

EFFECTIVENESS OF A TOPICAL SALVE (DYNEXAN®) ON PAIN SENSIVITY AND EARLY WOUND HEALING FOLLOWING NONSURGICAL PERIODONTAL THERAPY

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Abstract

The purpose of the present study was to evaluate clinically the effect of an anaesthetic gel (lidocaine 20mg/g as active agent) on pain sensitivity and early wound healing following nonsurgical periodontal therapy. A total of 40 patients with chronic periodontitis were enrolled in this randomized, split-mouth, double-blind, placebo-controlled clinical trial. Each subject had 3 sites in each of 2 contra-lateral jaw quadrants with a probing pocket depth (PPD) of ≥ 5 mm and bleeding on probing (BOP+). All experimental sites received scaling and root planing without local anesthesia followed by irrigation with sterile saline and assessment of pain sensitivity using a standardized Visual Analogue Scale (VAS). After treatment, the patients randomly received the active or placebo gel into the periodontal pockets and overall pain was again assessed immediately after debridement and after 10, 20 and 30 minutes. The VAS showed a statistically significant ($p \leq 0.0001$) reduction in reported pain, favoring the active gel over the placebo at all 3 different points in time. After 30 minutes the median VAS score was 0.3 in the Dynexan® group as opposed to 1.7 in the placebo-treated group ($p \leq 0.0001$). In terms of wound healing no differences were found between the test and control sites after 1 week. The results of the study showed that the anaesthetic gel was statistically more effective than the placebo in reducing pain following nonsurgical periodontal therapy. However, in terms of early wound healing no significant differences were seen between the two treatment sites.

Key words: Topical salve, anesthesia, pain sensitivity, wound healing

INTRODUCTION

The effectiveness of nonsurgical periodontal therapy to reduce gingival inflammation, decrease probing depths and to prevent further progression of periodontal disease has been shown in numerous clinical trials (Ramfjord 1990, Renvert et al. 1990, Egelberg and Claffey 1994). Badersten et al. (1981, 1984a, 1984b) have studied extensively the effects of nonsurgical periodontal therapy on single rooted teeth in moderate and deep pockets demonstrating a reduction in pocket depth irrespective of initial pocket depth, operator or method of instrumentation. The changes

in pocket depth were accomplished by a combination of gingival recessions and improved probing attachment levels. Periodontal scaling procedures or even diagnostic procedures like probing of pocket depths are often accompanied by painful experiences for the patient. Therefore most of the periodontal scaling procedures performed involve some kind of anesthesia and are either a nerve block or infiltration. Although the nerve block/infiltration anesthesia provides sufficient elimination of pain, the main drawbacks are the pain of needle insertion, duration of action and inconvenience due to soft tissue anesthesia, which may limit patient acceptance. In a study by Milgrom et al. (1997) more than 25 % of adult patients exhibited some fear of dental injections and almost 5 % of the questioned adults avoided, cancelled or did not appear for dental appointments because of fear of dental injections. Thus, newer techniques involve the use of topical agents, like e.g. an anesthetic gel containing lidocaine plus prilocaine (Oraqix®) or the use of a lidocaine transmucosal delivery system (DentiPatch™) in order to make treatment more comfortable and convenient. The intrapocket anesthetic (Oraqix®) as well as the transmucosal lidocaine patches (DentiPatch™) have been shown to provide sufficient pain control for therapeutic scaling and root planing procedures (Donaldson et al. 2003, Perry et al. 2005). An anesthetic mouth gel (Dynexan™, Kreussler, Wiesbaden, Germany) containing lidocainhydrochlorid 20 mg/g as active agent has been developed to provide pain control of the oral mucosa. The objectives of the present study were to evaluate clinically the effect as well as the safety aspects of an anaesthetic gel (Dynexan™) compared to a placebo on pain sensitivity and early wound healing of soft tissues following nonsurgical periodontal therapy. The study also investigated the patients' experience to pain during the scaling and root planing procedures performed without local anesthesia.

MATERIAL AND METHODS

A total of 40 patients (24 females, 16 males), aged 29-73 years (mean age: 55 ± 6.5 years) with moderately advanced chronic periodontitis were included in this split-mouth, randomized, double-blind, placebo controlled clinical trial of one-week duration. Criteria for inclusion in the study were: (1) no systemic diseases

