PROPHYLAXIS FREQUENCY AS A PROTECTIVE FACTOR IN PERIODONTAL DISEASE INITIATION AMONG ADULTS

by

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A THESIS

Presented to the Department of Public Health and Preventive Medicine

and the Oregon Health Sciences University

School of Medicine

in partial fulfillment of

the requirements for the degree of

Master of Public Health

April 1997

School of Medicine
Oregon Health Sciences University

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Acknowledgments

I would like to thank my thesis committee for their suggestions, guidance, and encouragement:

Don Freeborn, Ph.D., chair

Mark Helfand, MD

Jack Hollis, Ph.D.

B. Alex White, DDS, Dr.Ph.

I would also like to acknowledge Merwyn Greenlick, Ph.D. for his interest in the project and encouragement; James Bader DDS, MPH, for his comments on the manuscript and continuing encouragement; Gary Sexton Ph.D. and Joe Istvan Ph.D. for their comments regarding logistic regression sample size; Paul Cheek for the creation of SAS datasets that were used for the analysis; Sharon Peabody RDH and OraLee Olson RDH for their assistance with chart review and data collection.

Abstract

The importance of routine six-month tooth cleanings in protecting oral health is a basic belief among dental professionals and the public, yet neither the efficacy nor the effectiveness of that treatment has ever been demonstrated in a randomized clinical trial. Indeed, many studies have not found any relationship between prophylaxis frequency and periodontal health (Lightener 1971, Suomi 1973, Listgarten 1985, 1989, and Papapanou 1990). The VA Dental Longitudinal Study (Brown and Garcia 1994) found that utilization of routine preventive services was not predictive of attachment loss in community dwelling men. Yet these studies have not dispelled the strong belief among dentists and hygienists that frequent prophylaxes (prophys) are an important preventive service. During 1995, more than 90 percent of all adults who were seen for an exam in a large dental HMO were recommended to have a six-month prophy (quality assurance analysis for internal review, Permanente Dental Associates 1996).

The study reported here used information from an electronic database and paper chart reviews to examine the relationship between prophylaxis frequency and change in the periodontal health of adult members of a dental health maintenance organization over a minimum observation interval of four years. Periodontal health assessment was based on pocket depth recordings, as the radiographs needed to calculate alveolar bone loss were not consistently present in the records available for review. Subjects were nondiabetic, periodontally healthy insured adults with at least thirteen teeth at the baseline exam. Logistic regression models were built to predict the initiation of periodontal disease using the number of tooth cleanings per year as the primary independent variable. Patient-level covariates of age, sex, baseline plaque levels, and flossing behavior were included in the model. The frequency of tooth cleanings was not related in any model to the probability that the subject would form a periodontal pocket during the study interval. High and low utilizers of prophylaxis services did not

differ in the proportions of sites with pocketing or in the proportion of subjects who formed any pocket. When compared with those who remained periodontally healthy, subjects who formed any pocket did not differ in the number of tooth cleanings received throughout the study period. This retrospective effectiveness study did not find that a higher frequency of dental prophylaxis was protective against the initiation of periodontal disease in a group of periodontally healthy, insured adults in a dental HMO.

Introduction

The importance of frequent (i.e. six-month) tooth cleanings in promoting oral health is a basic belief among dental professionals and the public, yet the neither the efficacy nor the effectiveness of that treatment has ever been demonstrated in a randomized clinical trial. The purpose of this paper is therefore two-fold. First, the existing literature is reviewed in detail to evaluate the basis of the belief that frequently performed tooth cleanings are efficacious for healthy adults. Second, a study is reported (set in a real -world dental HMO), that evaluates the effectiveness of frequent dental prophylaxis in protecting periodontally healthy patients against periodontal disease initiation.

Review of The Literature

The Historical Evidence: Löe and Axelsson

The two classic studies by Löe and Axelsson, which form the historical backbone of dental preventive treatment planning strategies, bear close examination. Neither study examined the efficacy of prophylaxes every six months.

The dental profession's understanding of pocket depth formation and attachment loss builds upon seminal work done by Löe in the 1970's, and although cited as having demonstrated the efficacy of frequent preventive care in preventing the progression of periodontal disease, both Löe's study design and published conclusions are silent on that issue. Axelsson showed that adults could be motivated to achieve excellent levels of oral hygiene and demonstrated that those who practiced careful plaque removal had very low rates of oral disease. When describing the methods used for his study, Axelsson does not indicate that the participants were randomized and he did not address the efficacy of frequent prophylaxes (Axelsson 1978, 1981).

The relationship between gingivitis and plaque was classically demonstrated by Löe in 1965. Twelve individuals with healthy gingiva ceased all plaque removal efforts until their gingiva became inflamed (approximately 10-21 days). The individuals were instructed in oral hygiene, and resumed oral cleansing until the tissue returned to health, over a period of 10 days. Löe also demonstrated a change in the bacterial ecology as the inflammation progressed (Löe 1965). The groundwork was thus laid to focus our preventive therapies on the prevention of gingivitis, and therefore prevent its progression into periodontitis. Since these early studies, it has become well accepted that gingivitis and periodontitis are two different diseases, and that gingivitis does not necessarily progress to periodontitis (Löe 1994). Yet, our treatment goal remains the same: to prevent gingivitis with frequent tooth cleanings.

Löe's watershed longitudinal study of gingival health and periodontal disease in Norwegian academicians and Sri Lankan tea workers offered a careful evaluation of periodontal disease progression over time in two very dissimilar populations (Aenerud 1979, Löe 1978a, Löe 1978b, Löe 1978c). The tea workers were illiterate Tamils, second- or third-generation descendants from South Indian immigrants who had no exposure to dental treatment or any oral hygiene procedures. Their nutritional condition was described as "fair", and they did not have access to general health care. Examinations were done outdoors in a portable dental chair without additional light (Aenerud 1979). The Norwegians were non-dental students and professors living in Oslo where comprehensive dental care (including recall visits provided on an annual basis) had been provided to individuals aged three to twenty-three since 1936. Between 1937-1976, more than 90 percent of those eligible had participated. Oslo had an extensive network of private practitioners available for the 10 percent of the population who chose to not access the public system. Additionally, since 1963, schoolchildren up to age 14 had participated in a supervised program of brushing with fluoride four times per year. Since 1947, all schoolchildren in grades one through seven had received yearly oral hygiene instruction. This cohort was chosen due to the "maximum exposure to conventional dental care throughout its life" (Löe 1978a). The exams were performed in a modern, well-lit dental facility (Aenerud 1979).

Löe's stated goal was to describe two extremes of periodontal disease progression using these two vastly different groups. He urges that "great caution should be used in comparing directly the various disease parameters in these groups in order to explain the differences" (Löe 1978a). The Norwegians had excellent oral hygiene and healthy gingiva at baseline, and, as a group, had a slow, steady rate of attachment loss over the duration of the study. The Sri Lankans had poorer gingival health at baseline, nonexistent oral hygiene, and a more rapid rate of attachment loss. Any conclusions about the effect of dental treatment on the oral health of the two populations directly violates Dr. Löe's pointed cautionary statements (Löe 1978b). The oral health of these populations is affected by differences in socio-economic status, general health, hereditary susceptibility as well as access to medical and dental care.

Axelsson's work in Sweden is offered as evidence that frequent prophylaxis is important in the prevention of caries and periodontal disease. Indeed, Axelsson studied an intensive preventive intervention for six years, and showed that the experimental group had less periodontal disease and fewer caries than the control group (Axelsson 1981). The extent that selection bias affected this outcome, though, is open to discussion due to the methodological questions that arise from the published description of the recruitment procedures for the trial (Axelsson 1978). Participants were recruited from the recall lists of three general private practitioners and the waiting list of three large public dental clinics. Only individuals receiving dental care yearly during the previous five years were eligible for recruitment. Potential participants of the intervention group received a letter inviting them to volunteer for the study, while potential members of the control group were told that they would receive an exam, followed by yearly recall to the public health clinic for treatment over a three year period. There is no discussion of how subjects were selected to be potential participants of the test group instead of the control group, nor what the recruitment rates were for the two groups. Baseline periodontal and caries scores were similar for the age-matched groups, although there is no discussion of whether the examiners were blinded at either baseline or follow-up to the status of the individual (Axelsson 1978).

The experimental group received a rigorous preventive regimen (intensive oral hygiene instruction and prophylaxis with fluoride paste) every two to three months for six years, while the control group received yearly exams and treatment for any identified dental needs. The control group was given no oral hygiene instruction during the study period, and it is not clear if prophylaxes or fluoride were provided. At the end of six years, the experimental group demonstrated excellent oral hygiene, no loss of attachment, minimal gingivitis, decreased pocketing over baseline levels and very low caries rates. There was no change in oral hygiene or gingivitis scores over baseline for the control group who also exhibited an increase in the number of pockets deeper than three mm, a mean attachment loss/year of .13-.26 mm and a mean caries incidence of 2.3 surfaces per year (Axelsson 1981). While disease rates were significantly different for the two groups, Axelsson's own conclusions attributed the excellent oral health of the intervention group to their utilization of proper personal oral hygiene techniques (Axelsson 1978, 1981).

