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Efficacy of Carisolv™ as an Adjunctive Therapy to Scaling and Root Planing on Subgingival Calculus Removal

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The purpose of this study was to evaluate the effectiveness of subgingival application of Carisolv™ gel as an adjunctive therapy to scaling and root planing (SRP) on calculus removal compared to conventional instrumentation. Forty-five teeth requiring extraction due to severe periodontal disease were randomized to the following treatments: 1) SRP alone; 2) placebo gel + SRP; 3) Carisolv™ gel + SRP. Either test or placebo gel was applied subgingivally for 1 min and then the root were instrumented until a smooth and calculus-free surface was achieved. Instrumentation time and the number of strokes required were recorded. After extraction, the efficacy of root surface instrumentation was measured by percentage of remaining calculus. There was no statistically significant difference ($p>0.05$) between the treatment groups regarding either time required for instrumentation or the percentage of residual calculus. The subgingival application of Carisolv™ gel prior to SRP did not provide any additional benefit to root instrumentation compared to scaling and root planing alone.

Key Words: scaling and root planing, periodontal treatment, calculus, Carisolv™.

INTRODUCTION

In periodontal diseases, the root surface is exposed to the subgingival environment and bacterial plaque. Exposure to crevicular fluid as well as to enzymes and metabolites produced by subgingival plaque bacteria induces physical and chemical alterations on root cementum (1). Additionally, periodontitis-affected root surfaces frequently have dental calculus. Dental calculus formation results from calcification of microbial plaque on tooth surface. Whatever the mineral composition is, the surface of dental calculus always remains covered with dental plaque, endotoxins and proteins derived from gingival crevicular fluid and inflammatory exudate (2).

Traditional scaling and root planing (SRP) procedures relies on mechanical removal of plaque, calculus, root-bound toxins and contaminated cementum. These procedures are essential for a successful periodontal treatment and improvement of periodontal health.

Studies of the effectiveness of SRP alone have shown that, in spite of the dentist's best efforts, complete removal of subgingival plaque and calculus is hardly achievable and is unlikely to be successfully performed when probing depth exceeds 5 mm (3,4). Due the limitations of conventional SRPprocedures, several instruments have been developed to improve the access to root surfaces. Additionally, there has been considerable interest in the use of chemical agents to assist root detoxification.

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Chemical agents have been proposed to facilitate calculus detachment (5,6), smear layer removal (7), decalcification of planed root surfaces and exposure of dentinal or cemental collagen matrix. These procedures are aimed at providing a biologically acceptable surface for new connective tissue attachment (8).

Carisolv™ gel (Mediteam, Sävadelen, Sweden), a chemomechanical caries removal system, has been developed for use in dentistry as an adjunctive therapy to the mechanical excavation of carious dentin. This system consists of a mixture of sodium hypochlorite and three amino acids (lysine, leucine and glutamic acid) in a gel preparation. This product softens the carious dentin, which is then hand-excavated (9,10). The ability of Carisolv™ to remove carious tissue without affecting the underneath healthy dentin structure has been demonstrated in various studies (11,12).

In view of the advantageous characteristics of Carisolv™, our research team has conducted a scanning electron microscopic analysis of Carisolv™ effect on periodontally compromised human root surfaces and found that the chemomechanical therapy caused significant changes in root surface morphology of periodontally involved teeth compared to SRP alone only when Carisolv™ was applied using the burnishing technique. Additionally, multiple applications of Carisolv™ combined with SRP procedures could remove the contaminated cementum and expose its healthy structure (13).

In Periodontics, the possibility of chemically dissolving calculus and contaminated cementum to improve their removal by mechanical instrumentation is one of the most promising applications of Carisolv™ gel. Although the use of Carisolv™ associated with SRP would improve root detoxification, its efficacy on calculus removal has not yet been evaluated. Therefore, the purpose of this study was to evaluate the efficacy of subgingival application of Carisolv™ gel as an adjunctive therapy to SRP on calculus removal compared to conventional periodontal instrumentation.

MATERIAL AND METHODS

Twelve patients (mean age 44.5 ± 10.5 years; 7 males and 5 females) with severe chronic periodontal disease in a total of 45 single-rooted teeth were selected for this study. The teeth had indication for extraction based on their periodontal prognosis as hopeless teeth. The inclusion criteria were: at least one hopeless tooth with one site with probing depth >5 mm, tooth mobility degree II or III, no root caries or any restoration with subgingival margins, presence of subgingival calculus detected clinically and radiographically, radiographic evidence of at least 50% of bone loss and no history of periodontal treatment within the past 6 months. All subjects signed a written informed consent form to participate in the study prior to any treatment procedure was done. The study protocol was approved by the Ethics in Research Committee of the School of Dentistry of Araraquara, SP, Brazil.

