Periodontal Disease: Assessing the Effectiveness and Costs of the Keyes Technique

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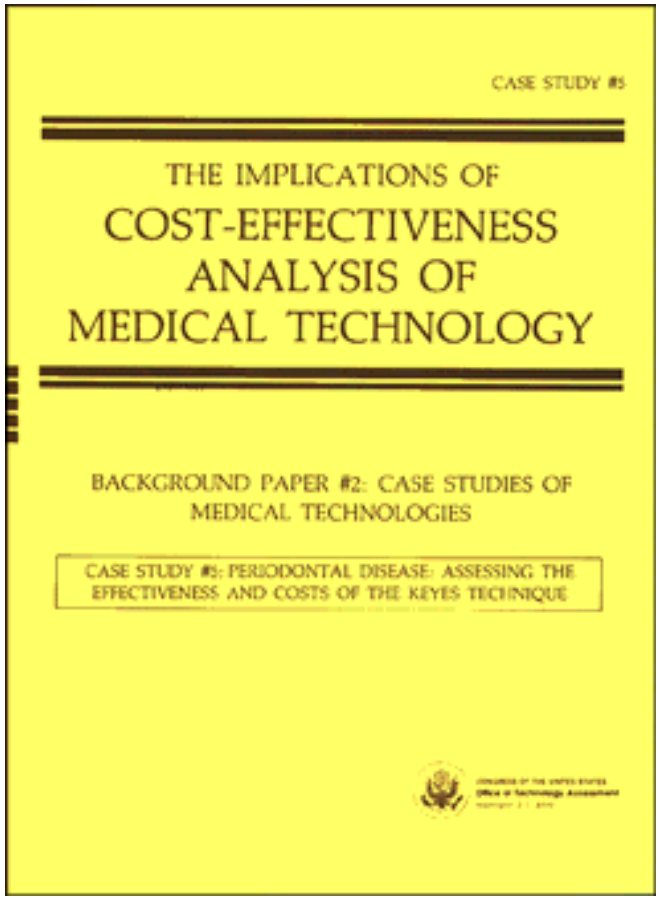

THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY

MAY 1981

BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #5: PERIODONTAL DISEASE: ASSESSING THE EFFECTIVENESS AND COSTS OF THE KEYES TECHNIQUE

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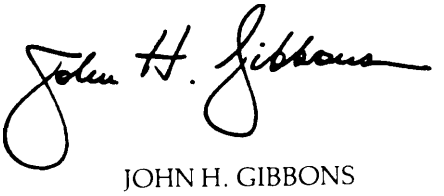
Foreword

This case study is one of 17 studies comprising Background Paper #2 for OTA's assessment, *The Implication of Cost-Effectiveness Analysis* of *Medical Technology.* That assessment analyzes the feasibility, implications, and value of using cost-effectiveness and cost-benefit analysis (CEA/CBA) in health care decisionmaking. The major, policy-oriented report of the assessment was published in August 1980. In addition to Background Paper #2, there are four other background papers being published in conjunction with the assessment: 1) a document which addresses methodological issues and reviews the CEA/CBA literature, published in September 1980; 2) a case study of the efficacy and cost-effectiveness of psychotherapy, published in October 1980; 3) a case study of four common diagnostic X-ray procedures, to be published in summer 1981; and 4) a review of international experience in managing medical technology, published in October 1980. Another related report was published in September of 1979: *A Review* of *Selected Federal Vaccine and Immunization Policies.*

The case studies in *Background Paper* #2: *Case Studies of Medical Technologies* are being published individually. They were commissioned by OTA both to provide information on the specific technologies and to gain lessons that could be applied to the broader policy aspects of the use of CEA/CBA. Several of the studies were specifically requested by the Senate Committee on Finance.

Because of particular circumstances regarding this case study on interventions for periodontal disease, a commentary by a group of dental scientists and clinicians is presented immediately following the case study. The case study authors' response is presented after the commentary.

Drafts of each case study were reviewed by OTA staff; by members of the advisory panel to the overall assessment, chaired by Dr. John Hogness; by members of the Health Program Advisory Committee, chaired by Dr. Frederick Robbins; and by numerous other experts in clinical medicine, health policy, Government, and economics. We are grateful for their assistance. However, responsibility for the case studies remains with the authors.



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Preface

This case study is one of 17 that comprise Background Paper #2 to the OTA project on the *Implications of Cost-Effectiveness Analysis of Medical Technology.* * The overall project was requested by the Senate Committee on Labor and Human Resources. In all, 19 case studies of technological applications were commissioned as part of that project. Three of the 19 were specifically requested by the Senate Committee on Finance: psychotherapy, which was issued separately as Background Paper #3; diagnostic X-ray, which will be issued as Background Paper #5; and respiratory therapies, which will be included as part of this series. The other 16 case studies were selected by OTA staff.

In order to select those 16 case studies, OTA, in consultation with the advisory panel to the overall project, developed a set of selection criteria. Those criteria were designed to ensure that as a group the case studies would provide:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (such as general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (such as cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide informative material relating to the broader policy and methodological issues of cost-effectiveness or cost-benefit analysis (CEA/CBA); and
- examples with sufficient evaluable literature.

On the basis of these criteria and recommendations by panel members and other experts, OTA staff selected the other case studies. These 16 plus the respiratory therapy case study requested by the Finance Committee make up the 17 studies in this background paper.

All case studies were commissioned by OTA and performed under contract by experts in academia. They are authored studies. OTA subjected each case study to an extensive review process. Initial drafts of cases were reviewed by OTA staff and by members of the advisory panel to the project. Comments were provided to authors, along with OTA's suggestions for revisions. Subsequent drafts were sent by OTA to numerous experts for review and comment. Each case was seen by at least 20, and some by 40 or more, outside reviewers. These reviewers were from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists and decision analysts also reviewed the cases. In all, over 400 separate individuals or organizations reviewed one or more case studies. Although all these reviewers cannot be acknowledged individually, OTA is very grateful for their comments and advice. In addition, the authors of the case studies themselves often sent drafts to reviewers and incorporated their comments.

These case studies are authored works commissioned by OTA. The authors are responsible for the conclusions of their specific case study. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of the review and revision process, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view. In two cases, OTA decided that in order to more fully present divergent views on particular technologies a commentary should be added to the case study. Thus, following the case

* Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology*, GPO stock No. **052-003 -00765-7** (Washington, D. C.: U.S. Government Printing Office, August 1980).

studies on gastrointestinal endoscopy and on the Keyes technique for periodontal disease, commentaries from experts in the appropriate health care specialty have been included, followed by responses from the authors.

The case studies were selected and designed to fulfill two functions. The first, and primary, purpose was to provide OTA with specific information that could be used in formulating general conclusions regarding the feasibility and implications of applying CEA/CBA in health care. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of CEA/CBA, OTA was able to better analyze the potential contribution that these techniques might make to the management of medical technologies and health care costs and quality. The second function of the cases was to provide useful information on the specific technologies covered. However, this was not the major intent of the cases, and they **should not be regarded as complete and definitive studies of the individual technologies. In many instances, the case studies do represent excellent reviews of the literature pertaining to the specific technologies and as much can stand on their own as a useful contribution to the field. In general, through, the design and the funding levels of these case studies was such that they should be read primarily in the context of the overall OTA project on CEA/CBA in health care.**

Some of the case studies are formal CEAS or CBAS; most are not. Some are primarily concerned with analysis of costs; others are more concerned with analysis of efficacy or effectiveness. Some, such as the study on end-stage renal disease, examine the role that formal analysis of costs and benefits can play in policy formulation. Others, such as the one on breast cancer surgery, illustrate how influences other than costs can determine the patterns of use of a technology. In other words, each looks at evaluation of the costs and the benefits of medical technologies from a slightly different perspective. The reader is encouraged to read this study in the context of the overall assessment's objectives in order to gain a feeling for the potential role that CEA/CBA can or cannot play in health care and to better understand the difficulties and complexities involved in applying CEA/CBA to specific medical technologies.