The intervention study ended at the six-year examination when those remaining in the control group were invited to participate in the intervention arm. Axelsson followed 317 of the original experimental group for 15 years. Once the intervention study ended, preventive services were provided on an "as needed" basis, instead of routinely every two to three months. Using these individualized criteria, 65 percent of the subjects returned for preventive visits yearly for the next nine years and 30 percent returned twice yearly. The remaining 5 percent returned more frequently, as they were designated at high risk for either periodontal disease or dental caries. Even though the majority of subjects had only yearly prophylaxes, Axelsson reports that the group of 317 "had a low incidence of caries and almost no further loss of periodontal tissue support." Again, he attributes the low levels of disease to the rigorous oral hygiene instruction and subsequent meticulous home care performed by the study participants (Axelsson 1991).

While this study demonstrates that oral disease rates were very low for a highly motivated group of subjects willing to participate in a rigorous preventive regimen, the factor or factors responsible for achieving that excellent state of health remain unclear. During the last nine years of the study, the majority of individuals had only yearly prophylaxes, yet the oral health of the entire group did not decline. Axelsson's results are reported only by age group, so we are unable to draw any conclusions regarding preventive visit frequency and final disease status, and we do not have any information on the oral health of control group members who joined the experimental group in the seventh year. While it is perhaps tempting to attribute the success of the control group to their receipt of frequent cleanings, Axelsson's work is, in fact, silent regarding the effectiveness of frequent prophylaxis in preventing periodontal disease or caries in a population.

Other Longitudinal Studies

Two studies of healthy young men showed no differences in periodontal health between those who received annual cleanings, and those who had cleanings more frequently than yearly (Lightener 1971, Suomi 1973). Both studies rely on pooled measurements (e.g. mean gingival indices, mean attachment level changes scores) for comparison. Lightener (1971) followed 470 Air Force recruits for four years. They were randomized into three treatment groups and a control group, which received one yearly preventive appointment and no oral hygiene instruction. The treatment groups had increasingly frequent preventive schedules up to four cleanings per year. One subgroup of the four-cleanings-per year group received no oral hygiene instruction. No groups showed any statistically significant difference in their pocket depth/attachment loss index. After 46 months, the group that received four cleanings per year without oral hygiene instruction had gingival index, periodontal index, and plaque index scores more similar to the control group (one cleaning per year) than any of the groups with more frequent cleanings; indicating that personal oral hygiene instruction may be more important in controlling gingivitis, pocketing, and plaque levels than professional cleanings (Lightener et al 1971).

Coast guard recruits (N=473) were followed for three years to evaluate the effects of one, two, or three prophylaxes per year. Each subject was given a fluoride treatment after the cleaning, but no oral hygiene instruction. The investigators found no significant differences in mean amounts of debris, mean calculus scores, attachment loss, pocket depth or gingival inflammation scores between the three groups, which led them to conclude that there was no beneficial effect on the periodontium with two or three cleanings yearly, when compared to an annual cleaning in a physically healthy young male population (Suomi et al 1973).

Listgarten followed 61 periodontally healthy patients over three years. These patients were randomized into a usual care group (cleanings and exams every six months) and a treatment group. The treatment group received exams every six months, but their prophylaxis frequency was tied to the concentrations of periodontal pathogens in their dental plaque. When the microscopy was negative for these pathogens, the recall intervals were increased gradually, while positive pathogen screens resulted in shortening the intervals. Approximately one third (11 of 30) of the subjects in the treatment group completed the entire three year study without receiving any cleanings. Although some in this group had more calculus and stain at year three than the control group, none had deteriorated periodontally. The differences in the groups that existed at baseline tended to continue throughout the study period, and neither regimen was effective in eliminating gingivitis. The authors concluded: "..for a majority of an adult population with gingivitis but no periodontitis.., frequent prophylaxes may not be needed for the prevention of destructive periodontal disease" (Listgarten 1986).

Using a similar design, Listgarten studied the outcomes of bacteriologically determined cleaning frequencies for patients previously treated for periodontal disease. Usual care patients (N=47) had exams every six months with a prophylaxis every three months. The experimental group (N=33) had the same exam schedule as the usual care group, but only received a prophylaxis when the presence of periodontal pathogens exceeded a preset threshold, as evaluated by differential dark field microscopy. The experimental group had an increased drop out rate because some patients were concerned that they needed to have their teeth cleaned more often, even when the six month monitoring showed no disease recurrence. Three patients were dismissed from the study after having their teeth cleaned by providers outside the study. There was no significant difference in the rate of disease progression in the two groups, even though the experimental group had an average length between prophylaxes of 19.4 months, and at the end of the four year study, an average of 30.6 months had elapsed since the last cleaning (Listgarten 1989).

A survey was sent to 191 Swedish subjects who had received full mouth X-rays taken in 1975 and 1985. Based on the mean longitudinal bone level change, the population was divided into the "worst 7 percent " (N=14) and the "best 7 percent " (N=14). If prophylaxes are protective against periodontal disease, we might expect to find less disease in those individuals who receive frequent preventive care. The authors found no difference between the two groups in the frequency of receiving dental treatment, although the group suffering the most bone loss did report using a greater amount of periodontal services than those with a lower rate of bone loss. One weakness in this study is the categorization of dental visit frequency. One and two visits per year are compared with those who visited less frequently, and the type of service was not characterized, only the type of provider (dentist vs. dental hygienist) visited (Papapanou and Wennstrom 1990).

Swedish subjects (N=64) with mild to moderate periodontal disease were monitored for six years, without receiving any periodontal therapy (Lindhe 1983). Only 4 percent of the measured sites showed significant (greater than 2 mm) loss of attachment over three years, while 11.6 percent showed more than 2 mm of attachment loss over the entire six year period. Five subjects accounted for more than half of the sites which showed significant attachment loss.

A more detailed evaluation of utilization of dental services and periodontal disease was published by Brown and Garcia (1994), who followed 539 male subjects for ten years and evaluated whether the use of diagnostic and preventive services was predictive of alveolar bone loss. Several multivariate models were created that considered bone loss either as a continuous or a dichotomous variable. No model found the utilization of preventive and diagnostic services to be predictive of alveolar bone loss. Only the following variables were predictive of bone loss at the time of the outcome exam: the number of teeth at baseline, educational level, and the percent of teeth with more than 40 percent bone loss at baseline. As applied in routine practice, this study found preventive services to be ineffective in periodontal disease prevention.

Indeed, the literature review did not reveal any studies that clearly showed frequent prophylaxes to have a protective effect against periodontal disease in healthy populations, although studies by Lightener (1971) and Axelsson (1978, 1981, 1991) point to the importance of personal oral hygiene in periodontal disease prevention. While evidence of the effectiveness of frequent prophylaxis in preventing periodontal disease is consistently lacking in the literature, the fact remains that practice patterns have not been changed by this body of work. This lack of practice pattern change may be the result of several factors. First, for most of the population, a dental prophylaxis is a procedure with very few risks, and is routinely recommended for all patients as the current standard of care. The burden of proof for abandoning this low-risk treatment is therefore more stringent than that applied if assessing the effectiveness of an invasive surgical procedure. Additionally, when solid data are lacking, the provider's personal theories will drive the utilization of the treatment in question. After a thorough tooth cleaning, when the teeth are opalescent and free of debris, the mouth may simply look healthier to the dental provider, thus reinforcing the belief that oral health is better after the teeth are cleaned.

Secondly, many of the reviewed studies suggesting that prophylaxis may be ineffective were done on selected populations, who are likely to differ from patients seen in a private practice (Lightener 1971, Suomi 1973, Axelsson 1978, Löe 1978a). Some studies had follow-up durations of only three years (Suomi 1973, Listgarten 1985), used pooled measures (Lightener 1971) and had fewer than 100 subjects (Lindhe 1983, Listgarten 1985 and 1989, Papapanou and Wennstrom 1990). The outcomes of these studies are commonly reported in terms that clinicians do not use routinely, and have been published in either specialty or research journals, which are not widely read by practicing dentists and hygienists.

Thirdly, there is no financial incentive under a fee-for-service payment system to scrutinize the value of frequent prophys. The dental hygiene visit is often touted as the key to dental office productivity, both for any dental work that may be recommended to the patient and for the fees generated by the tooth cleaning procedure itself (Rossi 1996, Steele 1996).

Significance

Even without strong data to support the effectiveness of regular tooth cleanings, prophylaxes are performed so frequently that they constitute a large proportion of the resources used to prevent and treat oral disease. The cost of each prophylaxis is quite small, with fees in the $50.00 range (National Dental Advisory Service 1997), but since the procedure is recommended to virtually every dental office patient, the total cost can be surprisingly large. During 1995 alone, prophylaxis services valued at $3.86 million dollars were provided to adult members of the Kaiser Permanente Dental Care Program in the Northwest region, and tooth cleaning was the most frequently performed treatment in the Kaiser dental program. Also during 1995, Washington Dental Service reimbursed providers for 644,800 adult prophylaxes, at a cost of $37.6 million dollars (private communication with Dr. Max Anderson, Washington Dental Service, 1997). In a review of claims collected from a dental insurance clearinghouse between 1990 and 1994, an adult tooth cleaning was the procedure most frequently submitted for reimbursement. When submitted charges were ranked in order of totaled charges, dental prophylaxis was again at the top of the list, accounting for almost 13 percent of the paid claims at $25.6 million dollars. As a comparison, the second most costly procedure accounted for only 6 percent of all paid claims (Hayden 1997).