Each subgingival tooth surface was evaluated for the presence of calculus using a periodontal probe (Hu-Friedy, Chicago, IL, USA). Probing depth and gingival recession were recorded on 6 sites *per* teeth. After administration of local anesthesia on the test teeth, supragingival plaque and calculus were removed. Threreafter, a reference groove was made around the tooth circumference at the gingival margin level with a small high-speed round diamond bur. This groove provided a landmark for further residual calculus evaluation in order to determine supra and subgingival areas. Teeth were randomized to one of the following treatments (n=15 teeth): 1) SRP alone; 2) Placebo gel + SRP; 3) Carisolv™ + SRP.

In each tooth, the surface with subgingival calculus and probing depth >5mm was chosen for treatment. The placebo gel was identical to the test product in packing, color, consistency and taste. Applicator syringes were coded as either containing the placebo or the test product. The code was revealed by the supplier at the end of the study.

After relative isolation of the teeth with a cotton roll, the test or placebo gel was applied subgingivally for 1 min and then the root surfaces were instrumented with newly sharpened 5-6 Gracey curettes (Hu-Friedy) by a single investigator. Teeth were scaled and root planed until the operator achieved a hard and calculus-free root surface as determined by tactile sensation with a periodontal probe. The time required for each treatment was recorded measured with a stopwatch. The number of strokes performed during root instrumentation was also noted. After instrumentation, each experimental tooth was extracted as atraumatically as possible, washed in running tap water to remove blood clot and debris and stored in 2.5% glutaraldehyde.

The total area of the root surface exposed to the subgingival environment was delimited laterally with a

sharp pencil by the line angles of the root surface, coronally by the prepared groove and apically by the remnants of periodontal ligament. Within these boundaries, the root surface area covered by residual subgingival calculus was measured by using an image-analysis program (Mocha™, Jandel Scientific, San Rafael, CA, USA) . Tooth images were captured by a digital camera (Minolta, Dimage 7; Konica Minolta Photo Imaging USA, Inc, Mahwah, NJ, USA; 5.2 mega pixels), which was mounted on a fixed stand with the lens parallel to the tooth to ensure both minimal distortion of the image and reproducibility of the camera distance.

Digital photographs were taken and coded to maintain the examiner blinded to the treatments performed. The digital photographs were analyzed by an imaging analysis system comprising a computer and a digitizing tablet with a movable cursor in such a way that an automatic calculation of the surface area outlined by the cursor was obtained. The following areas were circumscribed with the mouse: 1) total pocket area and 2) areas covered with residual calculus. The sum of areas with residual calculus was expressed as a percentage of the total pocket area. Measurements were performed twice on different days and an average was obtained.

The single tooth served as the computational unit. Differences in the duration of instrumentation, number of strokes required for reaching the clinical endpoint and the percentage of residual calculus between the test gel, placebo gel and no gel were assessed by repeated measurement analysis of variance with Scheffé post-hoc test at 5% significance level.

RESULTS

There were no statistically significance difference between the treatments groups regarding probing depth (p=0.624) and gingival recession (p=0.518) (Figs. 1 and 2).

Figure 3 shows the minimum and maximum instrumentation time required for each treatment. The mean time taken to complete instrumentation for SRP alone, placebo + SRP and Carisolv™ + SRP was 101.33 ± 37.26 s, 84.13 ± 37.70 s and 89.46 ± 28.76 s, respectively. There was no statistically significant difference (p=0.391) between the treatment groups.

Figure 4 shows the minimum and maximum number of strokes needed to reach the clinical endpoint of calculus-free surface for all treatment groups. Statistically significant difference (p=0.034) was found among

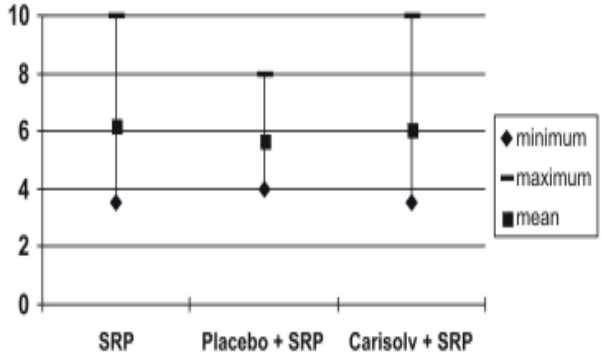
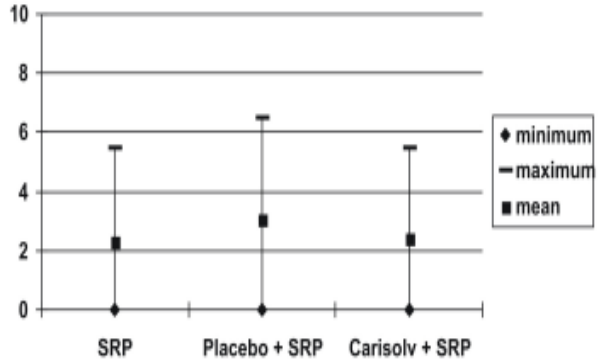