The 17 case studies comprising *Background* Paper #2 (short titles) and their authors are:

Artificial Heart:, Deborah P. Lubeck and John P. Bunker
Automated Multichannel Chemistry Analyzers: Milton C. Weinstein and Laurie A. Pearlman
Bone Marrow Transplants: Stuart O. Schweitzer and C. C. Scalzi
Breast Cancer Surgery: Karen Schachter and Duncan Neuhauser
Cardiac Radionuclide Imaging: William B. Stason and Eric Fortess
Cervical Cancer Screening: Bryan R. Luce
Cimetidine and Peptic Ulcer Disease: Harvey V. Fineberg and Laurie A, Pearlman
Colon Cancer Screening: David M. Eddy
CT Scanning: Judith L. Wagner
Elective Hysterectomy: Carol Korenbrot, Ann B. Flood, Michael Higgins, Noralou Roos, and John P. Bunker
End-Stage Renal Disease: Richard A. Rettig
Gastrointestinal Endoscopy: Jonathan A. Showstack and Steven A. Schroeder
Neonatal Intensive Care: Peter Budetti, Peggy McManus, Nancy Barrand, and Lu Ann Heinen
Nurse Practitioners: Lauren LeRoy and Sharon Solkowitz
Orthopedic Joint Prosthetic Implants: Judith D. Bentkover and Philip G. Drew
Periodontal Disease Interventions: Richard M. Scheffler and Sheldon Rovin
Selected Respiratory Therapies: Richard M. Scheffler and Morgan Delaney

These studies will be available for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Call OTA's Publishing Office (224-8996) for availability and ordering information.

Case Study #5

Periodontal Disease: Assessing the Effectiveness and Costs of the Keyes Technique

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INTRODUCTION

Of the $13.3 billion spent on dental care in 1978, approximately $350 million was spent on treating periodontal disease (10,12). About $250 million of this was received by periodontists (dentists who specialize in treating periodontal disease); the remaining $100 million was received by general dental practitioners who delivered periodontal services. [1]

A significant portion of expenditures for periodontal disease is for periodontal surgery. Such surgery can be quite expensive. Two types of periodontal surgery, mucogingival (gum) surgery and osseous (bone) surgery, for example, per quadrant of the mouth often cost the patient at least $200 and $250, respectively (2).[2,3] In many instances, periodontal surgery is performed on more than one quadrant of the mouth. However, questions about periodontal surgery's effectiveness in treating periodontal disease still remain.

Another technology for treating and preventing the two main forms of periodontal disease is the Keyes technique or rationale.[4] Currently being tested, this technology is a nonsurgical technique which utilizes oral hygiene measures and plaque (bacterial) control by the patient, supervision by the dentist, inexpensive and readily available chemicals (e.g., hydrogen

[1] The $100 million estimate for general practitioners was derived by multiplying national expenditures on dental care ($13.3 billion) (12) by 0.78 percent, which is the percentage of total expenditures collected by general dentists for periodontal services (10). The estimate of $250 million received by periodontists was derived by adding the average income of periodontists, $56,741, to the average expenses for all dental practices, $56,303 (3) for 1976 and adjusting for inflationary increases of 6 percent per year to express it in 1978 dollars. This sum ($126,144) was then multiplied by the approximately 2,000 periodontists practicing in 1978.

[2] Mucogingival surgery involves the removal of pockets by surgery on soft tissue only. Osseous surgery involves the removal of bone. Definitions of these and other dental terms used in this case study are provided in app. A.

[3] Fees charged for these services in 1976 (2) were inflated to 1979 dollars by using the dental care component of the Consumer Price Index.

[4] Although it has become common to speak of the subject of this case study as the "Keyes technique," Dr. Keyes himself prefers to refer to the collection of techniques as a rationale or regimen, and further suggests that a more appropriate name for the rationale would be "monitored and modulated therapy."

peroxide and baking soda and in some cases drugs), and assessment of bacterial control by regular microscopic examination of material from the periodontal tissues. It involves the use of water irrigation of the gums and other easily learned hygiene procedures. Some claim that, if properly used, the Keyes technique could reduce dramatically the quantity of peridontal surgery performed.

In the next three parts of this case study, we present layman's definitions of periodontal disease; a description of the technologies currently being used on a widespread basis to prevent and treat periodontal disease and an assessment of what is known about their effectiveness, based on a review of the literature: and a description of the Keyes rationale and how it may be used for diagnosing, controlling, and preventing periodontal disease.

Next, we present some preliminary results of our recent study on 18 dental practices in the Washington, D. C., Standard Metropolitan Statistical Area (SMSA) that use the Keyes technique. With data on ***190*** patients and over ***800*** dental visits, we provide a short-term assessment of the effectiveness of the Keyes technique and estimate the cost of delivering the Keyes technique to the patients in our study. The results of our study provide new and useful data on the Keyes technique, but larger scale and long-term studies are needed before more definitive conclusions can be drawn.

The final part of this study contains a brief summary of some of our major conclusions. Also discussed are a few of the steps that need to be taken in order to allow a complete cost-effectiveness analysis (CEA) of the Keyes technique. We did not perform a CEA of the current technologies used for treating periodontal disease, and no such analysis is available in the published literature. Hence, we are unable to compare the cost effectiveness of the Keyes technique to the cost effectiveness of the current treatment of periodontal disease.

PERIODONTAL DISEASE

Tooth loss, in contrast to popular opinion and mythology, is not a natural concomitant of age—it is caused by disease processes. The disease processes of the periodontal, or supporting, structures of the teeth, known collectively as "periodontal disease" or "periodontal infection," are responsible for 70 percent of all tooth extraction and are the principal cause of tooth loss (6,13,15,33).

Data show that some form of periodontal disease affects anywhere from 75 percent to virtually all of the adult population in the United States, and a destructive form involving tissue loss affects approximately one-third of the adult population (6, 15,16,22,29). Periodontal disease does afflict children, but it is more common and more severe among adults. Although the disease increases in prevalence and severity with age, it is not the aging process that causes it; rather, it is the length of time that the teeth and supportive tissues are exposed to the causative factors (21).

One of the difficulties in dealing with periodontal disease is its insidiousness. The onset of disease is gradual. Afflicted individuals are generally symptomless for long periods of time. Often patients have extensive disease, involving the loss of supporting structures and formation of deep pockets around the teeth, without being uncomfortable or even aware of the problem. All too often patients will have undiagnosed periodontal disease for years even though they have been regularly seen by a dentist.

The reasons for undiagnosed periodontal disease are several. Many dentists concentrate only on restorative problems of the teeth and thus ignore or fail to recognize periodontal disease until it has progressed to an advanced stage. The diagnosis of early or incipient periodontal disease requires not only visual inspection, but probing, staining for plaque, and radiographic (X-ray) diagnosis; typical symptoms such as bad breath, spontaneous bleeding, and pain tend to occur only after the disease has progressed to

the moderate or advanced stage. Furthermore, some dentists may not have been adequately trained in diagnosing and treating periodontal disease.