The assumption that frequent preventive care is an effective use of preventive dollars has been questioned before (Bader 1991). Sheiheim (1977) also called for a re-evaluation of the use of and payment for routine dental examinations every six months. In a clinical trial, when the recall frequency was arbitrarily extended from 12 to 24 months in children and adolescents in Norway, a 30 percent savings of the time needed to treat all the dental needs of this population was realized (Wang 1992). Certainly, if practice protocols are to change, more data are needed. Without it, some may claim that extending recall intervals is a false economy. If, however, other proven preventive services can be provided in lieu of frequent prophys for healthy adults— with no loss of periodontal health— gains in the overall health of the population should be realized without increased expenditures.

Materials and Methods

Hypotheses

The primary objective of this study was to examine whether more frequent tooth cleaning, after adjusting for patient-level confounders, was associated with decreased probability that a periodontally healthy patient would develop a periodontal pocket over a minimum study interval of four years. The null hypothesis investigated was that more frequent dental prophylaxis would have no effect on the initiation of periodontal disease. The alternate hypothesis was that more frequent dental prophylaxes would provide a decreased risk of periodontal disease initiation.

Two related questions were also investigated. First, groups of subjects who were either high or low utilizers of prophylaxis treatments were evaluated for any difference in periodontal health at follow-up, as well as whether they differed in the proportion who had a tooth extracted. Those subjects who formed any pocket ≥ 5mm during the study were also evaluated to determine if they differed in the frequency of prophylaxes received or in personal oral hygiene habits from those who had no pocket formation. Because a true protective effect might be masked by increased prophy utilization after periodontal disease was discovered, it was also hypothesized that those subjects who developed periodontal disease during the study would receive more cleanings as the study interval progressed when compared to those who did not develop pockets. The pattern of prophylaxis frequency was therefore also examined.

Research Setting

The Kaiser Permanente Dental Care Program is a prepaid group dental practice with 13 dental offices in the greater Portland-Vancouver-Salem area. In 1996, the dental program experienced 325,309 patient visits among 161,199 year-end enrollees. All members pay an office visit fee when they present for an appointment, which ranges from $0-$10, depending on their dental plan. This registration fee is not related to the reason for their visit, and the preventive care examined in this study has no additional patient copayment under any plan. Members who receive dental care outside the Kaiser system are not reimbursed for the cost of the nonplan care. This study was approved by the Kaiser Permanente Center for Health Research Human Subjects Review Board on October 16, 1996.

The data sources available for this retrospective study included an electronic administrative database, the traditional paper dental chart, and a regional electronic diabetes registry. The administrative database contains demographic information, membership data, and a record of all dental treatment received since 1987 by every member of Kaiser Permanente, NW region. Patients are identified by a unique health record number that is used both for their medical and dental record. Diagnostic information about periodontal disease is not included in this database but is available in the paper chart. The paper dental chart also includes written treatment notes, radiographs, and all information gathered at a yearly exam. Patients aged 21 and older routinely receive full mouth periodontal probings as part of their exam, with program guidelines dictating that any periodontal pocket ≥ 5 mm deep be recorded. As no information is available about pocket depths < 5 mm, conclusions are limited to those pocket measurements at least 5 mm deep.

Individuals were screened for diabetes through the Kaiser Permanente NW Diabetes Registry, a computer-based registry of members, who have either been diagnosed with diabetes or have received medications for diabetic treatment. This registry is maintained and administered at the Kaiser Permanente Center for Health Research, and automatically updated weekly. It is based upon hospital discharge diagnoses, pharmacy dispensings, diabetes education records and case management files, and was used in this study to electronically exclude diabetic subjects.

Inclusion and Exclusion Criteria

This study was intended to evaluate the effectiveness of preventive treatment frequency received by a periodontally healthy, low-risk population. Subjects were included if they had five years of continuous eligibility during the study period, thus increasing the likelihood that all preventive treatment received by that patient would be present in the Kaiser record. Since short observational periods are more likely to miss the onset of periodontal disease, a minimum observational period of four years was chosen. Subjects needed to have full mouth periodontal probings recorded at both the baseline and follow-up exams to allow determination of baseline health and outcome status. Exclusion criteria were selected that would minimize the representation in the study population of individuals at high risk for periodontal disease or who had periodontal disease at baseline.

Subjects whose identifiers were present in the regional diabetes registry or who had a dental chart documentation of AIDS were excluded from this study. When systemic diseases are reviewed, diabetes mellitus is consistently associated with an increased risk of periodontal disease, although the amount of risk depends upon the degree of metabolic control and the duration of the diabetes (Oliver 1994, Emrich 1991). Neutropenic states can also be associated with periodontal destruction, although studies of organ transplant patients who are treated with prednisone and cyclosporine showed no increased periodontal destruction (Oshrain 1983, Sutton 1983). AIDS patients, however, may experience aggressive bone loss (Hart 1994).

To select a periodontally healthy cohort at baseline, patients with current evidence of periodontal disease were excluded. Third molars were excluded from the study due to the frequency that pocket depths on third molars are associated with anatomic considerations, not disease. Patients who have fewer than 12 teeth have been shown to be more likely to have future attachment loss (Beck 1994, Brown 1994). To be eligible for this study, patients had to have more than 12 teeth present at baseline (excluding third molars) and could not have any periodontal pocket ≥ 5 mm on a non-third molar tooth at the baseline exam.

Smoking has been implicated as a risk factor both in the initiation and progression of periodontal disease. Patients who smoke are more likely to have periodontal disease that is resistant to treatment than nonsmokers (Grossi 1994, Beck 1994, Bergstrom 1994).

Unfortunately, none of the data sources available for this study included a consistent evaluation of patient smoking status, so periodontal changes attributable to smoking were not addressed in this study.

Sample Selection

The sample selection for this study occurred in two phases. Initially, an electronic screening was performed to eliminate those patients whose ineligibility could be determined without time-consuming chart review. A random sample of this screened population was then selected for chart review (N=1800). These charts were reviewed for eligibility using information available in the dental chart, resulting in a final sample of 377 individuals (Figure 1).

Figure 1: Sampling Diagram

Eligibility Criteria				**Electronic Screen**
•25 years old •Continuous eligibility		N = 48035		
•Non-diabetic		N = 44080		
•Exam in 1991 & 1995 ≥ 4 years apart		N = 8005		
Mean # prolyr calculated (Number and proportions in electronically screened population)	N = 2215 (0.277)	N = 5014 (0.626)	N = 776 (0.097)	
	Low Utilizers	**Moderate Utilizers**	**High Utilizers**	**Stratified Random Sample**
Final Random Sample	450	900	450	
Exclusions				**Chart Audit**
•Pocketing ≥ 5 mm	363	622	326	
•Insufficient data	13	37	18	
•< 13 teeth	4	22	15	
•< 4 years observation	0	2	1	
	70	217	90	**Final Sample**

Eligibility: Electronic Screening

A dataset was created at the Kaiser Permanente Center for Health Research by selecting all dental members who were at least 25 years old on December 30, 1990, and who had five years of continuous membership in the Kaiser Permanente Dental Program from January 1, 1991, through December 31, 1995 (N=48,035). Gaps in membership of three months or less were considered continuous in this dataset. Members with missing dates of birth were excluded from the study, as were Kaiser Permanente Center for Health Research employees and dependents.

All patients present in the Kaiser Permanente Diabetes Registry were excluded from the study, reducing the sample by 3,195 individuals. The electronically screened population was then selected to include only those who received an exam in both 1991 and 1995, with at least four years separating the two exam dates (N=8005). A pilot study by the principal investigator revealed that values for the mean number of prophys/year clustered around 1.5-1.8 prophys/year. Therefore, to ensure an adequate sample size for the bivariate analysis between high and low utilizers, it was necessary to oversample the low and high utilizers of prophy services. The group of electronically screened patients was divided into three samples, based on the mean number of prophys they received during the study period. Those who received—on average— fewer than one prophy/year were classified as low utilizers and those who received more than two were considered high utilizers. A stratified random sample was then drawn from the electronically screened population, with 25 percent of the patients in this final random sample from each of the low and high utilizer groups.

Eligibility: Chart Review

Charts were reviewed for eligibility on a hierarchical basis: screening for existing periodontal disease occurred first, then the number of teeth at baseline were determined, and finally the medical history was reviewed for presence of an AIDS diagnosis. (Since none of the reviewed charts contained an AIDS diagnosis in the dental record, no subjects were found to be ineligible due to this criterion.) Subjects were first eliminated if they had any periodontal pocketing of 5 mm or greater on a non-third molar tooth at their baseline exam. If the subject had no pockets, the number of teeth present at the baseline exam was then counted, and the record was included in the study if more than twelve non-third molar teeth were present. The reviewers determined the number of teeth first from the exam form, and then radiographs, if needed. All records reviewed had adequate information to determine the number of teeth present at the baseline exam.

Records that were missing either the baseline or follow-up periodontal probings or all of the baseline exam information were declared ineligible due to insufficient data. Due to the large number of charts to be reviewed, once a chart was ineligible, it was discarded and the reviewers did not assign multiple reasons for ineligibility (Table 1).

