EFFECTS OF THE PERIO-TEK SYSTEM ON GINGIVITIS, BLEEDING, AND BREATH ODOR[1]

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INTRODUCTION

This clinical study was carried out to evaluate the Perio-Tek system for efficacy in reducing the depth of periodontal sulci and gingival bleeding, caused by anaerobic bacteria P gingivalis, B. forsythus, and T. denticola, in accordance with the guidelines established by the American Dental Association Council on Dental Therapeutics (CTC) [3]. The study also was aimed at evaluating the effectiveness of the system for reducing breath malodor caused by the tongue bacteria, Stomatococcus mucilaginous. The need for effective yet safe therapeutic oral products to supplement traditional oral hygiene is apparent, since a vast majority of adults practicing good oral hygiene technique (daily tooth brushing and flossing) will still be affected with periodontal disease. Dentifrice formulations that include traditional antibiotics or topical antiseptics are not viewed as a viable solution, since mutation, which leads to antibiotic resistance, or acute irritation from powerful antiseptic agents will upset the delicate balance of the oral ecology required for a healthy oral cavity. The Perio-Tek system attempts to incorporate natural ingredients that have previously demonstrated benefits related to oral health and/or have anti-microbial or healing properties. It is postulated that these ingredients when combined and utilized in a systematic fashion would create a synergy greater than the sum, which would provide for a viable solution in periodontal care.

A Review of The Main Ingredients of The Gel

Cranberry Extract

Scientists from Tel Aviv University in Israel have published research in The Journal of the American Dental Association suggesting that chemicals in cranberries might make it more difficult for bacteria-causing plaque to stick to teeth - in much the same way cranberries might prevent bacteria from hitching to the bladder. [20] In this study, tests were conducted to determine if cranberries had indeed a non-stick effect on the bacteria that are most commonly found in the oral cavity. It was reported that the bacteria did not join to form plaque. Researchers have found that a substance exists in the tart berry that helps bacteria from adhering to one another to form plaque. [21-23]

Tea Tree Oil

Arthur Penfold, Curator and Chemist at the Technological Museum, Sydney first disclosed the scientific discovery of Tea Tree Oil in 1922 when he presented a paper to the Royal Society of New South Wales. [24] Further interest was created when Penfold and Grant published a work on Tea Tree Oil, which indicated that it had a Redealwalker co-efficient score of between 11 and 13. This score indicates that the oil is 11 to 13 times more powerful than Carbolic acid (Phenol) for killing bacteria and fungi yet non-caustic to the skin [25]. Since his early work, additional articles have been published detailing research proving the efficacy of Tea Tree Oil as an antiseptic and fungicide. V MacDonald [26] reported Tea Tree Oil as "an antiseptic, which more nearly answers the ideal than any previously tested." Also in 1985, researchers at the University of Queensland Dental School showed that tea tree oil acted against a variety of oral pathogens, which cause a variety of dental problems including tooth decay and gum disease. [27]

MSM

Methylsulfonylmethane (MSM) is a naturally occurring nutrient, a sulfur compound, found in normal human diets and the diet of all other vertebrates. Sulfur is an element present in all living organisms. Clinical has demonstrated that MSM topically applied in a lotion and taken internally demonstrated both pain relief and anti-inflammatory properties without serious side effects. [28] In oral applications MSM has been used in conjunction with toothpaste to decrease inflammation of the oral mucosa and to help clean teeth. [28] The researcher's postulate that MSM's anti-inflammatory properties may have a beneficial effect in reducing the swelling, redness and inflammation in the gum space.

MATERIALS AND METHODS

Forty-one dental patients in a private practice (25 males and 16 females), who exhibited clinical signs of gingivitis were recruited as subjects for this study. Subjects ranged in age from 33 to 79 years old, were in general good health, not pregnant, or taking any medication for birth control, hypertension, or immunosuppression. Subjects signed an informed consent to be randomized into the "usual care" (n=20) or the "usual care plus" (n=21) groups, knowing the risks and benefits involved.

