A Clinical Study of Root Surface Conditioning with an EDTA Gel. I. Nonsurgical Periodontal Treatment

Leif Blomlöf, DDS, PhD*/Ewa Bergman, Dent Hyg**/ Åsa Forsgårdh, Dent Hyg**/Lena Foss, Dent Hyg**/ Anita Larsson, Dent Hyg**/Barbro Sjöberg, Dent Hyg**/ Liliianne Uhlander, Dent Hyg**/Björn Jonsson, BA, PhD***/ Johan Blomlöf, DDS, PhD*/Sven Lindskog, DDS, PhD****

The present study was undertaken to investigate if subgingival administration of an EDTA gel has any adjunctive effect to subgingival and supragingival root debridement. The investigation was performed in one study center involving 6 clinical investigators and 91 patients. The patients were selected from 2 patient populations: 41 were included from a consecutive referral material on a voluntary basis, and 50 were included from a maintenance care material at the clinic. No significant differences were found between the EDTA-treated and control groups with respect to clinical attachment gain or probing pocket depth reduction. The referral patients showed a significant improvement of pocket depth and attachment gain compared to maintenance care patients at the clinic. In multiple regression analyses, it was found that patients with small attachment losses at baseline responded better to treatment than patients with severe periodontitis. Also, in multivariate analyses, referral patients responded better than maintenance patients when controlling for other predictors. (Int J Periodontics Restorative Dent 2000;20:561-565.)

Home care with toothbrushing and interproximal flossing has only a limited effect on probing depth reduction in patients with periodontitis. However, when professional plaque control is combined with nonsurgical root debridement, significant probing depth reduction can be expected.1 There seems to be no difference with respect to reduction of probing depth and reduction of bleeding scores following root debridement with hand or ultrasonic instruments.2 Even deep intrabony defects in single-rooted teeth and flat molar surfaces show favorable response to nonsurgical periodontal treatment. In contrast, sites involving furcations appear resistant to nonsurgical treatment (for review see Egelberg3). In such sites, hope has been put into antimicrobial preparations. However, subgingival administration of antimicrobial preparations, such as hydrogen peroxide 3%, chlorhexidine (0.1% to 2.0%), iodine (0.05%), or antibiotics, has shown no or very little adjunctive effect to nonsurgical root debridement in both single-rooted teeth and furcation involvements (for review

*Associate Professor, Department of Basic Oral Sciences, School of Dentistry, Karolinska Institute; and Public Dental Service, Stockholm County Council, Stockholm, Sweden.
***Associate Professor, Department of Women and Child Health, St Göran’s Hospital, Karolinska Institute, Stockholm, Sweden.
****Professor, Department of Basic Oral Sciences, School of Dentistry, Karolinska Institute, Stockholm, Sweden.

Reprint requests: Dr Leif Blomlöf, Department of Preclinical Oral Sciences, School of Dentistry, Box 4064, S-141 04 Huddinge, Sweden.
see Egelberg\(^3\)). Thus, the basis of periodontal therapy is still mechanical root debridement, with the aim of creating a root surface conducive to periodontal healing.

A periodontitis-involved root surface is hypermineralized\(^4\) and nonbiocompatible because of its adsorbed bacterial toxins.\(^5\) Low-pH etchants have been used to detoxify such surfaces during periodontal surgery. For many years, no attention was paid to possible side effects on adjacent periodontal tissues (for review see Lowenguth and Blieden\(^6\)). Recently, etching with low-pH etchants has been challenged by etching at neutral pH (with ethylenediaminetetraacetic acid [EDTA]) because in vitro and in vivo studies in animals and humans have shown that EDTA is superior to low-pH etchants with respect to:

- Collagen exposure\(^7-9\)
- Preservation of tissue vitality\(^10\)
- Promoting experimental periodontal healing in an animal model\(^11\)

Furthermore, an EDTA gel preparation applied in combination with subgingival root debridement has recently been shown to remove smear and expose collagen in situ in human periodontitis-affected teeth.\(^8,12\) In view of these favorable preclinical results with EDTA, the present study was undertaken to investigate if subgingival administration of an EDTA gel has any adjunctive effect to subgingival and supragingival root debridement on probing depth reduction and periodontal attachment gain, allowing for influence on healing from smoking as well as postsurgical oral hygiene.

### Method and materials

#### Patients

The investigation was performed in one study center involving 6 clinical investigators and 91 patients. The study was performed according to the Declaration of Helsinki. The patients were selected from 2 patient populations suffering from chronic adult periodontitis: 41 were included from a consecutive referral material on a voluntary basis, and 50 were included from a maintenance care material at the clinic. These patients had all undergone periodontal surgery during the past 5 years.

At examination, the patients were required to have at least one proximal site with a probing pocket depth of 5 mm or more. The teeth were randomly assigned to 2 treatment groups according to a randomization list, which resulted in slightly different numbers in the groups. The following criteria for exclusion were used:

- Patients under 30 years of age
- Patients who failed to maintain good oral hygiene
- Patients with systemic conditions that would preclude nonsurgical periodontal therapy
- Patients who were allergic to antibiotics
- Patients with acute infectious lesions in the areas intended for treatment
- Teeth with established endodontic-periodontal lesions
- Oral and facial tooth surfaces
- Teeth with furcation involvements

#### Test preparation

The EDTA gel preparation (24%, pH 7) was made up aseptically, heat sterilized, and stored at room temperature (batch No. 40150018, Apoteksbolaget Production Unit). Sterile saline was purchased from the Swedish Government Pharmaceutical Agency (Apoteksbolaget Production Unit).