that could influence the therapy, (2) presence of three tooth surfaces in each of two contra-lateral jaw quadrants with a probing pocket depth of ≥ 5 mm and bleeding following probing (BOP +), (3) one pair of sites with a PPD ≥ 6 mm, (4) experimental teeth must have a vital pulp or be asymptomatic after root canal treatment, (5) no periodontal debridement in the last 12 months. In addition exclusion criteria were long-term medication, systemic use of antibiotics within the last 6 months, systemic diseases and disorders affecting wound healing and psychiatric disorders that would preclude scaling and root planing. Pregnant women were also not eligible for the study. All subjects were given verbal and written information concerning the study and gave their written consent prior to the clinical examination. The study was approved by local ethics review board and was performed in agreement with the declaration of Helsinki. Following a screening examination, the patients were given instruction in supragingival plaque control measures and one session of scaling and root planing. The nonsurgical debridement was carried out on all teeth, except those that were selected as the experimental teeth (6 teeth per patient). After one week of self-performed plaque control the baseline examination of the oral cavity and the experimental teeth was performed and included assessment of probing pocket depth (PPD), bleeding on probing (BOP), Gingival-Index (GI, Loe 1967), Plaque-Index (PII, Loe 1967) as well as identification of hypersensitive teeth by the use of compressed air. All measurements were performed at baseline and 1 week following treatment by a blinded examiner using the same periodontal probe (PCP 15, Hu-Friedy, USA). The measurements were performed at six sites around all experimental teeth. Bleeding after probing was recorded as presence (+) or absence (-) within 15 sec. following pocket probing. The operator who performed the probing at the baseline examination also carried out the scaling and root planing procedure. Following initial examination the experimental teeth were subjected to a single session of scaling and root planing utilizing conventional curettes to remove pocket epithelium and granulation tissues. The periodontal debridement was performed without local anesthesia. The experimental and control sites were then carefully irrigated with sterile saline until no bleeding from the pocket could be detected. After instrumentation and irrigation with saline the active or placebo was randomly applied subgingivally in the periodontal pockets. The gel was delivered subgingivally by using a standard 30-gauge short needle placed at the bottom of the pocket until the pocket was over-filled. The subjects' overall pain from periodontal debridement was assessed immediately after debridement and after 10, 20, 30 minutes using a horizontal Visual Analogue Scale (VAS) ranging from 0-10 with the left endpoint marked "no pain" and the right endpoint marked "worst pain imaginable". Possible adverse events were monitored during the treatment and until the follow-up after one week.

All statistics were performed by SPSS (11.0 for windows). For the clinical parameters PPD, GI and PII data were expressed as mean values \pm standard deviation. The clinical parameter hypersensitive teeth by the

use of compressed air was recorded as dichotomous measures at the experimental and control sites. For the comparison of the two treatment modalities the paired t-test was used. P-values < 0.05 were considered as statistically significant.

RESULTS

All 40 patients recruited into the study completed the trial and were included in the statistical analysis. Each of the 40 patients contributed with 6 sites for the study with a total of 240 periodontal sites. No statistically significant difference ($p \geq 0.05$) was observed at baseline neither after 1 week between the groups for the measured parameters probing pocket depth (PPD), sum of plaque and gingival scores (Figs. 1 - 2). The mean values for probing pocket depth (PPD) decreased from an average of 5.5 ± 0.8 mm at baseline to 5.1 ± 0.8 mm after 1 week in the test group and from 4.6 ± 0.9 mm to 4.3 ± 0.9 mm in the control group. No statistically significant difference was found at 1 week post-treatment. The plaque scores showed reduced values after 1 week for both groups (Fig. 1). However, there was no statistical difference ($p \geq 0.05$) when test and control sites were compared. The mean GI score at baseline was 1.8 ± 0.6 for the control sites and 1.7 ± 0.6 for the test sites. After 1 week the corresponding data were 1.5 ± 0.7 versus 1.4 ± 0.6 (Fig. 2).

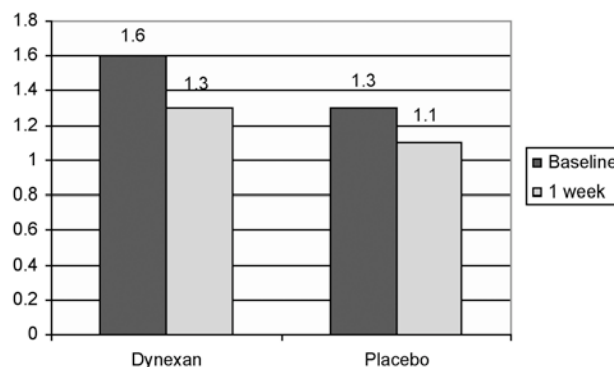


Fig.1. The mean Plaque-Index (PII) at baseline and after 1 week.

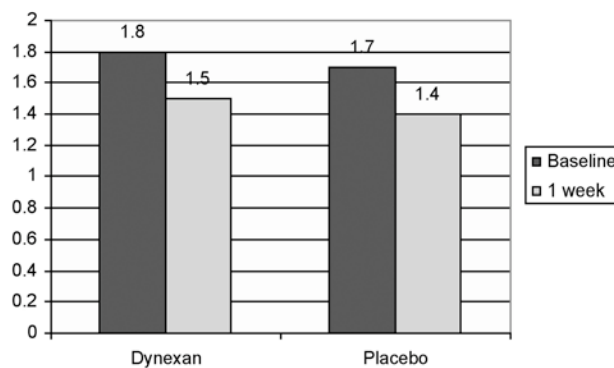


Fig.2. The mean Gingival-Index (GI) at baseline and after 1 week.

