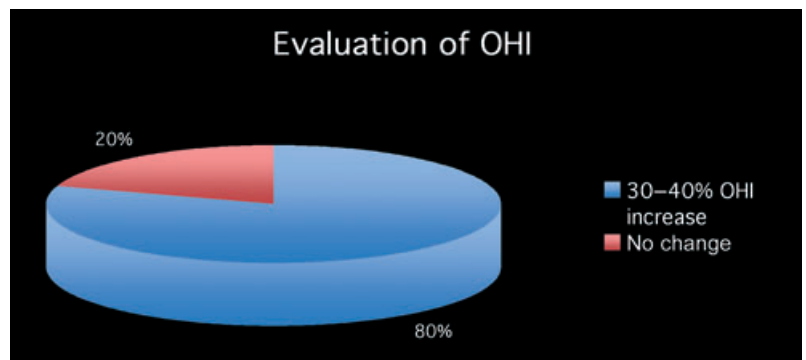


Fig. 4. The figure shows patients' OHI at T2; 20 = patient n° (80%) whose OHI improved after using Recaldent®; 5 = patient n° (20%) whose OHI was not improved after using Recaldent®.



3 Two patients showed a marked salivary pH decrease. The reason may be dietary or lifestyle factors. The low incidence of cases, however, may suggest compromised test results.

4 In three patients, the salivary pH level remained unchanged. In these cases, Recaldent® had no effect on the salivary composition.

5 Moreover, nine patients showed a salivary pH level decrease during the 3 weeks when the use of the product was sus-

pended (T2). In these patients, the product had an effect only in the first 3 weeks and for a limited period.

Evaluation of bacterial plaque pH

1 Twelve patients demonstrated an increased bacterial plaque pH with the daily use of the Recaldent®. In these patients, the paste only yielded results after 6 weeks (Fig. 3).

2 In four patients, Recaldent® unexpectedly caused a plaque pH decrease (i.e. more production of strong acid from bacterial plaque).

3 Five patients showed this plaque pH decrease during the 3 weeks in which the product was not used.

4 Four patients did not show any change in the plaque pH level during the period they were asked to use Recaldent® paste.

Evaluation of OHI

1 Twenty of the total 25 selected patients showed an improvement in oral hygiene ranging between 30% and 40% compared with the initial rate (Fig. 3).

2 Five patients did not show any improvement in oral hygiene after using Recaldent.

Finally, the study showed that patients' preferred flavour was 'strawberry'– chosen by 60% of patients. The remaining patients (40%) chose the other flavours (i.e. mint, strawberry, melon, tutti frutti and vanilla). Patients who chose vanilla flavour reported a change in taste during extended use.

Discussion

The results obtained from this study were inconclusive. Diet may have detrimentally affected the test results despite being carried out during the afternoon.

There was, however, an overall improvement in the OHI, as the above graph shows (Fig. 4). In terms of pH evaluation, Tooth Mousse (MI Paste) is a product that can have an effect on both the salivary pH and the bacterial plaque pH. However, the bacterial plaque pH showed an increase only in 48% of the patients while the salivary pH showed a higher rate (64%).

This study has not provided unquestionable evidence for the protective properties of Recaldent®. Our results may have been

marred by variables that can influence test precision, such as the level of oral hygiene, bacterial plaque acidity, diet, etc.

In conclusion, long-term studies with more test subjects are necessary to better understand the role of this molecule in the prevention of dental caries and tooth remineralization, specifically in orthodontic patients.

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