As is the case with many other chronic diseases, early diagnosis of periodontal disease affords a better chance for successful treatment. If disease is detected early, therapy requires less time and effort by the dentist, less discomfort to the patient during therapy, less difficult oral hygiene measures by the patient, and considerably less cost. Moreover, the destructive form of periodontal disease first goes through a relatively innocuous inflammatory stage, and, if diagnosed and treated at that time, the disease is in most instances easily reversible. The universality of periodontal disease is the most vexing part of the problem, because in over ***90*** percent of instances, such disease is potentially preventable by relatively inexpensive means known and available today (13,28,29).

Periodontal disease is a disease complex, a *group* of diseases placed under a single heading for purposes of convention. The term "periodontal disease" is generally used to refer to what are by far the two most prevalent periodontal diseases: gingivitis and periodontitis. Gingivitis is inflammation of the gingiva (gum) only and is generally considered a reversible process (8). Periodontitis is inflammation of both the gum and the other supporting structures of the teeth (i. e., the outer bone of the tooth socket, the outer layer (cementum) of the root of the tooth, and the soft tissues which attach these structures to one another). Periodontitis also connotes destruction or loss of the supporting structures of the teeth. Once destruction takes place, complete regeneration of the affected tissues does not occur (8). The **loss or** destruction of the supporting structures results in the formation of pathologic spaces or pockets around the teeth. [5] If this process continues, the teeth lose their supporting structure, become loose, and eventually have to be removed. Unfortunately, no accepted diagnostic method to determine at a given point in time whether the destructive process is active or quiescent is currently available (14), a circumstance with significant therapeutic implications.

Experientially, most dentists feel that the progression of gingivitis to periodontitis is part of a continuum ***(25),*** i.e., if gingivitis persists long enough, it will inevitably progress into periodontitis. However, there is no documented scientific evidence for this view. It is known that periodontitis does not develop in the absence of gingivitis ***(25);*** and it does appear that, in most instances, untreated gingivitis will progress into periodontitis (25). At the same time, there is great variability in the time it takes for progression to occur (gingivitis per se may exist for many years); and in some instances, progression does not occur at all ***(8,25). The distinction be***tween gingivitis and periodontitis is emphasized, because gingivitis, by far the most common form of periodontal disease, is relatively innocuous. Most important, it is potentially reversible in a majority of instances. Uncomplicated by any other factor, gingivitis is usually relatively easy to treat with methods that produce little or no discomfort to patients, and the cost of treating gingivitis is a small portion of what it costs to treat destructive periodontitis.

Bacteria] infection is the essential factor in the initiation and propagation of periodontal disease ***(30,32).*** The exact mechanisms by which the germs produce their deleterious effects remain undiscovered, but there is little doubt that bacteria are the principal cause of periodontal disease. The sine qua non in the etiology of periodontal disease is the presence of a microbial population in the form of dental (or bacterial) plaque. Dental plaque is a gummy bacterial substance that adheres to the teeth; it cannot be seen by the naked eye, but is easily demonstrated by various stains. In the absence of bacterial plaque, periodontal disease does not occur; removal of such plaque halts the progression of, produces remission of, or *reverses ex*isting disease. Further evidence of the role of bacteria in causing periodontal disease is the fact that antimicrobial agents are often effective in controlling such disease (25,32).

[5] The normal space between the gum and the tooth is called a SUlCUS. When this space deepens or extends past its normal boundary as a result of the inflammatory process, it is called a pocket.

Bacterial populations in the mouth differ under conditions of health and of disease, a finding which has also has therapeutic implications (13). Furthermore, the same evidence points to differences in the microbial composition of gingivitis and periodontitis. The importance of the role of bacteria in causing periodontal disease must be emphasized, because the fundamental aim of periodontal treatment is to control bacterial plaque or to facilitate its control by the patient, and the principal goal of prevention is to inhibit its formation.

Faulty or improperly placed margins of dental restorations (fillings) are recognized as a factor contributing to periodontal disease (21,29). In the face of these margins, plaque accumulates readily, and the existing inflammatory process is enhanced. What is not clear is whether faulty margins actually initiate or just worsen the disease process. In either case, improper margins have to be dealt with as a part of treatment.

There are other factors allegedly associated, causally, with periodontal disease. A list would include, in no relative order of importance, malocclusion (malpositioning of the jaws with respect to one another), faulty tooth position, genetic predisposition, systemic disease such as diabetes mellitus, and malnutrition. No further discussion about these factors is warranted, since they are not thought to be essential in causing periodontal disease, and at most are considered adjunctive to periodontal disease (i.e., they might exacerbate preexisting periodontal disease) (21,25,34). Also, the consideration of these factors in a CEA of periodontal therapy would be negligible.

TRADITIONAL TECHNOLOGIES USED TO TREAT PERIODONTAL DISEASE

The traditional technologies used to treat periodontal disease can be placed into two broad general categories—nonsurgical and surgical.

Nonsurgical Technologies

Plaque Control

There is a well-documented, direct relationship between the frequency of plaque removal and gingival and periodontal health ***(5,29,31).*** Daily plaque removal is considered optimally conducive to gingival health. Obviously, individuals cannot have dental care professionals remove plaque every clay. Patients must learn to remove plaque by themselves, a task not terribly onerous, but requiring some knowledge and mastery of technique.

The plaque control programs of periodontal therapy are aimed at instructing patients in the oral hygiene techniques that will remove plaque and prevent it from accumulating in harmful amounts. Basically, these oral hygiene techniques are the application of stain to detect plaque and the brushing and flossing of teeth to remove it. Professionally supervised practice of these techniques is usually a basic part of periodontal therapy. The outcome of periodontal therapy depends on how well the patient controls plaque formation. In the absence of plaque control, any therapy is of little or no value (4,23,26,29).

On the basis of the prevalence of periodontal disease (6,16,22), it appears that, unfortunately, most people do not effectively control plaque formation, including many who have had extensive instruction and have been treated for destructive periodontal disease. The issue is not simple. Plaque control is more than a question of instruction about the proper methods. It requires individuals to change or modify their behavior so they not only know the correct methods, but are motivated to use them routinely.

Scaling and Root Planing

Scaling and root planing are professionally applied mechanical techniques. Scaling is used to remove calculus (hard deposits) from the teeth, root planing to smooth the root surfaces,

ostensibly to make the roots less susceptible to microbial activity. The largest proportion of the time and effort expended in treating patients with periodontal disease is devoted to scaling and root planing (11). In some instances, surgical techniques are used to make the roots more accessible to this type of instrumentation.

Although it is generally assumed that the gingiva are irritated by the mere physical presence of calculus, this assumption awaits substantiation by scientific data (9). The microbial plaque covering the calculus is the noxious agent. Removal of gross or obvious calculus appears to be indicated; however, what is not clear is whether it is worthwhile to spend the time and effort required to remove small amounts of calculus that are difficult to detect, particularly since plaque re-forms in ***24 to 36*** hours (19,29).

There is also disagreement about the benefits of root planing. The little evidence available suggests that the primary rationale for root planing is to remove calculus; root smoothness may be inconsequential in retarding plaque formation ***(11,29).*** At any rate, the most important determinant of periodontal health is the degree to which patients exercise plaque control ***(23,27,29).***

Another issue relates to the frequency of prophylaxis (professional scaling) required to maintain periodontal health. A landmark study indicates that the optimal frequency is at 2-week intervals (5). However, other data suggest that quarterly intervals are also beneficial, although not as effective as 2-week intervals (29). Again, the benefits of scaling are believed to be less important than the patient's personal oral hygiene and plaque control. Unfortunately, more people rely on the dentist or hygienist for prophylaxes than practice good plaque control themselves. Thus, the issue of frequency must be examined, particularly from a standpoint of cost effectiveness. On the basis of available evidence, prophylaxis at 2-week intervals would be cost prohibitive for most individuals. Moreover, given current methods of dental practice, there is inadequate manpower to routinely clean people's teeth at 2-week intervals.