All subjects were provided with a thorough examination and cleaning. In the control group, subjects received four quadrants of root planing and curettage. All subjects were asked to keep a diary each day indicating the number of times that they brushed and flossed. In the experimental group, subjects received three Perio-Tek hygiene preventive treatments and four quadrants of root planing and curettage. All experimental subjects also took home a two- month supply of Perio-Tek home care kits. Experimental group subjects were asked to keep a diary each day indicating the number of times that they brushed, flossed, and used the three products in the home care kit (bicarbonate mint, probiotic chewable, and an immunobiotic capsule.

On day 1, the Doctor conducted the periodontal depth analysis and recorded results for the inner and outer aspect of each tooth on the data collection form, as well as information for the bleeding index and mouth odor. The Gingival Bleeding Index is measured by probing six surfaces of each tooth and evaluating on a scale of 0-5, 0 being no bleeding and 5 being severe bleeding. Periodontal pockets were measured by probing the base of six surfaces of each tooth and measuring in millimeters, ranging from 0 to the depth of the pocket. The Periodontal Pocket Index is a weighted mean (weighted by the number of areas measured in the mouth).

Experimental subjects on day 1 also had impressions made prior to cleaning, so that after the cleaning, or at the next cleaning appointment, the teeth and gums could be bathed for 5 minutes in the natural healing and antibacterial gel, using a syringe and custom fitted trays. The gel containing tea tree oil, cranberry extract, and MSM was then loaded into a syringe and injected into the periodontal sulcus areas and the custom tray was filled and placed over the teeth and gums in order to surround the gums and deeper periodontal lesions. This 5 minute treatment was designed to further reduce bacterial colonies and make the mouth relatively bacteria free at the point of the patient leaving the office.

On day 60, an examination and measurement of periodontal depth was conducted once more on the inner and outer surface of each tooth, with results recorded on the data collection form.
Compliance was ascertained using Patient Diaries on which subjects recorded the number of times they brushed and flossed each day.

The data was analyzed using a 2 (day 1 vs. day 120) x 2 (control vs. experimental group) repeated measures Analysis of Variance (ANOVA) for the Periodontal Bleeding Index and the Periodontal Pocket Index. A dependent t-test was used to assess change in breath odor.

RESULTS

Table 1 shows the means, standard deviations, and F ratios for four of the outcome measures in the Perio-Tek study. The 2 (treatment vs. control) x 2 (first visit and last visit) repeated Analysis of Variance (ANOVA) used to test for differences between treatment and control group subjects from first visit to last visit were significant for all three measures. As seen in Table 1, average pocket size showed a significantly greater decrease for the treatment group than the control group ($F(1,39)=39.56$, $p<.01$). The change is displayed in **Figure 1**. Although the controlgroup had a lower average sulcus depth at the first visit, their average depth had decreased less than the experimental group's by the end of treatment.