Figure 1. Probing depth means (in mm) for the treatment groups.



Figures 2. Gingival recession means (in mm) for the three treatment groups.

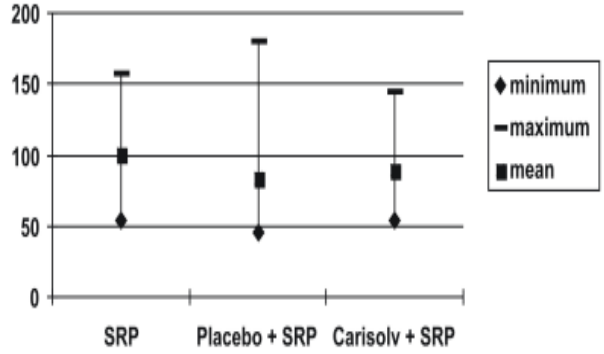


Figure 3. Instrumentation time means (in s) required to complete removal of subgingival calculus for the three treatment groups.

the treatment groups regarding the number of strokes performed during root instrumentation. Scheffé post-hoc test revealed that the number of strokes for SRP alone was significantly higher than that required for placebo + SRP (p=0.049). The number of strokes in Carisolv™ + SRP was not significantly different from the other two treatment groups (p>0.05). The mean percentage of residual calculus was higher for Carisolv™ + SRP (11.80 ± 11.32%) than for placebo + SRP (6.62 ± 7.81%) and SRP alone (7.77 ± 7.31%). However, there were no statistically significant differences between the treatment groups (p=0.264) (Fig. 5).

DISCUSSION

This study investigated the efficacy of subgingival application of Carisolv™ gel as an adjunctive therapy to SRP on calculus removal in comparison to conventional root scaling. The combination of Carisolv™ gel application and SRP had similar results to those obtained with mechanical instrumentation alone. Subgingival application of Carisolv™ gel prior to SRP procedures added no benefit in terms of decrease of instrumentation time, number of strokes to provide a calculus-free surface or subgingival calculus removal.

These results are consistent with those previous studies (5,6) that showed that the application of a prescaling gel combined with SRP did not improve the removal of calculus compared to conventional mechanical instrumentation.

Although our findings suggested that there was no advantage in using Carisolv™ gel as an adjunct to subgingival instrumentation, consideration must be given as to whether the chemical gel actually reached the periodontal pocket base and root surface, and whether the agent was present long enough to have any effect. According to the methodology of this study, Carisolv™ was injected subgingivally with a syringe and a blunt needle until the gel was visible supragingivaly. However, the calculus deposits adhered to root surface might have prevented gel penetration deeply into the pocket.

It is important to note that the gel was injected subgingivally for 1 min only prior to root instrumentation. The method of application could have influenced gel effectiveness on calculus removal. Multiple applications of Carisolv™ gel interposed with mechanical instrumentation could have improved its effect for root surface treatment of periodontally affected teeth.

The second point is whether the chemical gel was concentrated enough to produce any effect. The main component of Carisolv™ is 0.5% sodium hypochlorite, which is mixed with three amino acids (lysine, leucine and glutamic acid). These amino acids react with the sodium hypochlorite to form chloramines that remove the organic components of altered tissue. The formation of chloramines, however, reduces chlorine reactivity and concentration to 0.25% in order to neutralize its aggressive behavior on healthy tissue.

