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A LONG-TERM CLINICAL EVALUATION OF A CLAY-CONTAINING DENTIFRICE IN ANTARCTIC NAVAL PERSONNEL

by

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Bureau of Medicine and Surgery, Navy Department
Research Work Unit MR005.20.01-6056A.02

Released by:

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SUBMARINE MEDICAL RESEARCH LABORATORY
NAVAL SUBMARINE MEDICAL CENTER REPORT NO. 626

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SUMMARY PAGE

THE PROBLEM

Periodontal disease is an important oral health problem in the Navy. A new dentifrice was developed with the theoretical capability of adsorbing the toxic bacterial products thought to cause most gingivitis. A long term evaluation in a stable population was required to assess the practical usefulness of this dentifrice.

FINDINGS

Results of a double-blind clinical study in Antarctic personnel indicates no benefit from the test dentifrice. It was found that the oral health of both the test and control groups improved as the winter progressed.

APPLICATIONS

The experimental dentifrice was found to be ineffective and is not recommended for further use by the Navy.

ADMINISTRATIVE INFORMATION

This investigation was conducted as a part of Bureau of Medicine and Surgery Research Work Unit MR005.20.01-6056A - Clinical Evaluation of a Clay Containing Dentifrice. This report has been designated as Submarine Medical Research Laboratory Report No. 626. It is Report No. 2 on this Work Unit and was approved for publication as of 7 May 1970.

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ABSTRACT

Gingivitis is a common dental ailment in Naval personnel. A new highly adsorbent clay dentifrice has been developed. The theoretical action in vivo is thought to be the adsorbtion and consequent inactivation of the bacterial toxins responsible for gingivitis. A six month study was designed using 44 Antarctic Naval personnel as subjects. These subjects were divided into two groups; one group received the test dentifrice, and the other a placebo. Measurement criteria consisted of standard gingivitis indices, plaque scores, and calculus indices. Results indicated no benefit in the test group with any of the three measurement methods. A correllary finding was an improvement in the oral health of both groups during the Antarctic winter. It is concluded that this experimental clay dentifrice is without practical value in reducing gingivitis in naval personnel.

A LONG TERM CLINICAL EVALUATION OF A CLAY CONTAINING DENTIFRICE IN ANTARCTIC NAVAL PERSONNEL

INTRODUCTION

A dentifrice containing ultrafine kaolinite has been developed[1]. This experimental preparation was the result of observations that some clays are capable of binding bacteria and their products. It has been shown that the injection of oral bacterial plaque suspensions into laboratory animals results in the expected, almost uniform death of the animals. When the same suspensions were mixed with a highly adsorbant clay, all of the animals injected survived. It was postulated that such a clay in a dentifrice could also adsorb the toxic products of the bacterial plaque in situ. Assuming these products are the chief cause of periodontal disease, such an adsorbing agent should protect the host from gingival inflammation.

The U. S. Navy, long interested in the preventive aspects of dentistry, undertook the evaluation of this dentifrice at its Antarctic outpost, McMurdo Station, Antarctica[2]. McMurdo offers ideal conditions for research in that it becomes for the winter months an isolated community with a similar environment and diet for all resident personnel. The effects of the harsh environment itself on dental parameters can be assumed to be minimal, based on the data reported by previous Antarctic dentists[3,9].

MATERIALS AND METHODS

The forty-four persons involved in the program ranged in age from 20 to 41 with all but six in the 21 to 27 age group. These subjects were assigned at random to an experimental group, receiving the test dentifrice, and a control group, receiving a placebo dentifrice. The placebo was identical to the test dentifrice except that the kaolinite had been omitted. Neither the dental officer nor his assistant knew which dentifrice contained the clay. The dental officer conducted all of the examinations, the dental assistant recording his findings. The dental officer was not allowed access to the records until after the results of the last examination were recorded.

To properly evaluate the effect of the kaolinite dentifrice, it was necessary to utilize definitive clinical measurements of gingival inflammation, crevicular depth, and accumulation of bacterial plaque and calculus.

