APPENDIX #1

DRAFT

Periodontic Applications of Microcyn

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Background

Periodontitis, an infectious degenerative disease of bacterial etiology, is the second most important cause of tooth loss in the world, constituting a major public health problem. Current therapeutic modalities include scaling and root planing of the surfaces of the teeth to eliminate bacterial plaque and calculus, and the use of antiseptic solutions to combat the infectious process caused by a wide spectrum of oral micro-organisms. These antiseptics, however, have high toxicity and consequently cannot be used for prolonged periods. In addition, some of the commonly used antiseptics have adverse side effects such as distortion of taste and staining of teeth. Microcyn, a newly available super-oxidized solution for wound care, offers a radically improved approach to treatment of periodontitis. This neutral pH, no-rinse, superoxidized water was certified as an antiseptic for wound care in México in 2004. Animal tests were initially conducted to show that Microcyn does not induce irritation or sensitization in skin and mucosas (Gutiérrez, 2006). The active components of this solution include 99.98% superoxidized water and < 0.02% of various reactive species of chlorine and oxygen including hypochlorous acid, sodium hypochlorite, sodium chloride, ozone, and chlorine dioxide. However, the overall content of free available chlorine is low and ranges between 50 and 80 ppm. This SOW has bactericidal, virucidal, fungicidal and sporocidal activities and it is ready to use with no further dilution or mixing (Landa et.al., 2006). Of note, it does not require special handling or disposal and has an extended shelf life of >12 months.

In view of the limitations of existing oral antiseptics and water for use with ultrasonic scalers, the purpose of this communication is to present initial case studies which reflect our experience using Microcyn instead of water in the ultrasonic scaler (Cavitron). Further, we suggest the type of investigations needed to confirm the apparent striking benefit of this super-oxidized solution for treatment of periodontitis.

Case study

The well-documented case presented here is representative of the 14 patients [ages 22-53 years, 11 female] we treated initially. The patient, a female age 24, presented with a history of frequent gingival bleeding, especially the maxillary gingiva. Initial evaluation revealed the presence of materia alba, bacterial plaque, and calculus, causing a typical case of gingivitis and incipient periodontitis. This patient and the other 13 study subjects were treated, and then examined weekly for 12 weeks.

Figure #1 shows generalized gingivitis in this patient. Figure #2 is a close-up view of inflamed papillae between tooth number 7 and 8, and 8 and 9. Figure #3 shows the presence of materia alba on the patient's lower anterior teeth. In figure #4 a periodontal probe measures a six

millimeter pocket on the mesial of tooth #7. The following figure, #5, shows radiographically the existence of a bony defect between the central and lateral incisors. Figure #6 shows a periodontal measurement of only 3 millimeters on the distal of tooth #9. However on figure #7 we observe the destruction of the bony crests in all of the interproximal spaces. The next three figures (8, 9 10) show instrumentation with the Cavitron using Microcyn as the irrigating solution. Figure #11, taken two weeks after treatment, shows a considerable reduction of inflammation in the patient. In figure #12 a dramatic reduction in inflammation is observed in comparison with figure #2. Figure # 13 provides an additional example of resolution of inflammation two weeks post treatment. Importantly, figure #14 shows, on the mesial of tooth #7, a reduction of the pocket to a depth of 3 millimeters. The following figure, #15, shows the absence of inflammation in the lower anterior gingiva. The final figure, #16, indicates regeneration of the bony crest between teeth # 7 and #8.

Results

The other 13 patients in the study had comparable degrees of gingivitis and were treated with the Cavitron and Microcyn. All the patients were instructed in proper brushing technique and in the use of dental floss. In all of the cases we recommended the use of Microcyn mouthwash for two minutes, three times per day, preferably after meals. In none of the patients were adverse signs or symptoms observed in the use Microcyn as an irrigating solution or as a mouthwash. To our surprise, the period of resolution of the gingivitis was only two to four weeks. Bleeding upon brushing resolved in all patients within 24 hours to 4 days. Unexpectedly, in all patients two weeks post-treatment we observed radiographic evidence of bone regeneration similar to the described case. None of the patients received antibiotics or other medications.

Discussions and Conclusions

Prior to this study our standard treatment with similar patients was the use of an ultrasonic scaler with water, brushing and flossing instructions, and twice daily rinsing with chlorhexidine solution for 15 days. An important stimulus for undertaking this study was our longstanding concern about the use of chlorhexidine and its limitations. Based on our observations, we believe that Microcyn may offer several advantages over chlorhexidine and other common antiseptic solutions. We also believe the use of Microcyn both as an irrigating solution in the Cavitron and as a mouth rinse provides added benefits for the patient.

Recognizing the limitations of this preliminary descriptive report, we hope to stimulate investigators to undertake rigorous controlled studies using Microcyn in the treatment of gingivitis and periodontitis. These studies should include objective measures such as pocket depth, bleeding on probing, and standardized radiographs to document degree of bone regeneration. We believe such studies have a high probability of confirming and expanding initial observations.

Figures:



Figure 1





Figure 3



Figure 4



Figure 5

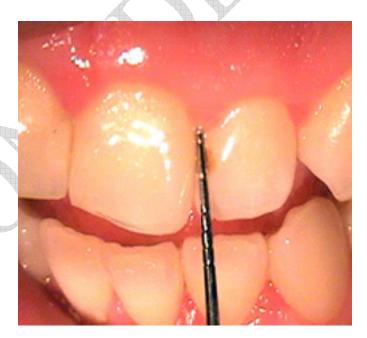


Figure 6



Figure 7



Figure 8



Figure 9



Figure 10



Figure 11



Figure 12



Figure 13

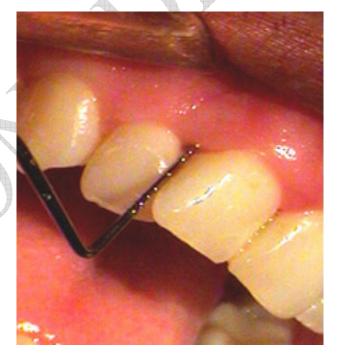


Figure 14



Figure 15



Figure 16

Gutiérrez AA. The Science Behind Stable, Super-Oxidized Water. Exploring the various applications of super-oxidized solutions. *Wounds*. 2006, Suppl. Jan: 7-10.

Landa-Solis, González-Espinosa D, Guzman B, Snyder M, Reyes-Terán G, Torres K and Gutiérrez AA. MicrocynTM a novel super-oxidized water with neutral pH and disinfectant activity. *J Hosp Infect* 2005, 61:291-299...