Correcting Margins of Restorations

Since improper margins of dental restorations contribute either to the initiation or severity of periodontal disease, the correction of such margins is an integral part of therapy. The most important reason for correcting improper margins is to facilitate plaque control, because in the face of an overhanging restoration, for example, plaque removal is exceedingly difficult. Generally, correction in the form of reducing bulk or smoothing is done at the time of scaling and root planing; but it is a requirement of periodontal therapy regardless of **when** it is done.

Chemotherapy

Substantiation of the fact that micro-organisms are a primary causative factor in periodontal disease has sparked much interest in chemotherapeutic control measures (1,20,29, 30). Some of the initial attempts to control periodontal disease with certain antimicrobial agents have been successful, but these attempts must be considered only trials. Essentially, insufficient evidence is available to warrant the routine use of these agents ***(29).*** Furthermore, a limitation of the studies thus far conducted is that they have been short-term. Periodontal disease is of long duration and requires what amounts to a lifetime of effort in controlling plaque formation; an antimicrobial agent may suppress bacteria or reduce plaque formation in a short-term clinical trial, but this does not mean that it will do so effectively and safely, without side-effects, for a long period of time. Nonetheless, further chemotherapeutic experimentation is warranted. However, at this time, chemotherapy is not considered a primary technology in the control of plaque or periodontal disease.

'Chemotherapy, the use of chemical agents—in this case antibiotics—to treat disease, is not an accepted, routine part of periodontal therapy. It is included here because the role of micro-organisms in causing periodontal disease has been shown only recently, and the principal method of treating microbial diseases generally is with these agents. As specific bacteria are identified as causative agents, much more emphasis is likely to be placed on the use of chemotherapy. The discussion of chemotherapy is also included because of cost implications.

Surgical Technologies

Periodontal surgery, in one form or another, is a common procedure used to eliminate the pockets that occur in destructive periodontal disease (24). Different surgical techniques are used for different purposes. Eliminating pockets, making root surfaces more accessible to removing plaque, inducing reattachment of tissues, and restoring destroyed tissues are the main clinical objectives of employing these techniques (7). In practice, two or more techniques often are used together to achieve a specific result.

Regardless of the objective of the specific surgical method, the fundamental rationale of periodontal surgery is to prolong the functional life of the teeth. The ultimate success or failure of the particular surgical method, therefore, should be judged by the extent to which the method conserves tooth life. Unfortunately, there are few baseline data on which to make objective evaluations. With only a few exceptions ***(7,23,24),*** the studies of the different surgical methods are short term. Longitudinal studies (longer than 5 to 10 years) required of diseases having the apparent chronicity of periodontal disease are needed. Until such scientific studies have been carried out, objective measurements of surgical effectiveness must remain tentative at best.

Those studies that have been done do not unequivocally point to one technique's being superior to another ***(7,23,24,27).*** Moreover, although the reasons for doing periodontal surgery can be supported experientially, scientific evidence does not show that any of these surgical techniques alone is effective in prolonging the life of the teeth. Periodontal surgery makes no difference in the absence of reasonable oral hygiene by patients combined with professional maintenance ***(23,24,26,27).*** The surgery by itself will not restore health to diseased periodontal tissues.

In summary, we conclude that there is considerable controversy surrounding the efficacy of the various surgical techniques used in the treatment of periodontal disease. It is also fair to note that the emphasis on surgical technology may be misplaced ***(29)*** and the type of surgery that is performed is considered far less important than whether or not the teeth can be maintained in a state of good oral hygiene ***(4,23,24, 26,27).***

THE KEYES TECHNIQUE

Dr. Paul Keyes and associates have developed and are testing a technology they believe suppresses plaque microbes and arrests, or markedly abates, the progression of destructive periodontal disease (17,18). This technology involves the use of a meticulous diagnostic and therapeutic regimen, the latter involving the application of certain salt solutions in all instances, and periodic courses of systemic antibiotics when indicated. Therapeutic regimens are based on microscopic sampling of plaque in the pocket areas as a means of monitoring bacterial activity. An integral part of the Keyes program is to show the patient the actual bacteriologic activity in the periodontal tissues though a microscope, the intent being to convince the patient of the extent of the problem and to motivate him or her to help in its remediation. Oral hygiene and plaque control instruction is given in a slow, stepwise fashion over a 3- to 4-week period. Patients are also advised to rinse their mouths after eating, whenever possible, and to use a pulsed-water irrigation device, such as a Water Pik, once a day.

Earlier we stated that there is no diagnostic method available to determine whether or not destructive periodontal disease is in an active state. The Keyes method purports to distinguish active from inactive disease by assessing the specific microbial population and inflammatory process in the pocket area. Dr. Keyes asserts what others believe but are not willing to assert without more substantiating evidence—that the

specific bacteria identified via the microscope are predictors of pathologic status and that the bacteria associated with disease differ from those found in healthy periodontal tissues. With the information obtained via microscopic examination, treatment is initiated which is aimed at suppressing the microbial population and facilitating the patient in controlling plaque formation.

Although the Keyes method is still in the early stages of being tested, Keyes has reported marked improvement in patients he has treated ***(18).*** It should be emphasized that the effectiveness of the Keyes method, like that of other treatments, depends on the patient's assiduously following the prescribed plaque control program (18). If it turns out that the Keyes method is as effective as its developers believe, then that would mean, among other things, that the patients using the Keyes method are doing a better job of controlling plaque than they would with other technologies. That in itself would be a most significant outcome.

Many individuals do not practice good oral hygiene. Even patients who have undergone extensive periodontal surgery and have received intensive oral hygiene instruction as a part of therapy often do not exercise adequate plaque contro; the recurrence rate of periodontal disease in such patients is high (24). If the Keyes method proves more effective than others, that will mean that something about this method enables or makes it easier for patients to exercise plaque control better than the other methods used to date. It could be the Keyes method's slow, stepwise fashion of patient instruction. Possibly, showing patients microbes taken from their tissues under a microscope impresses the nature of the problem upon the patients in a more effective manner. This is only speculation, and, of course, it is far too soon to tell if the Keyes technique has lasting effect. Much more evaluation—particularly long-term evaluation—is needed. (In the next part of this case study, we present the first systematic assessment of the effectiveness of the Keyes technique in multiple practice sites.)

Figure 1 shows some of the important similarities and differences between the Keyes and traditional technologies for treating periodontal disease. The "traditional" technology is shown in the lower half of the figure and the steps are labeled by capital letters. The "Keyes" technology is shown in the upper half of the figure, with the steps labeled by lower case letters.

Regardless of which technique will be applied to an individual patient, all patients—those who will be managed traditionally as well as those who will not—initially go through about the same diagnostic and treatment planning procedures. Once periodontal disease is diagnosed (Aa), patients can be treated either by "traditional" methods or the "Keyes" method. At this juncture, all patients with periodontal disease receive oral hygiene instruction and extensive tooth cleaning (scaling and root planing), see (B) and (b) on the figure. A comparison of (B) and (b) shows that the patients being treated by the Keyes method also receive a microscopic examination and are placed on a regimen that includes salt-solution therapy.