Table 1: Proportions of Screened Samples by Final Eligibility

Ineligible	Low Utilizers		Moderate Utilizers		High Utilizers		Total	
Pockets	363	81%	622	69%	326	72%	1311	73%
# Teeth	4	1%	22	2%	15	3%	41	2%
Data	13	3%	37	4%	18	4%	68	4%
Obs int	0	0%	2	0%	1	0%	3	0%
Eligible	70	16%	217	24%	90	20%	377	21%
Totals	450	100%	900	100%	450	99.9%	1800	100.00%

Data Collection

For each of the 1800 records in the random sample, a master list from the electronic record was created that included the following information: a unique patient identifier, sex, age, the dates of both the baseline and outcome exams, the length of the observational interval, the number of prophys received per year of observation, and a listing of all preventive, periodontal and extraction procedures received between the baseline and follow-up exam dates. Charts were reviewed in the order they appeared on the master list. All 1800 dental charts were reviewed by the principal investigator and two Kaiser Permanente Dental Program dental hygienists, who had each read and signed the Kaiser Permanente Confidentiality Statement. Charts were reviewed at the dental records facility unless needed for treatment, in which case only the principal investigator reviewed the chart at the dental clinic where the chart was being kept.

For those charts available at the chart room, one dental hygienist reviewed each chart for eligibility, as outlined above. If the record did not meet all the eligibility criteria, the reason for ineligibility was noted on the master list, and the chart was refiled. If the chart did meet all criteria, a data collection form was started for that subject by the dental hygienist. At both the baseline and follow-up exams, patient-reported daily flossing behavior and the levels of plaque, calculus, and bleeding were recorded from the exam form. The baseline exam was defined as the first exam performed in 1991, and the outcome exam was the last exam in 1995. If the information was missing on the exam form, the narrative treatment notes were reviewed for that visit, and the information abstracted from that source as needed. Pocket depths were obtained from the periodontal exam form, where pocket depths are recorded at six sites per tooth.

The chart with attached data collection sheet was then given to the principal investigator for a review of the treatment record. Every eligible chart was reviewed by the principal investigator to verify the dates and number of electronically reported prophy treatments, extractions, and periodontal treatments. Each visit with a treatment code equivalent to the American Dental Association code 0110 (adult prophylaxis) or code 4341 or 4345 (supportive or maintenance periodontal treatment) counted as one cleaning. A tooth cleaning was recorded as having been received if it was noted either in the electronic record or paper chart. Any periodontal surgery received was also noted on the master list, and verified through chart audit. All extractions, including the tooth number and date of extraction were recorded. The most recent pocket readings for any tooth extracted or receiving periodontal surgery were recorded and used in the calculation of the subject's periodontal health at follow-up. Reasons for extraction were abstracted from the chart by the principal investigator, using diagnoses and chart notes at the time of the extraction to assign a reason for the extraction (Phipps & Stevens, 1995). There were no discrepancies between the chart and electronic record for extraction codes, extracted tooth numbers, or any periodontal treatments.

The dental hygienist data collectors were trained by the principal investigator prior to data collection, and approximately 20 percent of the eligible charts (78 of 377) were reviewed by the principal investigator for accuracy. Separate error rates were not calculated for the individual dental hygienists. Only two types of errors were found that affected the data used for this study. One notation of plaque level was found to be inaccurate by one level (error rate of 1.28 percent), and three charts (error rate = 3.85 percent) were coded to indicate that they had no pockets at follow-up when a pocket was indeed present.

Variables

Dependent Variable

The primary dependent variable was the development of any periodontal pocket ≥5 mm on a non-third molar tooth. In addition to this dichotomous outcome measure, information about the extent and severity of periodontal disease at follow-up was also captured by evaluating the proportion of a subject's measured sites that exhibited pocketing of either ≥ 5 mm or ≥ 6 mm. While the unit of measurement used in studies of periodontal disease has been the subject of some disagreement, it is clear that evaluation of pooled sites (e.g. mean pocket depth change) within a patient can wash out the effect of treatment, because a large proportion of the sites are inactive, and will remain so regardless of intervention (Imrey 1986). Most sites in most subjects are inactive, and disease progression occurs infrequently, leading to difficulty in evaluating the effects of different treatment regimens in preventing attachment destruction (Page 1992). To enhance the ability of this study to discern any protective effect of dental prophylaxes, the most sensitive threshold for classifying a subject as diseased was chosen, the development of any pocket (DeRouen 1990).

Pocket depth is a traditionally used proximate outcome for periodontal disease, but the ultimate outcome of interest to the patient and clinician is tooth loss (Antczak-Boucoms

1991). This healthy population was not expected to experience enough extractions during the study period to allow meaningful analysis of the number of teeth extracted. However, those subjects who received any extraction were noted, with extraction measured as a dichotomous outcome.

To allow evaluation of the cost differences between low and high utilizers, the cost of prophylaxis services received by subjects during the study period was calculated. This cost was based upon the fee that Kaiser Permanente Dental Program would have charged a nonmember for prophylaxes, which remained unchanged at $48.00 over the study duration.

Independent Variables

The primary independent variable was the number of prophys received per year of observation. To create this variable, the interval in days between the baseline and follow-up exams was first divided by 365.25 to obtain the observational interval in years. The total number of prophys for each subject was then divided by their observational interval in years to determine the number of prophys received per year of observation. Utilization was also measured as a dichotomous variable, with the top and bottom quintiles of utilization being designated as high and low utilizers, respectively.

Patient-level co-variates such as gender and age were measured to control for their influence on the likelihood that a subject would develop periodontal disease. Daily flossing behavior was measured dichotomously at both baseline and follow-up, as reported by the patient. The levels of plaque noted by the dental hygienist at the time of the baseline exam were ordinal measures: none, light, moderate, or heavy.

To assess if the pattern of care differed between those who formed a pocket during the study interval and those who did not, the difference between the number of prophys received early in the study period and the number received later in the study period was compared between healthy and diseased subjects. All variables are summarized in Table 2.

Table 2: Variable Description

Outcome	Type
formation of any pocket	Dichotomous
proportion of sites pocketed >=5mm	Continuous
proportion of sites pocketed >=6mm	Continuous
Any extraction received	Dichotomous
Cost of prophylaxis services	Continuous
Mean change pro freq over time	Continuous
Independent	
Age	Continuous
Gender	Categorical
Baseline plaque levels	Ordinal
Number of teeth at baseline	Continuous
Baseline daily flossing	Dichotomous
Follow-up daily flossing	Dichotomous

Overview of Analyses

Weighting must be used when the data from a random stratified sampling process are used to calculate a population mean (Pagano and Gavreau, 1993). However, this study evaluated the effectiveness of a treatment on a healthy, low-risk, insured population and no conclusions are drawn about the treatment effectiveness beyond this selected population. The data for the analyses were therefore not weighted.

While it is customary to use Bonferroni's method of reducing the probability of a Type 1 error when multiple statistical comparisons are made, that correction was not used in these analyses, and the p value is reported as calculated, with no adjustment of the significance threshold. The Bonferroni correction "cost" of decreased power would increase the probability of Type 2 error (Hirsch and Riegelman 1992), which was the more important error to avoid in this study, as it was expected from the literature review that data analysis would fail to reject the null hypothesis. If the required significance level was made more stringent due to the number analyses performed and no treatment effect was demonstrated, some could question that the failure to reject the null hypothesis was due to the more stringent value of α required rather than the lack of a treatment effect. Therefore, conclusions regarding any associations which are significant at $p=0.05$ must be drawn with the understanding that multiple comparisons were made.

Sample Size

When comparing the low and high utilizer groups, the primary outcome of interest is the difference in the proportion of sites with pocketing. With a sample size of 78 per group, this study has a 90 percent probability of detecting a difference of 0.0004 sites, with an $\alpha=0.05$, two-tailed (Hulley and Cummings 1988). In clinical terms, this effect size would allow the detection of differences smaller than one site per person with all 28 teeth present.

For the regression model, the primary independent variable is the frequency of tooth cleanings, and this variable drove the sample size calculation. Standard sample size calculations are not precisely applicable for logistic regression analytic techniques, although an estimate of the sample's size may be made with a t-test (Browner et al 1988). Hsieh (1989) however, cautions against using sample size estimates for logistic regression models that have not been adjusted for both the number of covariates that are to be entered into the model and for the degree of correlation among those covariates. Self and Mauritzen (1988) have concluded that when there is no significant correlation between the exposure and confounder variables, the sample size requirements are essentially identical to a model without the confounders included. Although there is minimal correlation among the independent variables, the sample's size was adjusted for the multiple R associated with the prophy/year variable. Using tables calculated by Hsieh (1989) and correcting with the multiple R for the primary independent variable (0.6258), a sample size of 375 provides this study with an 80 percent probability of detecting an odds ratio of .7 for pocket initiation when the mean number of prophys/year a subject receives increases by 0.5 ($\alpha=0.05$, one-tailed).