Figure 1. Change in Average Pocket Size from First Visit to Last Visit

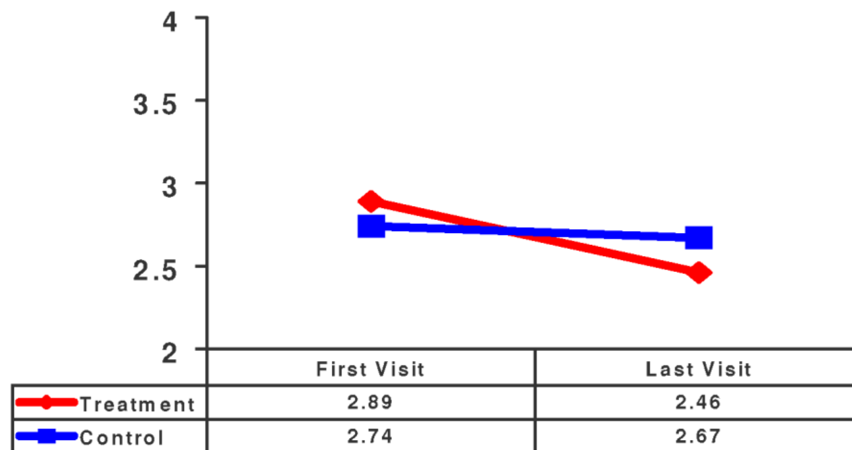


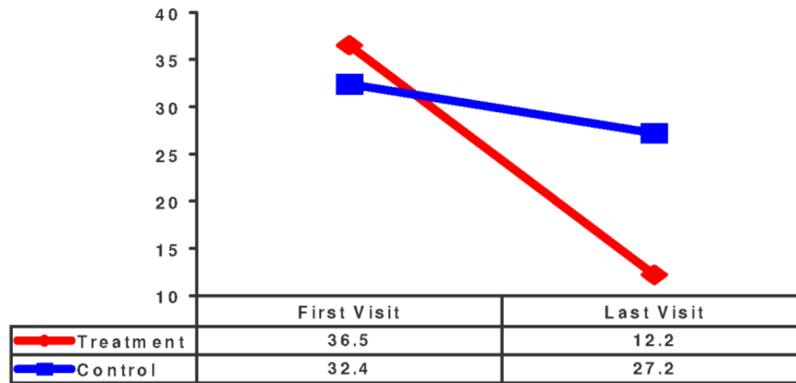
Table 1. Means, Standard Deviations and F-ratios for the Perio-Tek Measures

Measure	Experimental Group (N=21)				Control Group (N=20)				F
	First Visit		Last Visit		First Visit		Last Visit		
	Mean	S.D.	Mean	S.D	Mean	S.D.	Mean	S.D.	
Average Sulcus Depth	2.89	.52	2.46	.39	2.74	.28	2.67	.25	39.56**
Total Pockets Greater than 4	36.48	20.57	12.24	15.84	32.40	15.12	27.15	12.16	29.21**
Average Pocket Size for Pockets Greater than 4	4.37	.44	3.25	.50	4.06	.99	3.57	.88	78.20**
Bleeding Index	4.10	1.02	1.86	1.14	3.73	.99	2.75	.73	18.72**

*p<. 05
**p<. 01

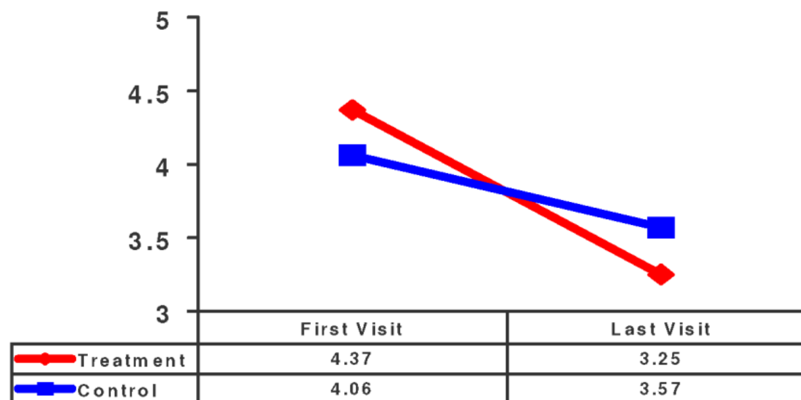
The number of pockets that had a size greater than four, as measured during the first visit, significantly decreased for the treatment group compared to the control group ($F(1,39)=29.21$, $p<.05$). The change in number of deep pockets over time by group is shown in **Figure 2**. Again, the experimental group began with more deep pockets than the control group, and declined 66%, compared with a 16% decrease in number of deep pockets in the control group.