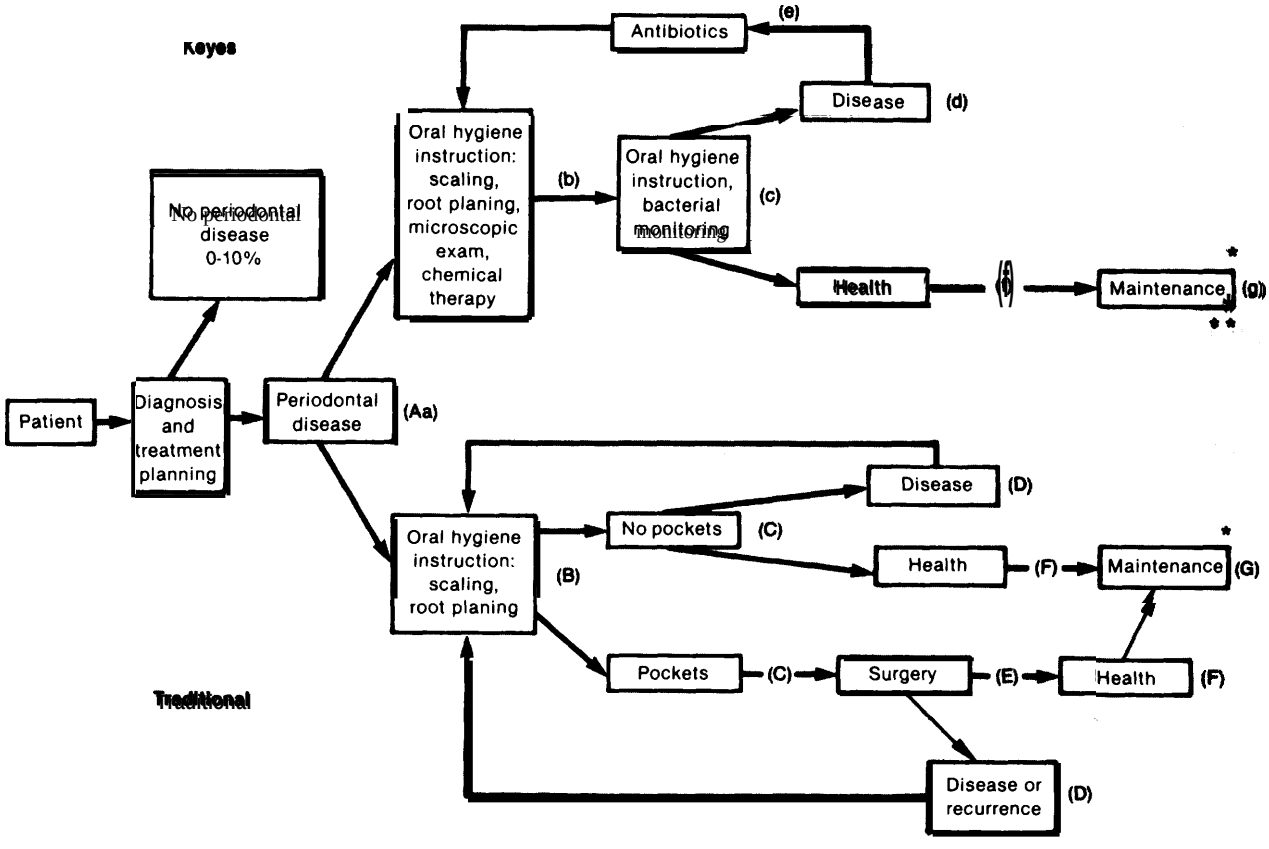
In patients being treated by the "traditional" method, a determination is then made of the presence or absence of pockets (C). If there are no pockets but disease is present (D), the patient receives further tooth cleaning and hygiene instruction (B). If pockets are present, some form of surgery is usually, but not always, performed (E). After surgery, if disease persists or recurs (D), the patient receives additional tooth cleaning and hygiene instruction (B). If no pockets are present and the patient is in reasonable oral health (F), a maintenance phase is begun (G).

In patients being treated by the "Keyes" method, by contrast, oral hygiene instruction and bacteriologic monitoring continue (c), but there is no surgery. If disease (d) persists, the patient is generally placed for 2 weeks on a regimen of antibiotics,[7] and oral hygiene instruction, microscopic examination, and tooth cleaning are continued (b). If the patient is in reasonable oral health (f), a maintenance phase is begun (g).

The Keyes technology differs from the traditional method of treating periodontal disease in three essential ways: 1) Microscopic diagnosis

[7]'Antibiotics may also be used in the traditional method, but are not used as routinely.

Figure 1.—Comparison of the Keyes and Traditional Methods Used To Treat Periodontal Disease



* Maintenance— assumes reasonable plaque control by patient, and assumes periodic professional scaling, oral hygiene instruction, etc.

** Includes bacteriologic monitoring.

and monitoring of microbial activity is the basis for therapeutic decisions; 2) salt solutions are used routinely and antibiotics are used often; and 3) periodontal surgery to eliminate pockets is used infrequently, since complete pocket elimination is not a goal of the Keyes method. The Keyes method is founded on Keyes' belief that halting the progression of the destructive process and allowing natural healing to occur does not depend on surgical elimination of the pocket, but does depend on controlling bacterial activity.

It should be emphasized that the steps shown in figure 1 are general, and some of the particular steps may differ, especially in the "traditional" technology. These differences or changes depend on several factors, such as extent of disease, the patient's overall health, the patient's ability or willingness to pay, and the personal treatment philosophy of the practitioner. Also, it should be reemphasized that the ultimate success of therapy, regardless of method, depends more on how well the patient practices good oral hygiene than on what the dentist does for the patient.

NEW EVIDENCE ON THE EFFECTIVENESS AND COST OF THE KEYES TECHNIQUE

Data Collection

To perform our study of the effectiveness and cost of the Keyes technique, we collected data in 1979 on ***18*** dental practices from the Washington, D. C., SMSA that currently use this technique.[8] Using written questionnaires, we collected data on each practice and on a selection of the patients in each practice who are currently being treated with the Keyes technique.'

Data on ***8*** of the practices were obtained via a mail survey, and data on the other 10 were collected by dental students.'" All 18 of the dental practices surveyed were owned and operated by solo general practitioners. The average age of these practitioners was 47. The average length of time they had been in practice was almost 12 years; they had used the Keyes technique for 13.7 months on the average.

Using information from the patients' records, we completed a written questionnaire on about 10 patients in each practice who were beyond their initial visit for the Keyes technique.[11] The questionnaire used to collect data on individual patients is reproduced in appendix B. Using this questionaire, we obtained data relating to the patient's oral health status before treatment and at the time the questionnaire was administered. Data were also obtained on the services delivered to the patient during the first six visits and the maintenance visit, on who delivered these services, and in what amount of time. The charges for each visit were also recorded. Usable data for our estimates were collected on 190 patients and over 800 dental visits. Approximately 63 percent of the patients were female. The average age of all patients was ***42.***

The Effectiveness of the Keyes Technique

In order to demonstrate the effectiveness or lack of effectiveness of the Keyes technology, five measures were used as general indicators of periodontal disease of the patients in the study before and after treatment. All five oral health indicators showed some improvement following treatment (see table 1).

A number of the important indicators changed dramatically. Bleeding of gums upon probing, an indication of early or beginning disease, dropped from 99 percent of the patients showing it before treatment to 34 percent of the patients showing it at the time the information was obtained. Another important change was the decrease from ***65*** to ***9*** percent in the number of patients with loose teeth. This change is im-

Table 1.—Periodontal Disease **Indicators: Effectiveness or Lack of Effectiveness of the Keyes Technique**

Indicator	Percentage of patients: Status before treatment	Percentage of patients: Current status
1. Bleeding on probing	99%	34%
	N = 185	N = 185
2. Suppuration	56	23
	N = 185	**N = 181**
3. Mobile teeth	**65**	**9**
	N = 178	**N = 173**
4. WBCS microscopically evident	94	78
	N = 182	N = 172
5. Motile forms microscopically evident	62	32
	N = 170	N = 148

N = number of observations.
Probing—Placing a dental instrument under the gingiva to determine whether or not bleeding will occur and to measure periodontal pockets, if present.
Suppuration—Pus (exudate).
Mobile teeth—Loose teeth.
WBCs—White blood cells.
Motile forms—Live or moving bacteria.