High Vs Low Utilizers

To determine how groups of high and low utilizers might differ from one another both in outcome and underlying characteristics, subjects who received a mean number of prophys/year in the top or bottom quintiles of the study population were classified as high or low utilizers, respectively. Low utilizers (N=78) received fewer than 1.04 prophys/year, and high utilizers (N=78) received more than 1.890 prophys/year. The proportion of sites at the follow-up exam that had periodontal pocketing ≥ 5 mm and the proportion with pocketing ≥ 6 mm were compared between the high and low utilizers, using a t-test for independent samples. Similarly, the two utilization groups were compared for differences in their mean age, length of observational interval, the number of teeth at baseline, and the cost of preventive care that they received. High and low utilizers were also compared on the proportions of their populations who formed any pocket, their levels of baseline plaque, their flossing behavior at baseline and follow-up, and their likelihood of receiving an extraction over the study period with a chi-square test.

Any Pocket Formed Vs Remained Healthy

Those subjects who formed any pocket at least 5 mm deep were compared with those who remained healthy throughout the study period to determine if any baseline measures available in the dental chart were correlated with the initiation of periodontal disease and also to assess the correlation between utilization and periodontal health at follow-up. A chi-square test was used to compare the two groups on their baseline plaque levels, their flossing behavior at both baseline and follow-up, gender, and utilization. The healthy and diseased groups were also compared with a t-test for independent samples for differences in the mean length of their observational interval, cost of prophy services received, number of teeth at baseline, age, and number of prophys received per year.

Logistic Regression Model

A logistic regression model was created to analyze the effect that the number of prophys received per year had on a subject's probability of developing periodontal disease during the study duration. The number of teeth present at baseline— as a patient-level risk indicator— was included in the regression model as were the potential confounders of patient age and gender. To assess the role that personal preventive behaviors might play in predicting future pocket formation, self-reported flossing behavior and plaque levels noted at baseline were also included in the model. The model was built with a step-wise method, entering one main effect at each step. Reference categories for the categorical variables were females for gender, "none-light" for plaque levels, and a positive report for daily flossing activity.

Pattern of Prophylaxis

The final analysis performed compared the pattern of prophys received during the study period between the subjects who formed a pocket and those who did not. This analysis was performed to determine if subjects who had pockets develop were more likely to increase the frequency of their tooth cleanings after the pocket was discovered. When disease (as evidenced by a periodontal pocket) is discovered, the clinician is likely to recommend that the patient receive preventive procedures at an increased rate. This bias can mask an underlying benefit of the preventive procedure if it is recommended more often to those who have developed disease. The prophy utilization pattern of those who formed any pocket (N=146) was compared to those who had no pocket formation (N=231). The observational interval was divided into four equal segments for each subject (observational subinterval 1-4, with subinterval-1 representing the first quarter of the subject's total observational period, subinterval-2 the second quarter, etc.), and the number of prophys received in each interval was calculated. The number of prophys received in subinterval 4 was subtracted from the number received in subinterval 1, and this difference was reported as the change in prophys from time 1 to time 4 for each subject. To capture changes that occurred during the middle of the study period, the same calculation was made subtracting subintervals 3 &4 from subintervals 1 & 2. The mean change in prophys between time intervals early and late in the study period was then compared between the pocketed and healthy groups using a t-test for independent samples.

Data Management

Data from the electronic record were provided by the Kaiser Permanente Center for Health Research. A complete copy of the dataset is maintained at the Center for Health Research. Data available from the electronic record were directly entered into an Excel© (Excel 1992) spreadsheet and imported into SPSS© for Windows Statistical Software (SPSS 1993). Data from the chart audit have been entered into the computer database by the principal investigator, and were analyzed with SPSS© for Windows Statistical Software (SPSS 1993) at Oregon Health Science University. Any corrections to the prophy counts or observational intervals were made by the principal investigator. All data collection forms, as well as the information from the electronic record are maintained by the principal investigator in her office at the Kaiser Permanente Building, Portland, Oregon.

Results

Study Participants

The sample had a mean age of 43 years, and was disproportionately female, with only 31 percent of the sample being male. Slightly more than one third of the study (38.7 percent) participants formed a periodontal pocket during the study interval. The sample mean for the number of prophys/year was 1.5. The mean number of teeth at baseline among the subjects was 26 (156 sites), and the mean proportion of sites with pockets 5 mm or more was 0.01. Plaque levels of either light or none were reported for 75 percent of the sample, and 43 percent reported that they flossed on a daily basis at baseline (Table 3). Twenty-three subjects lost twenty-nine teeth, and four subjects received periodontal treatment. No teeth were lost during the study interval due to periodontal disease.

Table 3: Sample description

	Mean	Std Dev	Min	Max
Proportion sites >=5mm	0.01	0.03	0	0.35
Proportion sites >=6mm	0	0	0	0.06
Number of teeth at baseline	26.33	2.87	13	28
Age (years)	43.07	12.04	25	78
# prophys/year	1.508	0.452	0.223	2.93
Observational Int (years)	4.32	0.231	4	5.15
	Number		Sample percent	
Formation of any pocket	146		38.7%	
Baseline daily flossing	162		43%	
Baseline plaque=light-none	284		75.3%	
Follow-up daily flossing	168		44.6%	
Receipt of any extraction	23		6.1%	
Receipt of any periodontal tx	4		1.1%	
Females	259		68.7%	

High Vs Low Utilizers

Low and high utilizers were compared with a Pearson chi-square test on the proportion of each population who were daily flossers at baseline or follow-up, who formed any pocket, who received any surgical procedure, who were female, and who had low or no levels of plaque at baseline. Low utilizers were no more likely to form a pocket or receive an extraction than high utilizers. Results are shown in Table 4. High utilization was significantly associated with daily flossing behavior at both baseline ($\chi 2$= 13.39, df=1, p<0.001) and follow-up ($\chi 2$=28.15, df=1, P<0.0001), but there were no other significant differences between the two groups among those variables tested.

Table 4: High vs Low Utilizers

Variable	High utilizers	Low utilizers	Pearson chi-square	p value
Formation of any pocket	35.90%	43.60%	0.96	p= 0.33
Daily flossing at baseline	57.70%	28.60%	13.39	p< 0.001
Daily flossing at follow-up	66.70%	24.40%	28.15	p<0.0001
Moderate plaque at baseline	23%	24%	0.008	p= 0.93
Receipt of any extraction	9.00%	2.60%	2.95	p= 0.086
Percent females	73.10%	75.60%	0.135	p= 0.714

df=1

No differences were found between the low and high utilizer groups in the number of teeth present at baseline or the proportion of sites with either 5 or 6 mm pockets at the follow-up exam, using a t-test for independent samples (Table 5). The high utilizers were significantly older (mean age 50.21 vs. 36.83 years, p<0.001, t-test for unequal variance) and utilized approximately $219.00 more on tooth cleanings over the observational period ($164 vs. $383, p<0.001, t-test for unequal variances). The study duration for the high utilizers was approximately 1.5 months shorter than that for the low utilizers. While this difference was significant statistically (p<0.001), the clinical significance of 1.5 months is negligible, as this is too short a time interval difference to lead to ascertainment bias in periodontal disease detection.

Table 5: Mean Differences Between High and Low Utilizers

Variable	High util	Low util	SE Mean Diff	CI for Difference	p value
Prop sites pockets >= 5mm	0.0081	0.0184	0.006	(-0.001, 0.021)	p= 0.066
Prop sites pockets >= 6mm	0.0003	0.0017	0.001	(0.000, 0.003)	p= 0.112
Age in years	50.2	36.8	1.814	(-16.96, -9.79)	p< 0.001
Observational interval in yrs	4.17	4.31	0.035	(0.068, 0.208)	p< 0.001
Cost of prophy services	$383	$164	10.06	(-238.96, -199.20)	p< 0.001^
Number of teeth at baseline	25.7	26.5	0.48	(-0.105, 1.797)	p= 0.081

two-tailed t-test for independent samples, unequal variances, all subjects
^t-test for equal variances, two-tailed, all subjects

Any Pocket Vs Remained Healthy

Subjects who formed any pocket during the study interval did not differ significantly in utilization, flossing behavior at either baseline or follow-up, baseline plaque levels, the receipt of any extraction, or gender when compared with subjects who remained healthy (Table 6). A Pearson's chi square test was used for this analysis.

Table 6: Any Pocket vs No pocket Formation

Variable	No pocket	Any pocket	Pearson chi-square	p value
Percent low utilizers	46.80%	54.10%	0.786	p= 0.38
Daily flossing at baseline	42.20%	44.80%	0.255	p= 0.61
Daily flossing at follow-up	46.80%	41.40%	1.041	p= 0.31
Moderate plaque at baseline	21.20%	29.20%	3.054	p= 0.08
Receipt of any extraction	6.10%	6.20%	0.002	p= 0.97
Percent females	67.50%	70.50%	0.378	p= 0.54

df=1

There was also no difference between the healthy and diseased subjects in mean age, mean cost of prophy services, length of observational interval, the number of prophys/year or the number of teeth at baseline when analyzed with a t-test for independent samples (Table 7). A power calculation for this analysis was done after the proportion of the sample who formed a pocket was determined. When comparing those subjects who formed at least one pocket (N=146) with those who did not form any pockets (N=231), this study has a 90 percent probability of detecting a difference of .02 prophys/year, with $\alpha=0.05$, two-tailed test (Hulley and Cummings, 1988).