Figure 2. Change in Number of Pockets Greater than 4 from First Visit to Last Visit



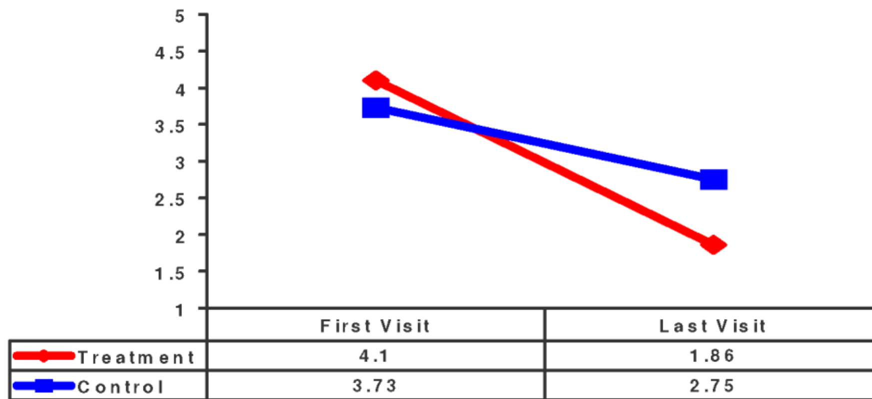
In addition, for those pockets that had a size greater than four, the average pocket size significantly decreased to a greater extent for the treatment group than the control group (F(1,39)=78.20, p<.05), as shown in Table 1. The change is demonstrated graphically in **Figure 3**. The experimental group's deep pocket size decreased 26%, while the control group's deep pocket depth only decreased 12%.

Figure 3. Change in Average Pocket Size for Pockets Great than 4mm from First Visit to Last Visit



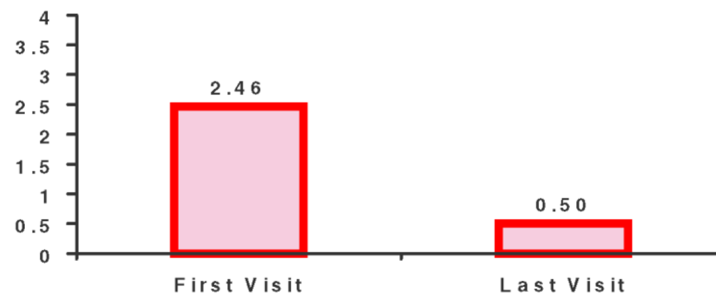
The Gingival Bleeding Index, which ranges in scores from 0 to 5 showed a significantly greater decrease from first visit to last visit for the treatment versus the control group (F(1,39)=18.72, p<.05), as shown in Table 1. There was a 55% decrease in the Bleeding Index for the experimental group, and only a 26% decrease for the control group (**Figure 4**).

Figure 4. Change in Bleeding Index from First Visit to Last Visit



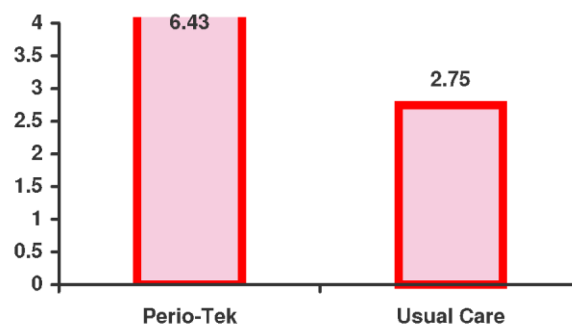
The fifth study measure that of perceived breath odor was performed for the treatment group only on the first and last visits. The dependent t-test (t(15)=4.75, p<.05) indicated a significant decrease in perceived breath odor from initial visit (mean=2.47) to last visit (mean=.50). This represents an 80% decrease in malodorous breath, as shownin **Figure 5.**

Figure 5. Change in Breath Scores for Treatment Subjects from First Visit to Last Visit



The sixth and final study measure was done on compliance and rate for self -care and was measured through examination of the Patient Journals in which the patients logged daily how many times they brushed and flossed (And in the case of the treatment group also how many times they used the Home Kit items). The compliance rate in use of the Home Care kit was evident (**as shown in Figure 6**.) and greater than usually expected with patient self-care between visits.