The subgingival application of placebo gel prior to mechanical instrumentation resulted in a less percentage of residual calculus, although there was no statistically significant difference between placebo gel and test gel. In addition, in this group, the number of strokes to reach the clinical endpoint of a calculus-free surface was significantly smaller in comparison to mechanical instrumentation alone. It is important to note that the

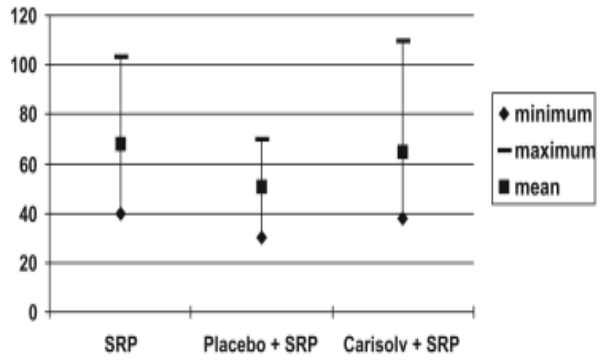


Figure 4. Number of strokes performed during instrumentation for the three treatment groups.

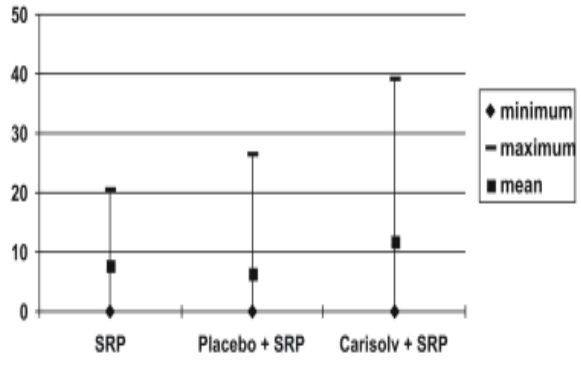


Figure 5. Percentage of residual calculus observed for the three treatment groups.

placebo gel used in the present study was similar to the test gel in color, packaging and in taste. However, sodium hypochlorite was not neutralized by the three amino acids. As a consequence, chlorine concentration in the placebo gel was higher than in the test gel.

Another reason for the lack of additional benefits of Carisolv™ application could be related to the limited effect of the chloramines presented in the gel on subgingival calculus. Dental calculus has mainly a mineral composition as a result of the calcification of microbial plaque on tooth surface. Whatever the mineral composition is, dental calculus surface always remains covered with dental plaque, endotoxins, proteins derived from gingival crevicular fluid and inflammatory exudates (2). Because chloramines remove the organic components of altered tissue, its mode of action onto periodontally affected root surface would be restricted to organic content of the diseased root cementum and limited to the superficial layer of dental calculus.

All groups presented similar amount of residual calculus after root instrumentation. There were only few root surfaces free of residual calculus. These results are in accordance with those of previous studies, which showed that it is not always possible to remove all calculus from all root surfaces, especially if the probing depth was deeper than 5 mm. (3,4,14,15).

The mean percentage of residual calculus observed in this study was lower than the 30% reported in a previous work that analyzed SRP effectiveness (16). This difference might be related to the distinct methodologies used. Assessment of residual calculus can be done by either grid-square analysis or computed image analysis. Eschler and Rapley (17) reported that grid-square analysis inherently overestimates the amount of residual calculus adhered to root surface. In that study (17), overestimation was likely to occur by a factor of 2 to 8 times compared to image analysis.

In the present study, the percentage of residual calculus was assessed by computed image analysis because it has the potential to avoid overestimation of root surface area occupied by calculus deposits. In addition, no histological staining was used to highlight residual calculus. The use of histological staining could result in false-positive results by staining not only the residual calculus but also the superficial layer of cementum, dentin and bacterial deposits (18-20).

The findings of the present study showed that the subgingival application of Carisolv™ gel did not provide any further benefits to root instrumentation in addition to those achieved with conventional scaling and root planing procedures alone.

RESUMO

O objetivo deste estudo foi avaliar a efetividade da aplicação subgengival do gel Carisolv™ em associação aos procedimentos de raspagem e alisamento radicular (RAR) na remoção do cálculo dental aderido à superfície radicular, quando comparado à terapia periodontal mecânica convencional. Foram utilizados 45 dentes indicados para a exodontia devido à doença periodontal avançada, os quais foram divididos em três grupos de tratamento: 1) RAR apenas; 2) placebo + RAR; 3) Carisolv™ + RAR. O tempo despendido e o número de movimentos realizados para a instrumentação das superfícies radiculares foram avaliados durante o tratamento. Em seguida, os dentes foram extraídos e avaliados quanto ao percentual de cálculo residual, por meio de um sistema computadorizado de análise de imagens. Não houve diferença estatisticamente significante ($p>0,05$) entre os grupos com relação ao tempo requerido para os diferentes tratamentos, assim como quanto ao percentual de cálculo residual. Os resultados indicaram que a aplicação do Carisolv™ não promoveu benefícios adicionais àqueles obtidos com a terapia mecânica convencional na remoção do cálculo subgengival.

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