Table 7: Mean Differences Between Subjects With and Without Pockets at Follow-

Variable	Any pocket	No pocket	SE Mean Diff	95% CI for Difference	p value
Number of prophys/year	1.49	1.52	0.048	(-0.069, 0.119)	p= 0.604
Age in years	42.8	43.2	1.275	(-2.04, 2.97)	p= 0.715
Observational interval in yrs	4.3	4.3	0.024	(-0.08, 0.016)	p= 0.189
Cost of prophy services	$304	$313	10.09	(-$10.60, $29.08)	p= 0.360
Number of teeth at baseline	26.6	26.2	0.287	(-1.015, 0.115)	p= 0.118^

two-tailed t-test for independent samples, all subjects
^t-test for unequal variances, two-tailed

Pattern Analysis

There was no difference in the pattern of prophylaxis care when those subjects who formed a pocket were compared with a t-test for independent samples to those who did not form a pocket. Both groups had a mean difference of 1.2 more prophys during the first half of the study period. The same difference was found when the last quarter of the study period was subtracted from the first quarter of the study period (Table 8).

Table 8: Difference in Mean Number of Prophys Over Time

First vs Second half of study period				
	Mean Difference	SE	95% CI for Diff	
Subjects w/o Pockets	1.221	0.071		
Subjects with pockets	1.226	0.099		
Difference	-0.0052	0.119	(-0.238,0.228)	p= 0.965
First vs fourth quarter of study period				
	Mean Difference	SE	95% CI for Diff	
Subjects w/o Pockets	1.195	0.054		
Subjects with pockets	1.253	0.069		
Difference	-0.0586	0.087	(-0.230, 0.112)	p= 0.501

t-test for independent samples, equal variances

Logistic Regression

The number of prophys a subject received was not predictive of whether the subject formed a periodontal pocket, and the regression model built from the available variables was not a reasonable predictor of periodontal health at follow-up. No model provided a high probability of predicting the observed results, with the overall predicted results from all models between 60-61 percent. As each main effect was added, small changes in either the Wald statistic or the -2log likelihood were noted, but none of the additions resulted in any measurement of improved model fit approaching significance, and the coefficient for utilization (prophys/yr) never differed significantly from zero. All first order interactions between prophys/year and the patient level co-variates were tested for significance. None were significant predictors of outcome status. The final model included all main effects and the interaction between prophy/yr and age. Baseline plaque was the only predictor variable with a β significantly different than zero (β=-0.2568, p=0.045, R=-0.065). Low levels of plaque, when compared with moderate levels of plaque, were associated with a decrease in the probability of pocket formation. The final model values are shown in the top half of Table 9. The interaction terms shown in the bottom half of Table 9 are not included in the final model shown in the top half of Table 9. The values for these interaction terms are taken from a model with all main effects and interactions forced into the model.

Table 9: Logistic Regression Model

Variable	B	SE	Wald	df	Sig	R	Exp (B)
Age	0.07	0.04	2.81	1	0.09	0.04	1.08
BL Plaque (1=low/none)	-0.26	0.13	4.03	1	.045*	-0.06	0.77
BL Floss	-0.09	0.12	0.53	1	0.46	0.00	0.92
Prophy/year	1.75	1.07	2.68	1	0.10	0.04	5.74
Sex (1=female)	-0.08	0.12	0.48	1	0.49	0.00	0.92
Teeth at BL	0.07	0.05	2.26	1	0.13	0.02	1.07
Pro/yr*age	-0.04	0.03	2.91	1	0.09	-0.04	0.96
Constant	-5.07	2.23	5.18	1	0.02		
Interaction terms	Not included in the model shown above						
Prophy*Plaque	0.27	0.30	0.80	1	0.37	0.00	1.31
Prophy*#Teeth	0.05	0.11	0.19	1	0.67	0.00	1.05
Prophy*Sex	-0.36	0.29	1.62	1	0.20	0.00	0.69
Prophy*Floss	0.00	0.29	0.00	1	1.00	0.00	1.00

Discussion

The question posed in this study was whether more frequent prophylaxes were protective against the onset of periodontal disease among periodontally healthy adults. The study reported here did not find any protective effect of more frequent prophylaxis as it is performed in a real-world setting. This underlying relationship was examined in several ways, with no approach finding that more frequent tooth cleanings were effective in preventing the onset of periodontal disease. Subjects who formed pockets did not differ from those who did not form pockets in the number of cleanings they received. Subjects who were high utilizers of prophys were neither more nor less likely to form pockets than those who were low prophy users. High and low prophy utilizers also did not differ in the proportions of each group who had a tooth extracted. Subjects who formed pockets did not receive more prophys as the study progressed.

The study reported here did not evaluate different prophy intervals to discern the ideal length of time between cleanings for a healthy population. The high (>1.9 prophy/year) and the low utilizer group (<1.04 prophys/year) comparisons can, however, be considered an initial evaluation of one yearly cleaning instead of two. Even though high utilizers reported more flossing behavior, which would be expected to influence their outcome positively, these groups did not differ in periodontal health at follow-up. Given these results, this study's findings are consistent with others' conclusions that healthy, low-risk adults can receive yearly instead of semi-annual tooth cleanings with no additional decrease in periodontal health.

Self-care behaviors that are thought to accompany regular preventive care were also measured to account for their contribution to periodontal health at the outcome evaluation. High utilizers were significantly more likely to report that they were daily flossers at both baseline and follow-up. This is consistent with others' findings that regular preventive attenders are also more likely to practice additional related health behaviors although the relationship between acceptable flossing and attending regular dental check-ups is likely confounded by education and income levels (Lang 1994). Surprisingly, plaque levels at baseline did not differ between the high and low utilizer groups, although flossing behavior did. One reason for this apparent discrepancy may be the lack of standardization among the dental plan's dental hygienists in reporting the levels of plaque. Another explanation may be that seventy-five percent of subjects were classified as having either low or no levels of plaque at baseline, raising the concern that this category may be so broad that subjects with quite different levels of plaque might receive the same classification. Plaque levels can also be changed if the patient brushes well prior to the appointment. In this case, a subject will be classified as having light plaque levels when their usual state is to have much heavier plaque levels. In the regression model however, plaque levels were a weak, but significant predictor of outcome. Even with a coarse measure of plaque levels, this study does show a mild increased risk for periodontal disease initiation associated with moderate levels of plaque.

Among the high utilizers, an increase in the number of daily flossers of 9 percent (N=7) was noted between the baseline and follow-up exams. While consistent with the expectation that regular attenders would be more likely to adopt daily flossing, the increase seems small when compared with the resources consumed. This may be due, at least in part, to the high levels of self-reported daily flossing in this population at baseline. Some reporting bias also must be expected with this self-reported measure. Subjects know that they are supposed to floss, and may be more likely to exaggerate their flossing frequency when reporting to the dental hygienist. This desire to appear compliant may result in an unknown amount of over-reporting of daily flossing, both at baseline and follow-up.

Brown and Garcia (1994) built a regression model using mean bone loss as the dependent variable and that explained more than 80 percent of the variation in the outcome. In their model, educational level, the number of teeth at baseline and the percent of sites with 40 percent bone loss at baseline predicted more bone loss at follow-up. Utilization of preventive services was not a predictor of outcome. Similarly, the study reported here also did not find that utilization was a predictor of outcome, yet the models built from the independent variables available in this study were not good predictors of outcome. The poor prediction found in this study's regression model is not surprising because information about educational level was not available, and the inclusion criteria restricted subject variation in baseline measures of periodontal health and the number of teeth at baseline.

The study sample included one outlier subject for the proportion of pocketed site variables. While this subject did not have any pocket depths recorded in 1991 ≥ 5 mm, the exams both prior to and following the 1991 exam did indicate the presence of multiple 5 mm pockets, as well as a diagnosis of periodontal disease. The subject did meet the inclusion criteria outlined for the study, and is therefore included in all the analyses presented. However, this subject is not one who would have been defined clinically as periodontally healthy, and would not be included in the cohort of patients where an extended prophylaxis recall might be recommended. In the comparison between the high and low utilizers, there is a difference in the proportion of sites with pockets ≥ 5 mm which approaches significance at $p=0.066$ when the outlier is included in the analysis, yet when the outlier is excluded from the analysis, the test no longer approaches significance ($p=0.170$).

Study Limitations

Periodontal pocket readings, when used as an outcome measure, do not capture information about attachment loss through gingival recession. While attachment loss is a more complete clinical outcome measure than periodontal pocketing, the limits of the data available to the study precluded attachment loss measurement. Periodontal pocket measurements, however, are not without precedent as acceptable indicators of periodontal health. For example, pocket depth has been a commonly used outcome variable in periodontal longitudinal studies (Lang 1991, Greenstein 1995). Minimizing the number of pocketed sites continues to be a therapeutic goal in clinical practice and the number of periodontal pockets in the mouth has been found to be the strongest risk indicator for future attachment loss (Haffajee 1991). Pocket depth is also the standard measure used by clinicians to determine if disease initiation or progression has occurred, and pocket eradication is a primary focus of periodontal treatment. In fact, both the American Dental Association and the American Academy of Periodontology have endorsed a method of periodontal disease screening which uses pocketing as the primary determinant of disease status (Nasi 1994).