'Currently, there are 26 dental practices using the Keyes technique in the Washington, D. C., SMSA. Except for the data collected at the National Institutes of Health by Keyes on his own practice, no other data of this type are currently available.

"The data collection for the study was supported in part by a grant (grant No. H.S.-O2577) from the National Health Care Management Center, Wharton School, University of Pennsylvania. That center is funded by the National Center for Health Services Research, Office of the Assistant Secretary for Health, Department ofHealth and Human Services.

"OA comparison of the data collected via mail and the data COIlected by the dental students did not show any important statistical differences. The data collected by the dental students were more complete.

"In some practices, we were able to complete questionnaires on more than 10 patients; in others, we had to settle for fewer.

portant because loose teeth are an indication of advanced disease, A "t" test on the difference between the percentages before and after treatment for each of the periodontal disease indicators in table 1 was statistically significant at the 0.01 level. Thus, these data indicate a significant overall improvement in dental health for our study population.

Moreover, at the time our study was done, ***65*** percent of the ***190*** patients in the study population had gone from treatment to maintenance, and only 35 percent required further treatment. We also performed an analysis of the data over time. This analysis included some of the patients being treated and then maintained by the Keyes method for more than ***24*** months. *[2] In these patients, the indicators of oral health continued to show almost the same level of improvement as in patients treated and maintained for less time.

Furthermore, our analysis of the data concerning the effect of the Keyes technology on the level of plaque control exercised by the patients showed that improvement in plaque control had occurred to the same extent as improvement in the other indicators (see table 2). For example, before treatment 93 patients were judged to have below-average plaque control, but at the time our data were collected only 12 patients were rated in this manner. A chi square test showed patient improvement in plaque control (as indicated by the before and after data in table 2) for all groups of patients to be statistically significant at the 0.01 level or greater. (This finding does not apply to the group of patients who were above average in plaque control before treatment.)

[12] The data used for this analysis are not presented in this discussion.

Table 2.—Plaque Control by Patients

Patient status before treatment	After treatment		
	Above average	Average	Below average
Above average (2).	2	0	0
Average (76). . , ...	56	19	1
Below average (93).	42	39	12
Total (171).	100	58	13

The Delivery and Cost of the Keyes Technique

The Keyes technique involves the delivery of 10 basic procedures. These procedures and the percentage of patients in our study population receiving them during each visit to the dentist are shown in table 3. The first visit usually involves a dental history ***(76*** percent) and a medical history (84 percent). If histories are not provided during this visit, that usually indicates that histories were provided at a visit prior to beginning the Keyes technique. This is also the case for radiographs and visual assessment. During the first visit, over half the patients undergo periodontal probing (7 I percent), a microscopic examination **(64** percent), and a scaling **(52** percent). About two-fifths of the patients receive periodontal pocket measurements (40 percent) and almost one-sixth (16 percent) receive root planing. Almost two-thirds of the patients (64 percent) also receive plaque control instruction during the first visit.

The percentage of patients receiving dental histories, medical histories, and radiographs, as expected, declines after the initial visit. Over the next two visits (visits 2 and 3), the percentage of patients receiving root planing and scaling increases. Later visits continue the use of scaling and root planing, as well as plaque control instruction and probing. The maintenance visit shows some increase in visual assessment, $scali_{ng}$, pocket measurement, and microscopic examinations. Clearly, the maintenance visit (except for the histories, diagnosis, and plaque control instruction) is somewhat similar to the initial visit in terms of the procedures performed.

To estimate the cost of producing the Keyes technique, we began with data on the amount of dentist and hygienist time used during each visit (see table 4). The majority of this time is used to instruct the patient in plaque control and provide maintenance. The first visit uses an average of 28 minutes of dentist time and 24 minutes of hygienist time. '3 For later visits (visits 5 and 6,

[13] It is interesting to note that the estimate of the average dentist time has a large standard deviation in comparison to the mean (coefficient of variation). A further analysis of the data showed that there was a significant variation among the 18 dental practices, as well as across the patients treated within each practice.

Table 3.—Mix of Services Delivered at Each Visit for the Keyes Technique

Service	Percentage of patients (N)						
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Maintenance visit
Dental history	76% N = 184	1 % N = 177	1 % N = 158	0 N = 135	0 N =99	0 N =69	4% N = 105
Medical history	84 N = 184	6 N = 177	N =[6]158	6% N = 135	4% N =99	1% N =69	N 105
Radiographs	71 N = 184	10 N = 177	7 N = 158	N =[7]135	5 N = 100	14 N =69	14 N = 105
Visual assessment	97 N = 184	71 N = 177	71 N = 158	70 N = 135	67 N =99	67 N =69	84 N = 105
Periodontal probing	71 N = 185	62 N = 177	60 N = 158	N=99	47 N =99	45 N =69	51 N = 105
Pocket measurement	40 N = 185	20 N = 177	17 N = 158	14 N = 135	12 N = 100	19 N =69	32 N = 105
Microscopic examination	64 N = 185	62 N = 177	54 N = 158	46 N = 135	47 N =99	51 N =69	54 N = 104
Scaling	52 N = 184	63 N = 177	66 N = 158	62 N = 135	N =69	68 N =69	83 N = 105
Root planing	16 N = 185	33 N = 177	35 N = 158	28 N = 135	N =1OO	32 N =69	36 N = 105
Plaque control instruction	64 N = 185	72 N = 176	54 N = 157	44 N = 135	37 N = 100	38 N =69	26 N = 105
Other	28 N = 185	30 N = 176	36 N = 157	33 N = 135	23 N = 100	22 N =69	35 N = 105

N = number of observations.

Table 4.—Average Dentist and Hygienist Time Used for Each Visit for the Keyes Technique

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Maintenance visit
Dentist time[a]	28 SD=22.46 N = 173	22 SD=19.83 N = 138	20 SD=18.1O N = 135	21 SD=19.00 N = 111	19 SD=16.84 N =93	22 SD=18.17 N =50	20 SD=17.56 N =92
Hygienist time[a]	24 SD= 22.43 N = 140	25 SD= 19.20 N = 143	23 SD= 19.99 N = 117	23 SD= 19.28 N =99	21 SD= 19.27 N =69	21 SD= 19.72 N =53	21 SD= 18.25 N =83

SD= Standard deviation
N = mumber of observations.
[a]Time in minutes.

and the maintenance visit), the amount of dentist time in each visit declines, while amount of hygienist time remains quite stable. (For purposes of our cost calculation, we assumed that the dentist time is spent with only one patient. However, it is likely that some dentists are treating more than one patient at a time. If that is the case, our estimates of the average variable cost of production may be too high.)

To estimate the average variable cost (in 1979 dollars) of producing the Keyes technique, we assume that the dental practice is already in operation and that the only additional expenses for producing the Keyes technique are the cost of the phase-contrast microscope and the cost of the dentist and hygienist time.[14] The scope cost is about ***$3,000,*** and we depreciate it over a 10-year period. For the purpose of our estimates, we allocate the cost of the scope to **100** patients being treated by the Keyes technique per year at $3 per visit.[15] The cost of dentist time, based on the yearly income of and hours worked by a

[14] In a technical sense, once the scope is purchased, it is a fixed cost **and not a** variable cost. Since the cost of the scope is modest, deleting the cost from our estimate would **have very** little impact.