Figure 6. Composite Hygiene Compliance Score



DISCUSSION

The first hypothesis of this study was that the entire Perio-Tek system, with its in-office and home treatments would reduce gingivitis as assessed by pocket depth and bleeding index. Statistically significant changes were obtained for the periodontal pocket depth measurements. This result speaks to an overall improvement to the gingiva, although both groups showed statistically significant improvement here. The greater mean improvement for the active group in comparison to the placebo group suggest that the Perio-Tek system was more active in reversing the symptoms of gingivitis, which is in accordance with what would be expected from an agent active in reducing pathogenic plaque bacteria.

In the controlled study, this hypothesis could not be rejected, as both pocket depth and bleeding index decreased over time to a significantly greater degree in the experimental group than in the control group.

The second hypothesis was that the Perio-Tek system would be even more effective in patients with serious gingivitis, than in the typical patient. It is known that gingivitis (infection of the gingival tissue) is caused by the abnormal growth of pathogenic bacteria. This overgrowth of harmful bacteria can lead to tooth loss and more importantly other harmful disorders in the human body. The designers of the Perio-Tek system postulated that these bacteria could be checked by a systematic approach to Full Mouth Disinfection (FMD) and with healthy flora support both systemically and to the oral cavity. For this hypothesis to be correct it would be demonstrated by a decrease in the pocket sizes of the affected gum spaces. Slopes of improvement for the experimental group shown in Figures 2 and 3 demonstrate that patients with deeper pocket depth had a more dramatic and statistically significant response to Perio-Tek than was seen in Figure 1 that included all patients.

The third hypothesis, that the Perio-Tek system would reduce malodorous breath, also could not be rejected. This finding speaks to the breath freshening properties of the bicarbonate lozenge and other components of the Perio-Tek system. It has been suggested that Halitosis-causing microorganisms are those anaerobic pathogens that colonize and thrive in periodontal pockets of older established plaque, where sulfur –containing substrates are available[32]. These anaerobic pathogens are known to reduce the sulfur-containing amino acids found there within as well as metabolize other substrates into malodorous species. Newbran [18] et al tested various salts, including sodium bicarbonate, for growth inhibition of the oral microflora. In this in vitro laboratory study, they determined that subgingival periodontal pathogenic microorganisms were susceptible to the bactericidal effects of sodium bicarbonate. With these findings from Newbran et al [18] as one of their premises, Arnold and Uman[19] showed the efficacy of an effervescent bicarbonate dentifrice composition in reducing periodontal pathogens, and as an antiplaque or antigingivitis agent in vivo. Thus, for those who suffer from halitosis or related oral malodor problems that are the consequence of poor oral hygiene, or from infections of the periodontal surfaces, the Perio-Tek system will likely provide relief.

CONCLUSION

The results demonstrated conclusively that: (1) the Perio-Tek system (Comprised of an in-office treatment and a Home Care kit) substantially improved the health of the gingiva through a reduction of the pocket sizes in the acute gum spaces (those of 4mm or greater) (2) the Perio-Tek system demonstrated an overall positive effect on the total gum measurements and substantially reduced bleeding of the gums (3) perceived breath malodor by the patient was significantly decreased. Additionally, through examination of the Patient Journals and Exit Surveys the compliance rate in use of the Home Care kit was evident and greater than usually expected with patient self-care between visits (there was a correlation with convenience of use and the lack of unpleasantness). This compliance rate may point to an advantage that the Perio-Tek system may provide in that of self-care. In summary, greater improvement in the health of the gingiva for the experimental group in direct comparison to the control group was observed in all the

measurements. These findings (as postulated) may indicate the beginning of a substantial clinical response to reduction in the pathogenic organisms responsible for gingivitis through use of the Perio-Tek system.