The incidence of marginal gingivitis was measured with a modified version of Russell's periodontal index[4]. Each tooth was scored for the clinical condition of its circumscribing free gingiva. The absence of overt inflammation was scored as zero; a single area of marginal inflammation was scored as one; and inflammation completely surrounding the tooth was scored as two. When in doubt, the lesser score was assigned. To arrive at a final index, the total score was divided by the number of existing teeth. For the purpose of this study an index of marginal gingivitis was needed rather than an index of total periodontal health, hence scores

described by Russell for advanced periodontal destruction were not utilized.

Crevicular depth was measured from the depth of the sulcus to the gingival crest on the following teeth:

Tooth number 3 (maxillary right first molar)

Tooth number 9 (maxillary left central incisor)

Tooth number 15 (maxillary left second molar)

Tooth number 19 (mandibular left first molar)

Tooth number 25 (mandibular right central incisor)

Tooth number 28 (mandibular right first bicuspid)

With the exception of tooth number 15, these are the teeth used by Ramfjord[5] as representative of the total periodontal condition of the individual. Mesial and distal measurements were made from the facial aspect of teeth number 3, 9, 15, and 25, and from the lingual aspect of teeth number 19 and 28.

Dental plaque was measured as described by Greene and Vermillion[6], utilizing the same surfaces from which the crevicular depths were measured: the facial surfaces of teeth number 3, 9, 15, and 25, and the lingual of teeth number 19 and 28. No discernable plaque was scored as zero; debris covering not more than one-third of the surface was scored as one; debris covering more than one-third but less than two-thirds of the surface was scored as two; and debris covering more than two-thirds of the tooth surface was scored as three.

Calculus was measured on the lingual surfaces of the four mandibular incisors in the manner of Volpe and Manhold[7] and recorded as the average height of the lingual band of calculus to the nearest half millimeter. The lower anterior teeth were scaled and polished following the first, fourth, and seventh examinations. One week following this polishing, the patients were recalled, and the percentage of the lingual gingival margin covered by newly formed calculus was measured and recorded. This represents the Marginal Line Calculus Index as described by Muhlemann and Villa[8]. Both the Volpe-Manhold measurements and the Marginal Line Calculus Index measurements were used as parameters of calculus accumulation.

RESULTS

Calculus measurements as depicted in Tables 1 and 2 are low and variable. There were only three subjects in the entire group that accumulated one mm or more of calculus consistently. There were no significant differences at the .05 probability level between the groups in rate of calculus deposition when measured analytically.

The formation of bacterial plaque or debris as portrayed in Figure 1 diminished consistently throughout the season. This improvement in oral hygiene in the entire group was apparent to the dental officer without access

Table 1. Average Height of Lingual Supragingival Calculus on Lower Incisor Teeth ± Standard Error of the Mean

	March*	April	May	June	July	August	September
Control Group	.41 ± .13	.10 ± .05	.26 ± .09	.32 ± .11	.23 ± .11	.17 ± .07	.26 ± .09
Experimental Gr.	.43 ± .09	.19 ± .07	.21 ± .08	.14 ± .06	.12 ± .05	.10 ± .06	.19 ± .06

*Teeth were scaled and polished following these exams.

Table 2. Marginal Line Calculus Indeces Expressed as Percentage of Lingual Gingival Margin of the Lower Incisors Encompassed by New Calculus ± Standard Error of the Mean

	March	June	September
Control Group	22.3 ± 6	25.0 ± 8	20.6 ± 6
Experimental Group	26.8 ± 7	28.0 ± 6	13.7 ± 6

to the records. There was again no significant difference between the two groups.

Figure 2 shows graphically the results of the improvement in oral hygiene. It is interesting to note that this trend bears a striking similarity to that observed by Lindsay in Deep Freeze '60[3].