[15] This estimate may be high, because dentists who use the Keyes technique probably treat more than 100 patients a year. In any event, the per unit cost of using the phase-contrast microscope is small; thus, alternative methods of computing its cost will have a small impact on *our* estimates.

general practitioner, is estimated at ***$25*** per hour (3). " To estimate the cost of hygienist time, we used the same costing procedure and added is percent for fringe benefits. This produced a cost of ***$8*** an hour for the hygienist time (3).17

To produce an estimate of the labor cost per visit, we applied these hourly rates to the minutes of time used by the dentist and hygienist. To this estimate, $3 was added for the use of the phase-control scope to produce estimates of the average variable cost of producing each visit (see table 5). According to our estimates, the average variable cost of producing the initial visit is higher than that of producing subsequent visits. The difference in average variable cost mostly reflects the reduction of time spent by the dentist and the different range of services provided following the initial visit (table 4).

Data from our survey on the average charge for each visit are presented in table 5. Again it is interesting to note that the average charge is highest for the initial visit. Moreover, for the maintenance visit, the average variable cost as a percentage of average charge is the lower than it is for any of the first six visits. For the dentists that charge for the Keyes technique on the basis of the total treatment cost, the average charge per case was slightly over $120. This charge per case is comparable to the total charge, on a per visit basis, of between five and six visits.

In addition to paying the dental charges for the Keyes technique, the patient needs to purchase an electric toothbrush and electrical irrigating device at a total cost of ***$30*** to **$40.** In about half the cases treated by the Keyes technique in our data base, drugs were utilized, usually tetracycline. The cost for tetracycline per prescription is between **$8** and **$10. In most** instances, one or two prescriptions are required for those patients using tetracycline. It is currentl$_y$ believed that after the patient has been treated successfully by the Keyes technique, two maintenance visits at an average charge of about **$26** per visit are required to ensure continued oral health ***(29).***

The Keyes technique may have benefits in addition to the treatment and prevention of periodontal disease. In some patients, a benefit may be a reduction in tooth loss. Furthermore, if surgery is avoided, the pain and discomfort associated with surgery are also avoided. By involving patients in improving their oral health, the Keyes technique may improve their awareness of dental disease and encourage their early use of dental services, while the disease is still treatable, often at a reduced cost.

[16]The hourly income rate of dentists in general practice was derived in the following manner. Yearly average income of general practitioner dentists for 1976 (3) was inflated to 1979 using the Consumer Price Index for dental services. The yearly income figure was then divided by the average number of hours worked per week and weeks worked per year (3).

[17]The hourly wage of hygienists for 1979 was derived by inflating their average yearly income in 1976 by the increase in the dental care component of the Consumer Price Index (3). For full-time hygienists, we divided their average yearly income by the average number of weeks worked and the average number of hours worked per week (3). To this estimate, we added an additional 15 percent for fringe benefits.

Table 5.— Estimates of the Average Variable Cost of Producing Each Visit and the Average Charge per Visit for the Keyes Technique

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Maintenance visit
Average variable cost[b]	$17.87	$15.33	$14.40	$14.82	$13.72	$14.97	$14.13
Average charge	$31.63	$26.63	$25.80	$26.21	$23.52	$23.17	$27.83
	N = 135	N = 132	N = 112	N = 90	N = 69	N = 45	N = 64

N = number of observations
[a]All figures in 1979 dollars
[b]Estimated using the cost of dental time, hygienist time, and a phase-contrast microscope.

CONCLUSION

Periodontal disease is a chronic disease that affects over 90 percent of the adult population in the United States **(6, 15,16,22,29).** Today, treatment of periodontal disease by dentists often involves surgery. The surgical procedures that are used may be painful to the patient, and they often carry with them postsurgical discomfort. More importantly, our assessment of the scientific literature shows that the effectiveness of the surgery alone in the treatment of periodontal disease has not been adequately demonstrated.

The Keyes technique is so new that long-term efficacy and effectiveness studies have not been possible, although the evidence to date appears promising. Our analysis, based on data from 18 general practices in the Washington, D. C., SMSA on ***190*** patients being treated with the Keyes technique and over 800 visits, found a measurable and statistically significant improvement in each of the five indicators of dental disease we employed. However, before more definitive conclusions on the effectiveness of the Keyes technique can be drawn, a more complete and longitudinal study is required.

Using our data base, we estimated the average variable cost of producing the Keyes technique for 190 patients representing over 800 patient visits. The estimated average variable cost of a visit in 1979 was between $17.87 and $13.72, depending on whether it was an initial, followup, or maintenance visit. These average variable cost figures should be viewed as only rough estimates, and by definition they omit the fixed cost of production (e. g., rent). By contrast, the reported charges in 1979 for the initial visit and the maintenance visit for patients being treated with the Keyes technique averaged $31.63 and $27.83, respectively. Given the charge data on visits, our average variable cost figures appear to be quite reasonable estimates.

The cost effectiveness of the Keyes technique, if i t does have a long-term effectiveness, depends in part on the amount of periodontal surgery that is avoided. Although we are currently unable to estimate this amount or to obtain an estimate from the published literature, the dentists in our study indicated that only between O and 5 percent of patients being treated with the Keyes technique also required a referral to a periodontist. If this estimate is correct and generalizable, then the potential savings of the Keyes technique are large.

Our assessment of the literature on the effectiveness of periodontal surgery suggests that further long-term clinical studies are needed. Such studies would be quite useful if they were designed to compare the Keyes technique to periodontal surgery and included a control group which did not receive either treatment. The patients under study should be randomly assigned to each of these three groups. The random assignment of patients into a nontreatment group raises an important ethical issue. However, our assessment of the current method of treating periodontal disease raises serious questions about its effectiveness, so the assignment of patients to a nontreatment group, with their informed consent, may be feasible. The costs of each of these alternatives—periodontal surgery, the Keyes technique, and no treatment—should be computed and compared.

APPENDIX A.–GLOSSARY OF DENTAL TERMS

Calculus.—Calcium phosphate and carbonate with organic matter deposited upon the surfaces of the teeth.

Cementum.—The bonelike connective tissue covering the root of a tooth and assisting in tooth support.

Gingiva. —Gum of the mouth.

Gingivitis.–Inflammation of the gingiva (gum) only.

Keyes **technique.—A nonsurgical method of treating periodontal disease which involves microscopic determination of the microbial status, the application of certain salt solutions** in all instances, periodic courses of systemic antibiotics when indicated, and an extensive regimen of oral hygiene instruction.

Maintenance.—Patient seen periodically for assessment of periodontal health status, cleaning (prophylaxis), microscopic assessment of bacterial activity, and oral hygiene instruction if needed.

Mobile teeth. —Loose teeth.

Mucogingival surgery. —Surgical removal of pockets involving soft tissue only as part of the surgical approach to treating periodontal disease.

Osseous surgery .—Surgical removal of bone as part of the surgical approach to treating periodontal disease.

Quadrant. -A term used for descriptive purposes to designate any one of four areas of the teeth and gums (e.g., the upper right quadrant or the lower left quadrant).

Periodontal disease.—Diseases of the supporting structures of the teeth (e. g., gingivitis, periodontitis),

Periodontist. —A dental specialist who concentrates on periodontal disease.

Periodontitis. —Inflammation of the supporting structures of the teeth including bone, The use of this term connotes destruction of the periodontal tissues.