REFERENCES

1. The study was carried out in the fall of 2002 under the direct supervision of Dr. Marvin Frager, DMD at a private practice in San Clemente, CA.
2. Vital Research, LLC, 8380 Melrose Ave, Suite 309, Los Angeles, California 90069.
3. American Dental Association Council on Dental Therapeutics (CTC) acceptance program for chemotherapeutic mouthrinses, which resulted in guidelines for the conducting of clinical studies to demonstrate efficacy (CTC, 1986). Philstrom BL, WolffLF, Bakdash MB, et al. J PERIODONTOL 1987; 58:291.
4. Wolff LF, Philstrom BL, Bakdash MB, et al. J PERIODONTOL 1987; 58:310.
5. Bakdash MB, Wolff LF, Philstrom BL, Aeppli DM, Bandt CL. J PERIODONTAL 1987; 58:308.]
6. Greenwell H, Bissada N, Maybury J, DeMarco. J AM DENT ASSOC 1983; 106-457.
7. Greenwell H, Bakr A, Bissada N, et al. J CLIN PERIODONTOL 1985; 12:327.
8. Wolff LF, Philstrom BL, Bakdash MB, Schaffer EM, Aeppli DM, Bandr. J AM DENT ASSOC 1989; 118(1): 67.
9. Amigoni NA, Johnson GK, Kalkwarf KL. J AM DENT ASSOC 1987; 114:217.
10. Keyes PH, Wright WE, Howard SA. QUINTESSENCE INT 1978; 9:51.
11. Keyes PH, Wright WE, Howard. QUINTESSENCE INT 1978; 9:69.
12. Keyes PH, Rogosa M, Rams T, Sarfart D. Diagnosis of creviculoradicular infections; disease-associated bacterial patterns. IN: Genco RJ, Mergenhagen SE, eds. HOST-PARASITE INTERACTION IN PERIODONTAL DISEASES. Washington, DC: American Society of Microbiology, 1982:395-403.
13. Rams TE, Keyes PH, Jenson AB. QUINTESSENCE INT 1984; 15:835.
14. Keyes PH, Rams TE. J AM DENT ASSOC 1983; 106:803.
15. Rams TE, Keyes PH, Wright WE, Howard SA. J AM DENT ASSOC 1985; 111:429.
16. Keyes PH. NEW YORK STATE DENT 1986; 52(8): 10.
17. Rams TE, Keyes PH. GEN DENT 1986; 34:54.
18. Newbrun E, Hoover CI, Ryder M. J PERIODONTAL 1984; 55(11) 658.
19. Arnold M, Uman G, 1996 Clinical Study at the University of Southern California (USC) Dental Clinic
20. Weiss E, Lev-Dofl R, Kashamin T, Goldhari J, Sharon N, Ofek I. J AM DENT ASSOC Vol.129 December 1998
21. Avorn, J., et al JAMA, 1994; 271(10): 751-754.
22. Howell AB, et al.,. N Engl J Med. 1998; 339:1085-1086.
23. Howell AB, et al JAMA, 2002; 287(23): 3082-3083.
24. Journal and Proceedings of the Royal Society of New South Wales, V56.1922.P219
25. Journal and Proceedings of the Royal Society of New South Wales V59.1925.P346
26. Australian Journal of Dentistry – 1930 (V34.P218-285)
27. Periodontology 8,p. 11-15, 1987.
28. Herschler, RJ: Methylsulfonylmethane and methods of use. United States Patent 4,296,130; October 20, 1981
29. Shahani, K. M., J. R. Vakil, and R. C. Chandan. 1972. Antibiotic acidophilus and the process for preparing the same. U. S. Patent 3,689,640. Sept. 5.
30. Reddy, G. V., K. M. Shahani, B. A. Friend, and R. C. Chandan, 1983. Natural antibiotic activity of L. acidophilus and bulgaricus. III. Production and partial purification of bulgarican from L. bulgaricus. Cultured Dairy Pro. J., 18(2): 15-19.
31. Chandhan, R.C.Y., G. Reid, R.T. Irvin, A. W. Bruce, and I.W. Costerton. 1985. Competitive exclusion of uropathogens from human uroepithelial cells by Lactobacillus.Infect.Immun, 47:84-89.
32. Van Steenberghe D, Rosenberg M. Bad Breath: A Multidisciplinary Approach. Leuven Univ. Press 1966: 3-15