



The following study was done prior to the selection of the PERIACTIL® brand name. Where the study refers to “the gel containing the proprietary buffer”, the gel is PERACTIL®. This study was performed in Costa Rica and has been translated from Spanish to English.

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The effect of the gel containing the proprietary buffer in orthodontics

For many years, it has been observed that orthodontic apparatus when applied on teeth and neighboring gingiva, will lead to plaque accumulation, gingivitis and formation of periodontal pockets. This is easily explained by the fact that the hardware in orthodontic patients makes it difficult to remove alimentary remains when carrying out standard oral and dental hygiene.

Gingivitis characterized by edema, erythema and gingival morphological changes are common early during treatment and will lead to plaque accumulation. Plaque is the first step leading to periodontal disease and in fact periodontal pockets do form in these subjects.

Due to these problems, this doctoral thesis was conceived to test a muco-adhesive gel containing a proprietary buffer with the objective of substantiating its utility as an adjunct to orthodontic techniques, in reducing gingivitis, plaque accumulation and periodontal pocket formation.

Introduction

Patients treated with orthodontic devices are liable of developing gingival complications mainly due to the bacterial plaque that is retained by the tools employed during treatment. Professionals try to fight this disturbance by prescribing the use of dental brush, floss and mouth wash, attempting to reduce plaque accumulation and gingival inflammation. The various tools used for orthodontics for performing several techniques, independently of the design for the specific apparatus, all contribute invariably to plaque accumulation and make it quite difficult to keep tenure of the correct oral hygiene that will extend to 2 years; the common duration of the treatment.

Several recent design improvements of the tools have been introduced, seeking to reduce spaces that are difficult to clean and leaving better access to the dental surfaces, supposedly facilitating plaque removal. Nonetheless, gingival pathology remains in a large number patients that carry the corrective tools.

The gel containing the proprietary buffer, which according to its manufacturer has efficacy in controlling periodontitis (pyorrhea) and is useful in treating various mucosal events including the pharynx and causing frequency of upper respiratory events to lessen, would be interesting to test if it is useful in the



inflammatory complications that can disturb orthodontic procedures. This is the purpose of this work. Positive results for this application would be suggestive that benefits derived from the use of the gel containing the proprietary buffer are also amenable to other branches of orthodontics.

So this study will test the efficacy of the gel containing the proprietary buffer in eliminating gingivitis and other complications stemming from bacterial plaque accumulation in orthodontic procedures, in age groups of 16 to 23 years.

Antecedents

The gel containing the proprietary buffer is a new product and relatively few studies can be found regarding its efficacy. However, references can be extracted from studies done for a predecessor product (Statactil), since the gel containing the proprietary buffer is closely related to this product in view of the fact that they have the same active principle. Acute and sub-acute toxicity of this active principle was tested in the last quarter of 2000 with excellent results, showing the LD50 to be at 6178.32 mg/Kg and no signs of organ damage for the sub-acute tests.

Regarding the disturbances created by the orthodontic corrective tools in adolescents that practice good oral hygiene and with a low plaque index, studies have shown that they develop generalized but moderate gingival hyperplasia, one to two months after the corrective apparatus is installed. It is generally accepted that malocclusion, except in very severe cases, has little or no relation with gingivitis but rather is closely related to bacterial plaque accumulation, according to Hosl and Zachrisson in (Schulanger, Youdelis, 1977)

In a non-controlled series of 15 patients, gingivitis was improved by the gel containing the proprietary buffer remarkably well. A controlled study of patients with serious pyorrhea that required surgical treatment shows that the gel containing the proprietary buffer used during surgical treatment and for 14 weeks thereafter, will impressively diminish number and depth of periodontal pockets and restore dental fixity. In this study there was a relative improvement of radiological alveolar bone density. Further studies are needed to validate the bone density improvement. In two cases of acute necrotic pyorrhea, the remission was remarkable 14 weeks after treatment; Zarate and Gutiérrez. (2003).

