

ABSTRACT

Text Methods for demonstrating clinical efficacy of anti-tartar agents have been well established. These clinical models typically select high tartar forming populations from short-term pre-test periods. This paper evaluates the consistency of tartar formation in pre-test periods in a common population. Two randomized, controlled 6-month tartar control studies were conducted over a 4 year period at a single center using a common design except for use of different examiners. Both studies used a 2-month pre-test period to evaluate calculus formation of participating subjects with a non-tartar control dentifrice. At the beginning of this period, all subjects received a prophylaxis, and were provided a regular dentifrice and a toothbrush and instructed to brush their teeth twice daily. After 8 weeks, subjects were assessed for the accumulation of supragingival calculus on the lingual surfaces of 6 mandibular anterior teeth using the Volpe-Manhold Calculus Index (VMI). The two studies have a total of 58 common subjects which completed the pre-test phase. In the first study, VMI scores at the end of pre-test phase ranged from 5.0-40.5 with a mean of 17.0±7.8, and in the second study, the scores ranged from 0.5-45.5 with a mean of 9.7±8.7. While the mean scores are significantly different ($p=0.0001$), Pearson correlation analysis shows that VMI scores in the two studies were significantly correlated ($r=0.60$, $p=0.0001$). Spearman's rank correlation coefficient was also highly significant ($r=0.57$, $p=0.0001$). **The data demonstrate that VMI scores in pre-test phases can be strongly related within subjects over several years and different examiners.**

INTRODUCTION

Clinical studies to support the efficacy of anti-calculus products have been widely published and standard testing models have been well established.¹ One of these models which has been used more recently is selecting high tartar forming populations from short-term pre-test periods for efficacy trials.²⁻⁴ In the pre-test period, subjects receive an oral prophylaxis, use a placebo product for 2-3 months and then are evaluated for supragingival calculus formation. The subjects are stratified into different study groups based on their pre-test VMI scores.

Evaluating the consistency of tartar formation in pre-test periods in a common population provides a unique opportunity to understand the epidemiological aspect of calculus formation.

MATERIALS AND METHODS

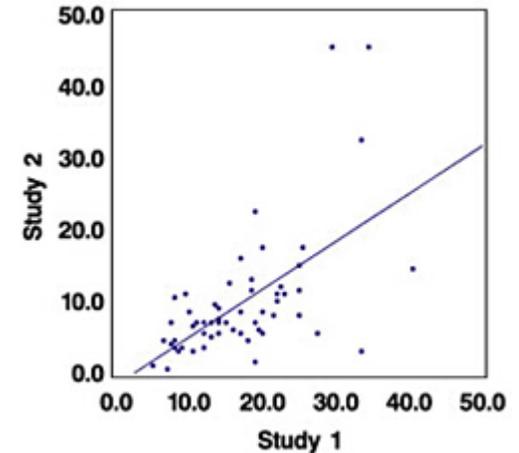
Two randomized, controlled 6-month tartar control studies were selected for this analysis. These studies were conducted over a 4 year period at a single center using a common design except for use of different examiners. Both studies included a 2-month pre-test period to evaluate calculus formation potential of participating subjects with a non-tartar control dentifrice. Before starting this period, all subjects received a prophylaxis, and were provided a regular dentifrice and a toothbrush and instructed to brush their teeth twice daily. After 8 weeks, subjects were assessed for the accumulation of supragingival calculus on the lingual surfaces of 6 mandibular anterior teeth using the Volpe-Manhold Calculus Index (VMI). For the purpose of this study, common subjects were identified from these two studies and descriptive statistics and correlation analyses were performed on their pre-test phase VMI scores.

RESULTS

The two studies have a total of 58 common subjects that completed the pre-test phase. Thirty-four were females and 24 were males. Their ages ranged from 28 - 69 years old, and the mean age was 45 at the beginning of the first study. In the first study, VMI scores at the end of pre-test phase ranged from 5.0 - 40.5 with a mean of 17.0 ± 7.8, and in the second study, the scores ranged from 0.5-45.5 with a mean of 9.7 ± 8.7 (Table 1). While the mean scores are significantly different ($p=0.0001$), Pearson correlation analysis shows that VMI scores in the two studies were significantly correlated ($r=0.60$, $p=0.0001$). Spearman's rank correlation coefficient was also highly significant ($r=0.57$, $p=0.0001$) (Figure 1).

Table 1: Pre-Test Phase VMI Scores

Study	Minimum	Maximum	Mean	Std
Study 1	5.0	40.5	17.0	7.8
Study 2	0.5	45.5	9.7	8.7



CONCLUSION

The data demonstrate that VMI scores in pre-test phases can be strongly related within subjects over several years and different examiners and supports use of this model.

REFERENCES

- Volpe AR, Petrone ME, Davies RM: A review of calculus clinical efficacy studies. *J Clin Dent* 4:71-81, 1993.
- Schiff T. et al. Effects of two fluoride dentifrices containing triclosan and a copolymer on calculus formation. *Am J Dent* 3:S43-S45, 1990.
- Lobene RR, et al. Anticalculus effect of a fluoride dentifrice containing triclosan and a copolymer. *Am J Dent* 3:S47-S49, 1990.
- Segreto VA, et al. Safety and efficacy of a novel tartar control dentifrice containing 3.3% pyrophosphate: a controlled six-month clinical trial. *J Clin Dent* 9:26-29, 1998.