The measurement accuracy of pocket recordings is influenced by the type of probe used, the operator using the probe, the anatomy of the site being probed, and the condition of the tissue being probed (Baderstein 1984, Lang 1991, Simpson 1990). Due to this imprecision, measured pocket depth changes of less than 2 mm may be within the measurement error inherent in pocket depth recordings (Lindhe 1983). Page (1992) concludes that when traditional probes are used, a change in attachment of at least 2 mm must be measured to conclude that the change represents true attachment level change, not just measurement variation. Because a subject could have had an unmarked 4 mm pocket present at baseline, some of the 5 mm pockets noted at follow-up will represent measurement variation instead of true periodontal disease initiation. Conversely, an unknown proportion of those subjects deemed healthy at follow-up, will actually have experienced periodontal destruction, but due to measurement variation a true 5 mm pocket measured <5 mm. This source of error can therefore either over or underestimate the level of disease present at follow-up, but can be expected to occur at the same rate regardless of utilization frequency, so should not introduce any systematic bias into the study.

The four percent error rate in pocket notation discovered during the quality control review will result in an unknown proportion of subjects being classified as healthy when in fact, they had developed a periodontal pocket. Again, this error is expected to occur at the same rate across the study sample regardless of utilization frequency, and should not bias the results in either direction.

Records of any dental care received by a study subject outside the Kaiser system would not be present in the data sources available to this study. Some members with a dual dental benefit do not access the Kaiser dental program at all, but it is unlikely that an individual would meet the study inclusion requirements (continuous eligibility and two exams) and receive prophylaxis services elsewhere. The electronic and paper utilization data in the study therefore is assumed to be a complete record of the subject's dental care throughout the study interval. Any error resulting from this assumption would not be expected to occur disproportionately among those who formed periodontal pockets, and consequently, would not be expected to alter the results reported here.

This study sample was selected from an insured population and did not include diabetics, people who had already lost many teeth, or those with periodontal disease. The external validity of this study is therefore limited to groups who are similar to the study population in these characteristics, and conclusions drawn beyond low risk adults must be done with great care, if at all.

Since no treatment effect was found in this study, an assessment of the study's power is in order. The regression model described in this study would be unable to detect a decrease in the probability of developing a periodontal pocket of less than 30 percent when the mean number of prophys a subject receives increases by 0.5. While it is conceivable that an increase in prophy frequency of 0.5 may have provided a more modest protective effect than a 30 percent decrease in the odds ratio, we do know that this increase does not provide a 30 percent or more decrease in the odds ratio.

In addition, the analysis between high and low utilizers had enough power to detect with a 90 percent probability a difference of one site per person, yet no effect was observed. The study reported here consistently found no treatment effect across various analyses and dependent variables which lends weight to the conclusion that more frequent prophylaxis treatments may not be an effective preventive treatment for this population. Future studies are needed to determine if a higher cleaning frequency will provide a 10 or 20 percent decrease in the odds ratio of developing a periodontal pocket, and clinicians will need to address what size of protective effect is important to detect.

As of year-end 1991, 52.8 percent of the Kaiser Permanente Dental Program eligible members were female, although the final study population is comprised of 68.7 percent females. Females are more frequent utilizers of routine health care services (US Dept. of Health and Human Services, 1990), and pocket depth prevalence was found to be greater among men than women in a national examination survey (NHANES III) conducted between 1988-1991 (Brown, et al 1996). To be included in the final study sample, subjects had to be insured, have at least two diagnostic appointments within four years, and have no periodontal disease detected at the first exam. As these criteria can be expected to select for more females in the final sample, the greater representation of females in this study is consistent with citations in the current dental literature.

The results of this observational study must also be interpreted with an understanding of the confounders that may be present. If a subject received a recommendation for frequent cleanings because of a perception that he or she was at increased risk for disease (confounding by indication), those with increased utilization might be expected to have poorer outcomes. While this confounder may have been present to a small extent, two factors limited its presence in this study. First, recommendations for twice yearly dental prophylaxes are made to almost all dentate patients, and when treatments are so widely recommended across a population, the chances for confounding by indication are decreased (Selby 1994). Secondly, by eliminating those subjects with periodontal disease at baseline, the exclusion criteria used for this study allowed for the selection of a more periodontally homogeneous group of subjects, although subjects may have differed in ways that were not measurable at baseline. Confounding, however, could have occurred by indication if subjects received more frequent prophys after they formed a pocket. If disease presence was influencing prophy frequency, we would expect subjects with pockets to have received more cleanings as the study interval progressed, yet there was no difference in prophy frequency over the study interval between diseased and healthy subjects, as shown by the prophy pattern analysis.

Conversely, confounding by self-selection was not controlled for during this study. Information on subjects' socio-economic status or educational level was not available, so the results of this study could not be adjusted to account for these differences, which are known to be related both to increased self-care behavior and decreased disease at follow-up (Brown & Garcia 1994, Lang 1994) . Compliant patients (those who attend twice yearly as recommended) are likely to influence their outcome in a positive way. This confounder would have biased the results in favor of prophys being found to be effective, yet no treatment effect was detected.

Implications

The cost implications of decreasing the frequency of prophylaxis for healthy, insured adults are significant. Of Kaiser dental patients who had risk assessments performed at their exam appointment through year-end 1996, 35 percent were considered low risk, having neither attachment loss ≥ 3 mm nor pocketings ≥ 5 mm. Even if another 8 percent were eliminated from low risk status due to diabetes, more than one quarter of the 1996 year-end Kaiser adult utilizers (approximately 20,700 people) can be identified who may not benefit from frequent prophys.

Data from three different settings indicates that fees for adult prophylaxis range from 9.5 to 15 percent of the of total dental expenditures (Hayden 1997, Kaiser Permanente internal actuarial data 1997, Washington Dental Service internal actuarial data, 1997) as shown in Table 10. The impact of continued reliance on an unproved treatment for the prevention of periodontal disease is costly. Prophylaxes are performed frequently and they constitute a large proportion of the resources used to prevent and treat oral disease. If, however, resources saved can be redirected to target those at increased risk for the application of effective preventive therapy, gains in the overall health of the population could be realized.

Table 10: Adult Prophylaxis as a Percentage of Total Dental Costs		
	Prophy costs, percent	Prophy costs, in millions
Kaiser Permanente, NW:1995	9.50%	3.86
Claims Clearinghouse: May '90- April '94	12.88%	25.6
Washington Dental Service: 1995	15.00%	37.6

The Institute of Medicine (IOM) study on dental education bluntly stated that dental schools, as well as the dental profession, needed to change their current focus to emphasize patient outcomes and efficient care delivery to advance the oral health of the nation. The dental profession was also indicted for the dearth of data currently available on treatment outcomes and effectiveness (Field 1995). Given the large impact that prophylaxis services have on dental resources, it is critical that information be gathered to assess the appropriate use of this preventive procedure. If appropriate treatment is defined as imparting a benefit that outweighs the costs associated with that treatment (Grembowski 1997), the appropriateness of recommending frequent dental prophylaxes for periodontally healthy adults must be questioned.

Uncertainties regarding the appropriateness of different treatment modalities must be resolved, at least in part, using real world settings to determine the effectiveness of the treatment in question (Bader 1992a). Funding from NIDR (National Institute of Dental Research) for dental health services research continues to be quite limited (Bader 1992b), and many basic efficacy, as well as effectiveness, questions may need to be answered with observational methodology. While randomized controlled trials have historically been the gold standard for study design, funding and ethical limitations may preclude the use of a randomized clinical trial in many instances. For research questions that cannot be answered through randomized clinical trials, practice-based research is an increasingly accepted research tool, particularly when considering treatment effectiveness (Nutting 1991). In fact, practice-based research may be preferred when evaluating outcomes for unselected populations, or examining how diseases and conditions affect "most of the people most of the time" (Alexander 1994). If appropriateness questions are to be answered and evidence-based practice is to become a reality in dentistry, studies such as this one are needed to utilize existing practice data in a careful, deliberate manner.

Summary and Conclusions

This retrospective effectiveness study did not find that a higher frequency of dental prophylaxis was protective against the initiation of periodontal disease in a group of periodontally healthy, insured adults in a dental HMO. Within the limits described earlier, more frequent tooth cleanings were not found to be an effective preventive treatment for adults who do not have evidence of existing periodontal disease.

This study attempted to strengthen the existing literature by examining a sample of patients from a private practice setting who are periodontally healthy at baseline, and by measuring the periodontal health outcome in terms that practicing dentists and hygienists are familiar with. The patients, treatment evaluated (prophylaxes), and outcome measures were similar to those situations that clinicians encounter on a daily basis.

More data are needed to assess the effectiveness of many routinely provided dental services and facilitate the allocation of dental resources to treatments and population groups where a clear benefit to the population's oral health will be demonstrated. This study examined the effectiveness of more frequent prophylaxis for a narrow group of subjects, and the scope of future studies should be expanded to discern for which populations the treatment may indeed be effective. This study is silent regarding an ideal prophy interval and more data are also needed to identify appropriate prophylaxis intervals.

References

Alexander G and Clancy C. Practice-based research: Laboratories for health care reform. J Fam Prac 1994; 38(4): 428-430.

Anerud A, Löe H, Boysen H, and Smith M. The natural history of periodontal disease in man: Changes in gingival health and oral hygiene before 40 years of age. J Periodontol Res 1979; 14: 526-540.