Problem and objectives

Patients receiving orthodontic treatment have difficulty in controlling plaque buildup. There will be a response in the tissue to either plaque accumulation and/or to the vectors exerted by the external forces applied on the ligament. These forces will disturb vascularity and bone, which is reabsorbed by osteoclasts in areas receiving tension and which will tend to be newly formed by odontoblasts in the areas receiving pressure; Bascones (1998).

Therefore the intent is to study the effect of the gel containing the proprietary buffer in orthodontic patients, due to its muco-adhesive properties and its composition. The efficacy of the gel containing the proprietary buffer in patients that carry fixed corrective tools will be studied.



The following objectives are established:

General

Evaluate the favorable clinical changes that can be detected in patients in age groups of 16 to 23 years, treated with fixed orthodontic ware at the Clinica de Especialidad Medica Ulacit and Dr. Truque Private Clinic in a period extending from December 2002 to March 2003.

Specific

1. Establish oral health of patients prior to treatment by taking the plaque index and sounding of periodontal pouches and comparatively observe the evolution of patient during and at 3 months after treatment. In all, 3 evaluations of patient will be carried out.
2. Measure gingivitis index and observe its evolution as indicated above in n° 1.
3. Setup 3 study groups of 20 patients each, one using the gel containing the proprietary buffer plus standard oral hygiene; another using placebo and oral hygiene; a third as negative control using only oral hygiene.
4. Complement the clinical findings with extensive oral photographic material.

THE GEL CONTAINING THE PROPRIETARY BUFFER

The gel containing the proprietary buffer was created from the Statactil solution. Due to the remarkable results observed in the study by Zarate and Gutierrez in severe pyorrhea, a special gel to be used on gums, oral cavity and pharynx became a necessity. The result was an edible and non-carcinogenic gel that uses the same active principle OXCP. Muco-adhesiveness can be obtain in fully humid conditions, so that it will adhere to all mucosal surfaces of the oral cavity and pharynx, specially gums. It maintains pH equilibrium around 7 in the oral cavity so that it will not de-mineralize enamel. It is composed from two gel systems, one based on modified starch at 5.5%, gelatin with xanthan/guar gum and xylitol. The second system is highly loaded with xylitol, maltitol and sorbitol dispersed in water and hydroxyethylcellulose. Final content of xylitol is 11.5% and with a total 15% of polyols. During the processing of these systems a proprietary active principle is added. This active principle is designated with the OXCP abbreviation and can be considered as GRAS (Generally Regarded as Safe) substance or fit for a *medical device*. Others ingredients are glycerine, emulsifiers, menthol and salicylic acid. The final result is a semi-IPN of two organic systems with muco-adhesive properties. The protective properties of the gel in the pharynx have been exploited in helping asthmatics forestall frequent upper respiratory events. Other experiences in veterinary have shown that boosting mucosal immunity is possible with OXCP. Finally physiological stimulation of salivation has been observed in individuals using the gel containing the proprietary buffer, condition that is thought will accrue the anti-carcinogenic possibilities of the product.

Indications

The gel containing the proprietary buffer is recommended to be used three times daily after having practiced standard oral hygiene. The dose is at will, the patient extruding from the tube a piece of gel



on his fingertip and then massaging the product over his gums. The rest he will distribute in the oral cavity with his tongue and may swallow whatever is left at the end. The patient will discover that the swallowed portion will not progress further than the pharynx. Usually a 0.5 to 1 cm in length portion will suffice.

Method

Set up 3 study groups of 20 patients each, one using the gel containing the proprietary buffer plus standard oral hygiene; another using placebo and oral hygiene; a third as negative control using only oral hygiene. Record changes during two evaluations following the initial one prior to treatment taking into account: Silness and Loe plaque and gingival index, plus periodontogram. Gather photographic material to complement clinical observations.