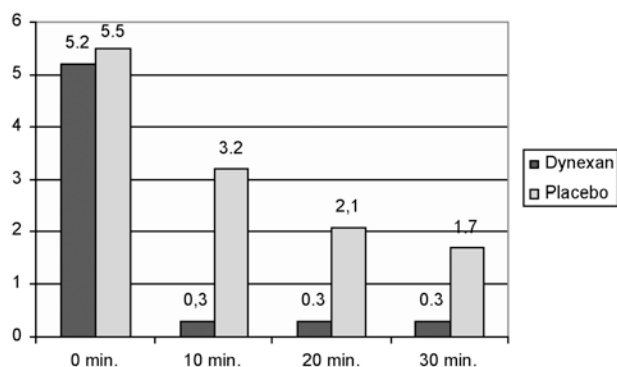


Fig. 3. The pain reduction as assessed by a VAS scale (0-10) after scaling/ root planing and application of either Dynexan or the Placebo gel.

The overall VAS pain score, assessed after completion of scaling and root planing was 5.2 ± 1.4 in the active group and 5.5 ± 1.4 in the placebo group (Fig. 3). No significant differences ($p \geq 0.05$) between the two groups were seen at this point of time. The mean VAS pain score decreased in the anesthetic gel group from 5.2 ± 1.4 immediately after scaling and root planing to 0.3 ± 0.1 after 10 min. and remained at 0.3 after 20 and 30 minutes. In the placebo group the mean VAS score decreased from 5.5 ± 1.4 to 3.2 ± 1.9 after 10 min., 2.1 ± 1.6 after 20 min. and 1.7 ± 1.0 after 30 min. The VAS showed a statistically significant ($p \leq 0.0001$) reduction in reported pain for both groups, favoring the active gel over the placebo at all 3 different points in time ($p \leq 0.0001$). The proportion of teeth demonstrating dentin hypersensitivity did not increase in both groups following the treatment procedure and there was no statistical significant difference ($p \geq 0.05$) between the groups. There were no local reactions or adverse events, like e.g. numbness and soreness of the throat or the tongue or discomfort during application of the gel. No signs of systemic toxicity or mucosal irritation were seen during the trial.

DISCUSSION

The results of the present study have shown that the subgingival application of a topical anesthetic mouth gel (Dynexan™) following nonsurgical periodontal therapy was significantly more effective in reducing pain compared to the placebo for a duration of about 30 minutes. The application of Dynexan™ resulted in a significantly greater reduction in reported pain as assessed by using a VAS. The use of a VAS for pain scoring has been evaluated in several studies for different conditions (Luria 1975, Scott and Huskisson 1976) and therefore the VAS represents an adequate method for measuring subjective pain. However, due to the subject nature of VAS an over or underestimation of the efficacy of the test gel can not be precluded. The present study indicates that most of the patients experience scaling and root planing as a painful periodontal procedure. This observation is supported by data from findings by Svensson et al. (1994). They reported that about 2/3 of patients associate gingival scaling with some degree of pain and unpleasantness. It is un-

known to what extent patients refuse to return for periodontal care as a result of this experience. The efficacy of the anesthetic mouth gel in the present study in pain reduction after intra-pocket application is similar to results from studies evaluating EMLA® cream (lidocaine plus prilocaine) for the prevention of procedure related pain in the mouth (Svensson et al. 1994) or Oraqix® (lidocaine plus prilocaine) for pain control for scaling and root planing (Jeffcoat et al. 2001, Magnusson et al. 2003). Thus, Oraqix® has been shown to provide efficient pain control during scaling and root planing after an application time of 30 s, with a mean duration of action of about 17 to 20 minutes and with a high acceptance among the patients (Friskopp et al. 2001). A study by Matthews et al. (2001) also demonstrated that the majority of periodontal patients would rather prefer an anesthetic gel than an injection anesthesia.

No side effects like inflammation or pain were reported at sites subjected to Dynexan™ application. In addition the use of Dynexan™ did not alter periodontal healing in any way. In this context, however, the findings from Roesch et al. (2005) may be of importance as they reported a case of a life-threatening immediate-type hypersensitivity caused by Dynexan™ and which was a positive reaction to Meyprogat™, an ingredient of Dynexan™.

The changes in gingival scores and probing pocket depth in both sites due to the short-term effect of nonsurgical periodontal therapy are consistent with previously reported data (Morisson et al. 1980, Boretti et al. 1995) and were not statistically significant between the test and the control sites. Therefore, in terms of early soft tissue wound healing no beneficial effect of the test gel compared to the placebo could be observed after 1 week.

In conclusion, results from the present study clearly demonstrated that the subgingival application of Dynexan™ was overall statistically significant more effective than the placebo in reducing pain following nonsurgical periodontal therapy. Dynexan™ showed no clinical signs of mucous membrane irritation and is safe following application in periodontal pockets. However, further studies are needed to investigate if Dynexan™ may offer an alternative to injection anesthesia as well as the long term effect on the healing of soft tissues following nonsurgical periodontal therapy.

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Received: September 12, 2007 / Accepted: March 1, 2007

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