#### Study design

The patients were instructed in oral hygiene. The sites selected for treatment, one in each patient, were randomly assigned to test (EDTA) or control (saline) treatments according to a randomization table. The site, which was defined as the deepest part of a proximal area selected for periodontal treatment, was anesthetized and subgingival root planing performed as required. The treated area was rinsed with saline for 20 seconds (group 1). The same treatment was performed in group 2 with the addition of etching the root surface in the pockets with EDTA at pH 7.2 for 2 minutes. The EDTA preparation was applied with a syringe. Following etching, the
treated areas were rinsed with saline for 20 seconds. Tobacco habits and possible posttreatment complications were recorded.

Prior to treatment (at baseline) and 6 months after subgingival root planing, presence or absence of plaque, bleeding on probing, probing pocket depths, and clinical attachment levels were registered in the experimental sites with periodontal probes (Hu-Friedy) by the same operator that performed the treatment. The cementoenamel junction or a supragingivally located restoration was selected as the reference point for measurements of attachment levels. On standardized radiographs, periodontal breakdown was measured and evaluated, and horizontal as well as vertical destructions were recorded. To be classified as vertical destruction, the site had to be at least 2 mm in the vertical dimension.

Evaluation of healing was based on comparisons of clinical registrations from baseline and 6 months posttreatment. Changes in probing pocket depth and clinical attachment level were calculated. Inquiries about subjective symptoms and discomfort were made at each recall visit. Any local and general reactions not normally encountered after treatment were recorded.

During the phase of clinical healing, all patients were subjected to professional tooth cleaning comprising oral hygiene instruction and removal of visible plaque at least every month. Until the final examination 6 months posttreatment, the interval between recall appointments was adjusted to the individual patient's capacity to maintain adequate oral hygiene. Following treatment, no subgingival instrumentation was performed for 6 months.

Statistical methods

Conventional statistical methods were applied. For between-groups comparisons, the nonparametric Mann-Whitney test was used. For within-groups comparisons, the Wilcoxon signed ranks test was applied. Multiple regression analysis was applied using the predictors age, sex, and baseline measurements when analyzing the outcome variables attachment gain and pocket depth reduction.

Results

Of the 91 sites that underwent treatment—45 control sites and 46 treated with the EDTA preparation—all were reexamined. Patient population characteristics and means for treatment variables are presented in Table 1. There were no statistically significant differences with respect to gender, age, Plaque Index, smoking habits, or pocket depth and attachment level at baseline between the 2 groups. Bleeding and plaque scores did not differ significantly between the treatment groups at baseline or at 6 months posttreatment. Over the 6-month observation period, bleeding scores were significantly reduced for both treatments (P < 0.04). No adverse effects were registered for the treatments.

Outcome statistics on clinical data for comparisons are presented in Table 2. No significant differences were found between the EDTA-treated and control groups with respect to clinical attachment gain or probing pocket depth reduction, either for the whole material or for subgroups such as referral or maintenance patients, nonsmokers, or horizontal and vertical destructions (Table 3). One subgroup, referral patients, showed a significant improvement of pocket depth (P < 0.001) and attachment gain (P < 0.004) compared to maintenance care patients at the clinic.

In multiple regression analyses, the only predictors that showed a significant association with the outcome variables were attachment at baseline (P < 0.06) and referral patients (P < 0.02). Patients with a small attachment loss at baseline responded better to treatment than patients with severe periodontitis. Also, in multivariate analyses referral patients responded better than maintenance patients when controlling for other predictors.
Discussion

In the present study 91 patients with 91 sites were treated. In an ideal situation each patient should have 2 comparable sites, one control site and one site treated experimentally. In practice, this situation is rarely encountered. The results of the statistical analysis at baseline justify comparisons of treatment results.

The results failed to demonstrate any significant differences between control and EDTA treatments with respect to probing pocket depth reduction and clinical attachment gain. Thus, EDTA etching of root surfaces in the present study did not contribute to the elimination of periodontal pockets or increase clinical attachment when combined with conventional nonsurgical periodontal therapy. However, such therapy only aims at eliminating periodontal pockets and maintaining the status quo with respect to clinical attachment level.

The present study, however, emphasizes patient susceptibility to periodontal disease in that patients with a small attachment loss at baseline responded better to treatment than patients with...
severe periodontitis. In multiple regression analyses, the only predictors that showed a significant association with the outcome variables were attachment at baseline and referral patients. It has previously been shown that the only reliable measure of susceptibility to marginal periodontitis is previous disease history, specifically radiographic attachment loss. Interestingly, referral patients responded better than did maintenance patients. This may be because of the fact that maintenance care patients at a specialist clinic have already expended their initial healing potential, whereas referral patients still may show significant improvement of pocket depth and attachment from improved oral hygiene and additional root planing.

EDTA application in combination with nonsurgical periodontal therapy failed to add to the clinical healing result. Thus, further studies are justified to evaluate the precise clinical role of EDTA conditioning of root surfaces.

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References