Results and conclusions

The gel containing the proprietary buffer was effective in diminish bacterial plaque index during orthodontic treatment in view of the fact that prior to initiation of the intervention the groups had a mean index of 1.27 for the proprietary buffer group, 1.64 for the placebo group and 1.33 for the negative control group. At the third evaluation these group had improved 59% for the proprietary buffer group, 31% for the placebo and 7.5% for the control. The ANOVA test showed statistical significant changes with absolute diminution of 0.75. 0.51 and 0.10 respectively.

From the periodontal viewpoint, prior to treatment the proprietary buffer group presented a minimum depth in pouches at 4mm with a 15.22% incidence and a maximum at 7mm with a 0.11% incidence. In the placebo group the minimum depth was at 4mm with 17.6% incidence and a maximum of 5mm with 1.72% incidence. In the control group the minimum depth was 4mm with 10.59% incidence and the maximum 6mm with 0.27% incidence. After treatment, the proprietary buffer group showed at the third evaluation a reduction of 53.3% of the 4mm pouches and a 94.6% reduction of the 6mm ones and a complete disappearance of the 7 mm pouches. The placebo group showed a diminution of 4mm pouches of 24.9% and of 63.9% in the 5mm ones. The control group showed an increase of 15% in the 4mm pouches; the 5mm pouches diminished 41.4% and the 6mm diminished 14.8%.

The gingival index prior to treatment was 1.13 for the proprietary buffer group, 1.35 for the placebo group, and 1.12 for the control group. At the third evaluation the index was at 0.47 for the proprietary buffer group showing a 58.41% reduction. The placebo group finished at 1.04 showing a 22.9% reduction. The control group ended at 1.15 with a 2.6% reduction. The ANOVA test shows a statistically significant difference between changes shown by the proprietary buffer group with respect to the Placebo group.

In spite of the results with the proprietary buffer being categorical, it is very interesting to single out the placebo group results properly. No ANOVA test is shown between these results and the negative control group. However it is clear that this molecule presents significant results on its own. The presence of xylitol in the placebo formulation, confirms what has been revealed about this remarkable molecule in the literature. Also very significant is that xylitol in these formulations



doesn't go beyond 12% concentration giving merit to the prolonged contact that muco-adhesiveness offers and the enhancement that this route will cause at the bioavailability end. This is quite relevant when evaluating the effect of xylitol in the oral cavity, if somehow it can be made to adhere to the mucosa. Then the matrimony of xylitol with OXCP seems that it couldn't be a better situation. According to the results observed, current sources of xylitol could be made to multiply by 9 in order to make benefits available to huge populations and improve oral health at large. Other devices like pastilles, lolly-pops, chewable tablets and chewing gum could be tested with the OXCP/xylitol combination to see if these remarkable outcomes can be effectively made available to masses in simpler and more economical presentations.

Finally the fact that both the "placebo" and the gel containing the proprietary buffer are effective in presence of metallic devices that stay in the oral cavity for many months deserves a special mention. The devices on the other hand, are not affected by the gel containing the proprietary buffer or xylitol. Photographic material speaks on its own, adding worth to the clinical evaluations.

Recommendations

For specialists and orthodontists

- Orthodontists should be more aware of consequences that metallic devices can cause in the gingival.
- The gel containing the proprietary buffer is ideal for fighting such changes, since it combats effectively common complications and will not affect the devices.
- The gel containing the proprietary buffer is unique in fighting gingival inflammation
- Further studies regarding pH in the bacterial plaque are worth pursuing

For patients receiving orthodontic treatment

- The gel containing the proprietary buffer can be freely used in orthodontics, since it has been scientifically demonstrated that it is very effective in correcting complications that are liable to occur when the orthodontic devices are used.
- Since the use of the gel containing the proprietary buffer is safe and simple, patients can benefit from enhancing their mucosal defenses against upper respiratory events, if the manufacturer's claims can be substantiated.