Antczak-Boucoms A and Tulloch JFC. Measuring outcomes in clinical research. In: Vig KD & Vig PS, editors. Clinical Research as the Basis of Clinical Practice. Craniofacial Growth Series 25, Center for Human Growth and Development; The University of Michigan, Ann Arbor, 1991. p. 141-154.

Axelsson P and Lindhe J. Effect of controlled oral hygiene procedures on caries and periodontal disease in adults. J Clin Perio 1978; 5: 133-151.

Axelsson P and Lindhe J. Effect of controlled oral hygiene procedures on caries and periodontal disease in adults: Results after six years. J Clin Perio 1981; 8: 239-248.

Axelsson P, Lindhe J, and Nystrom B. On the prevention of caries and periodontal disease: Results of a 15 year longitudinal study in adults. J Clin Perio 1991; 18: 182-189.

Bader JD. Dental hygiene realpolitik affecting education. J Dent Educ 1991; 55: 193-203.

Bader JD. Guest Editorial: The emergence of appropriateness-of-care issues. J Dent Res 1992a; 71(3): 502-504.

Bader JD. Health services research in dental public health. J Pub Hlth Dent 1992b; 52(1 Spec Iss): 23-26.

Baderstein A, Nilveus R, and Egelberg J. Reproducibility of probing attachment level measurements. J Clinical Perio 1984; 11: 475-485.

Beck JD. Methods of assessing risk for periodontitis and developing multifactorial models. J Periodontol 1994; 65: 468-478.

Bergstrom J and Preber H. Tobacco use as a risk factor. J Periodontol 1994; 65 (5): 545-550.

Brown LJ, Brunelle JA, and Kingman A. Periodontal status in the United States, 1988-91: Prevalence, extent and demographic variation. J Dent Res 1996; 75 (Spec issue): 672-683.

Brown LJ and Garcia R. Utilization of dental services as a risk factor for periodontitis. J Periodontol 1994; 65 (5): 551-563.

Browner W, Black D, Newman T, and Hulley S. Estimating sample size and power. In: Hulley, Stephen and Cummings, Steven eds. Designing Clinical Research: An epidemiologic approach. Williams and Wilkins 1988.

DeRouen TA. Statistical models for assessing risk of periodontal disease. In: Bader, JD, editor. Risk assessment in dentistry. Chapel Hill: University of North Carolina Dental Ecology, 1990. pp. 239-244.

Emrich LJ, Schlossman M, and Genco R. Periodontal disease in noninsulin-dependent diabetes mellitus. J Periodontol 1991; 62: 123-130.

Excel©, Microsoft, version 5.0. 1994.

Field MJ, editor. Dental education at the crossroads: Challenges and change. Washington: National Academy Press, 1995.

Greenstein G and Lamster I. Understanding diagnostic testing for periodontal diseases. J Periodontol 1995; 66: 659-666.

Grembowski D. The role of health services research in the renaissance of the dental profession. J Dent Educ 1997; 61(1): 10-15.

Grossi SG, Zambon JJ, Ho AW, Koch G, Dunford RG, Machtei EE, Norderyd OM, and Genco RJ. Assessment of risk for periodontal disease. I. Risk indicators for attachment loss. J Periodontol 1994; 65: 260-267.

Haffajee AD, Socransky SS, Lindhe J, Kent RL, Okamato H and Yoneyama T. Clinical risk indicators for periodontal attachment loss. J Clin Periodontol 1991; 18: 117-125.

Hart T, Shapira L, and Van Dyke T. Neutrophil defects as risk factors for periodontal diseases. J Periodontol 1994; 65(5): 521-529.

Hayden WJ. Dental health services research utilizing comprehensive clinical databases and information technology. J Dent Educ 1997; 61(1): 47-55.

Hirsch RP and Riegelman RK. Statistical First Aid: Interpretation of Health Research Data. Taunton (MA): Blackwell Science Publishers; 1992.

Hsieh FY. Sample size tables for logistic regression. Stat in Med 1989; 8(7): 795-802.

Hulley S and Cummings S, editors. Designing clinical research: An epidemiologic approach. Baltimore: Williams and Wilkins; 1988.

Imrey PB. Considerations in the statistical analysis of clinical trials in periodontitis. J Clin Perio 1986; 13: 517-528.

Lang NP and Bragger U. Periodontal diagnosis in the 1990's. J Clin Perio 1991; 18: 370-379.

Lang NP, Farghaly MM, and Ronis DL. The relation of preventive dental behaviors to periodontal health status. J Clin Perio 1994; 21: 194-198.

Lightener LM, O'Leary TJ, Drake RB, Crump PP, and Allen MF. Preventive periodontal treatment procedures: results over 46 months. J Periodont 1971; 42 (9): 555-561.

Lindhe J, Haffajee AD, and Socransky SS. Progression of periodontal disease in adult subjects in the absence of periodontal therapy. J Clin Perio 1983; 10: 433-442.

Listgarten MA, Levin S, Schifter CC, Sullivan P, Evian CI, Rosenberg ES, and Laster L. Comparative longitudinal study of 2 methods of scheduling maintenance visits: 2 year data. J Clin Perio 1986; 13: 692-700.

Listgarten MA, Schifter CC, and Laster L. 3-year longitudinal study of periodontal status of an adult population with gingivitis. J Clin Perio 1985; 12: 225-238.

Listgarten MA, Sullivan P, George C, Nitkin L, Rosenberg ES, Chilton NW, and Kramer AA. Comparative longitudinal study of 2 methods of scheduling maintenance visits: 4-year data. J Clin Perio 1989; 16: 105-115.

Löe, Harald. Experimental gingivitis in man. J Periodontol 1965; 36: 177-187.

Löe, Harald. Periodontal disease as we approach the year 2000. J Periodontol 1994; 65 (5): 464-467.

Löe H, Anerud A, Bosen H and Smith M. The natural history of periodontal disease in man. J Periodontol 1978a; 49(12): 607-620.

Löe H, Anerud A, Boysen H and Smith M. The natural history of periodontal disease in man: Study design and baseline data. J Periodontol Res 1978b; 13: 550-562.

Löe H, Anerud A, Boysen H and Smith M. The natural history of periodontal disease in man: Tooth mortality rates before 40 years of age. J Periodontol Res 1978c; 13: 563-572.

Nasi, JH. Background to, and implementation of, the Periodontal Screening and Recording (PSR) procedure in the USA. Int Dent Journal 1994; 44 (suppl 1): 585-588.

National Dental Advisory Service, Comprehensive Fee Report, January 1997.

Nutting PA. Practice based research: Laboratories for outcomes and effectiveness research. In: Hibbard H, Nutting PA, and Grady M, editors. Primary care research: theory and methods. Rockville, Md; Agency for Health Care Policy and Research, 1991. AHCPR publication No. 91-0011.

Oliver R and Tervonen T. Diabetes - A risk factor for periodontal disease in adults? J Periodontol 1994; 65 (5): 530-538.

Oshrain HI, Telsey B, and Mandel I. A longitudinal study of periodontal disease in patients with reduced immunocapacity. J Periodontol 1983; 54(3): 151-154.

Pagano M and Gavreau K. Principles of Biostatistics. Belmont, California: Duxbury Press; 1993.

Page RC and DeRouen TA. Design issues specific to studies of periodontitis. J Periodont Res 1992 (Spec issue) 27: 395-404.

Papapanou PN and Wennstron JL. A 10 year retrospective study of periodontal disease progression: Clinical chracteristics of subjects with pronounced and minimal disease development. J Clin Perio 1990; 17: 78-84.

Phipps K and Stevens V. Relative contribution of caries and periodontal disease in adult tooth loss for an HMO population. J Pub Health Dent 1995; 55 (4): 250-252.

Rossi B. Doctor, is your hygiene department profitable? Dent Econ 1996; 86(12): 22-27.

Selby JV. Case-control evaluations of treatment and program efficacy. Epi Reviews 1994; 16(1): 90-101.

Self SG and Mauritzen RH. Power/sample size calculations for generalized linear models. Biometrics 1988; 44: 79-86.

Sheiham A. Is there a scientific basis for six-month dental examinations? Lancet 1977; 2(8035): 442-4.

Simpson DM. Reactor paper: Selection of suitable indicators of periodontitis. In: Bader JD, editor. Risk assessment in dentistry. Chapel Hill: University of North Carolina Dental Ecology, 1990. pp. 75-77.

SPSS Base System User's Guide; SPSS, Chicago, Illinois 1993.

SPSS for Windows Advanced Statistics, Release 6.0. SPSS, Chicago, Illinois 1993.

Steele DC. Optimum maintenance. Dent Econ 1996; 86(4): 36-42.

Suomi JD, Smith LW, Chang JJ, and Barbano JP. Study of the effect of different prophylaxis frequencies on the periodontium of young adult males. J Periodontol 1973; 44(3): 406-410.

Sutton, RBO and Smales FC. Cross-sectional study of the effects of immunosuppressive drugs on chronic periodontal disease in man; J Clin Perio 1983; 10: 317-326.

US Department of Health and Human Services. Oral Health of United States Adults; the National Survey of Oral Health in U.S. Employed Adults and Seniors: 1985-1986. December 1990.

Wang N, Marstrander P, Holst D, Ovrum L, and Dahle T. Extending recall intervals- effect on resource consumption and dental health. Comm Dent Oral Epidemiol 1992; 20: 122-4.