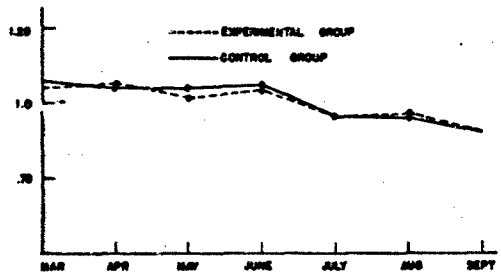

Figure 1

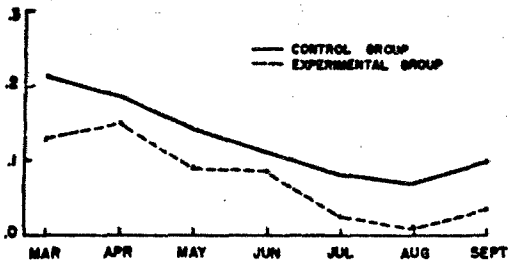

FIG. 2 FREQUENCY OF GINGIVAL INFLAMMATION

Figure 2

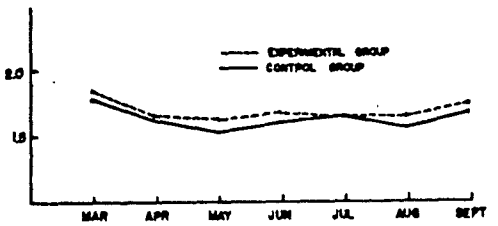

Figure 3

Adams[9] also observed a similar improvement in his study.

As might be expected, the average crevicular depth decreased in proportion to the decrease in gingival inflammation (Fig. 3). There was, however, no significant difference between the experimental group and the control group in this improvement.

DISCUSSION AND CONCLUSION

The reduction in debris accumulation and the reduction of gingival inflammation is somewhat surprising and is certainly not what would be expected from the winter diet, which is almost void of detergent foods during the period of isolation from March until October. This improvement in oral health could possibly be the result of environmental conditions peculiar to the Antarctic, but it is more than likely due to an increased awareness of the importance of oral hygiene on the part of the subjects because of their involvement in the program[10]. Also to be considered is the fact that there was a notable lack of abrasive in both the control and the experimental dentifrice. As a result, there was a striking accumulation of stain in both groups, this stain being most apparent on the labial surfaces of anterior teeth of those who smoked or drank tea. In fact, many people from both groups complained that they could not keep their teeth clean. These patients were encouraged to continue using the dentifrice with the promise that they would have their teeth polished at the termination of the study. It is conceivable that this accumulation of stain caused patients to brush with greater frequency and vigor, the result being less plaque accumulation. Although an excess of toothpaste was available at no cost to the people involved, no one expressed interest in continuing usage beyond the termination of the study.

In any case the study certainly revealed no merit in the experimental dentifrice either in the prevention of periodontal disease or in patient approval.

SUMMARY

1. A clay containing dentifrice, manufactured by E. R. Squibb and postulated to have the effect of reducing gingival inflammation, was tested by the U. S. Navy at McMurdo Station, Antarctica.

2. Forty-four subjects were divided into an experimental and a control group and evaluated periodically in terms of gingival inflammation, crevicular depth, and accumulation of bacterial plaque and calculus.

3. There was an overall improvement in the oral hygiene and gingival health of both groups during the Antarctic winter.

4. There were no significant differences found between the experimental group and the control group for any of the measurements employed.

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Gingivitis is a prevalent dental ailment in naval personnel. A new, highly adsorbent clay dentifrice has been developed. The theoretical action in vivo is thought to be the adsorption and consequent inactivation of the bacterial toxins responsible for gingivitis. A six-month study designed using 44 Antarctic personnel as subjects. These subjects were divided into two groups; one received the test dentifrice and the other a placebo. Measurement criteria consisted of standard gingivitis indices, plaque scores, and calculus indices. Results indicated no benefit in the test group with any of the three measurement methods. A corollary finding was an improvement in the oral health of both groups during the Antarctic winter. It is concluded that this experimental clay dentifrice is without practical value in reducing gingivitis in naval personnel.

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