Periodontium. —The tissues investing and supporting the teeth, including the cementum, periodontal ligament, alveolar bone, and gingiva.

Plaque.—A gummy, almost exclusively bacterial substance which adheres to the teeth and is discernible only by applying stains, Plaque is the primary causative agent in periodontal disease.

Pocket.—The deepening of the normal space between the gum and the tooth due to inflammation.

Probing.—Placing a dental instrument under the gingiva or gum to determine whether or not bleeding will occur and to measure periodontal pockets, if present,

Prophylaxis.—The use by professionals of appropriate procedures and/or techniques to clean the teeth.

Radiograph.—A film of internal structures of the mouth produced by X-ray.

Root planing.–Smoothing of the root surfaces of the teeth using certain instruments.

Scaling.—Removal of calculus material from the tooth surfaces and that part of the teeth covered by the marginal gingiva.

Sulcus.—The normal space between the gum and the tooth,

APPENDIX B.–QUESTIONNAIRE USED TO COLLECT DATA

Dentist _____ Age _____ Years in Practice _____

1. Approximate length of time you have been using the Keyes technique:
   _____ Years

2. For approximately how many patients have you used the Keyes technique?
   _____ Patients

3. Do you use the Keyes technique as a preventive method as well as a treatment method?
   _____ Yes _____ No

4. Approximately what percentage of the patients with whom you have been using the Keyes technique also require some form of periodontal surgery?
   _____ 0-5% _____ 5-10% _____ 10-20% _____ 20-30%

5. How much do you refer patients to periodontists now as compared to before you began to use the Keyes technique?
   _____ More _____ Less _____ Same

6. Considering all of your patients that have been treated by the Keyes technique, approximately what percentage do you consider to have been treated:
   _____ % Successfully _____ % Unsuccessfully

7. What do you believe are the principal reasons for lack of success?
   (Use the back of this page if necessary.)

8. Would you be willing to allow me to ask the patients on whom you have completed a questionnaire to answer a few questions about their feelings?
   _____ Yes _____ No

9. **If yes, please** sign your name:

   _____

Patient_____ Age_____ sex_____

Address_____

Date patient began treatment with Keyes technique_____ Today's Date_____

Total number of visits for the Keyes technique made by patient to date_____

Total number of maintenance visits to date _____

PERIODONTAL STATUS
(Please check where appropriate)

At Initial Visit		At This Time
_____	Healthy, on maintenance care only	_____
_____	Gingival inflammation only	_____
_____	Bleeding on probing	_____
_____	Suppuration	_____
_____	Radiographic evidence of bone loss	_____
_____	Number of mobile teeth	_____
_____	Number of quadrants of involvement	_____
_____	Microscopic - many WBC's	_____
_____	Microscopic - many motile forms	_____

ASSESSMENT OF PATIENT'S PLAQUE CONTROL

_____	Above average (doing well on own)	_____
_____	Average (needs some professional instruction)	_____
_____	Below Average (needs a great deal of professional instruction)	_____

Approximate total number of hours of plaque control instruction given _____

By whom: Dentist_____
Hygienist_____
Dental Assistant_____

Frequency of prophylaxis _____times per year

USE OF ANTIBIOTICS TO TREAT THE PATIENT

Yes_____ No_____

If yes, how long was each course? -weeks. How many courses?_____

PATIENT USES:
(please check correct response)

Baking soda and peroxide	Yes_____	No_____
Fluoride	Yes_____	No_____
Irrigation	Yes_____	No_____
Other, please indicate	Yes_____	No_____ _____

Has this patient been treated for periodontal disease prior to seeing you?
Yes__ No__

If yes, was it by a general dentist____ or a periodontist__?

PLEASE CHECK WHICH PROCEDURES ARE DONE AT EACH VISIT FOR THIS PATIENT USING THE KEYES TECHNIQUE

	VISITS						
	1st	2nd	3rd	4th	5th	6th	Maintenance
Dental history	—	—	—	—	—	—	—
Medical history	—	—	—	—	—	—	—
Radiographs	—	—	—	—	—	—	—
Visual assessment	—	—	—	—	—	—	—
Periodontal probing	—	—	—	—	—	—	—
Pocket measurement	—	—	—	—	—	—	—
Microscopic examination	—	—	—	—	—	—	—
Scaling	—	—	—	—	—	—	—
Root planing	—	—	—	—	—	—	—
Plaque control instruction	—	—	—	—	—	—	—
Other_____(list)	—	—	—	—	—	—	—
Other_____(list)	—	—	—	—	—	—	—

PLEASE ANSWER THE FOLLOWING FOR THIS PATIENT USING THE KEYES TECHNIQUE

1. Average chair time per patient visit (minutes)	—	—	—	—	—	—	—
2. How many minutes of this time was with:							
Dentist	—	—	—	—	—	—	—
Hygienist	—	—	—	—	—	—	—
Dental Assistant	—	—	—	—	—	—	—
Other (specify)	—	—	—	—	—	—	—
3. Approximate cost to patient per visit	$ —	$ —	$ —	$ —	$ —	$ —	$ —

4. If cost **was** on the basis of a total case, what was the cost per case? $___

5. What was the average charge to patient for maintenance visit? $___

COMMENTS

If you feel that these questions will not show the correct information about either effectiveness or cost using the Keyes technique for this patient, please supply the information you believe will help on the back of this page.

REFERENCES

1. "Agents for the Control of Plaque: A Symposium Presented at the Meeting of the International Association for Dental Research, " J. Dent. *Res.* **58:2378, 1979.**
2. American Dental Association, Bureau of Economic Research and Statistics, "Dental Fees Charged by General Practitioners and Selected Specialists in the United States, 1977, " J. *Am. Dent. Assoc.,* October 1978.
3. _____ *The 1977 Survey of Dental Practices (O@&: ADA, 1977).*
4. Axelson, P., and Lindhe, J., "Effect of Controlled Oral Hygiene Procedures on Caries and Periodontal Disease in Adults, " J. *Clin. Periodont. 5:133, 1978.*
5. _____ "The Effect of a Preventive Programme on Dental Plaque, Gingivitis, and Caries in Schoolchildren: Results After One and Two Years,"]. *Clin. Periodont.* 1:126, 1974.
6. Chilton, N. W., and Miller, M. F., "Epidemiology of Periodontal Disease: Position Report and Review of Literature, " in *International Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich.: University of Michigan, 1977).
7. Cohen, D. W., "Role of Periodontal Surgery,"). Dent. *Res.* 50:212, 1971.
8. Committee Report, in *lnternational Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich.: University of Michigan, 1977).
9. Committee Report: "The Etiology of Periodontal Disease, " in *World Workshop in Periodontics, S.* P. Ramfjord, et al. (eds.) (Ann Arbor, Mich.: University of Michigan, 1966).
10. Douglass, C. N., and Day, J. M., "Cost and Payment of Dental Services in the United States," J, *Dent. Educ. 43(7) :33o, 1979.*
11. Garrett, J. S., "Root Planing: A Perspective, " J. *Periodont. 48:553,* 1977.
12. Gibson, R. M., "National Health Expenditures, 1978, " *Health Care Fin. Rev. 1(1),* summer 1979.
13. Henry, J. L., and Sinkford, H. C., "The Economic and Social Impact of Periodontal Disease: Position Report and Review of Literature, " in *International Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich.: University of Michigan, 1977).
14. Hurt, W. C., "Periodontal Diagnosis–1977: A status Report, " J. *Periodont, 48:533, 1977.*
15. Ingle, J. I., "The Health, Economic, and Cultural Impact of Periodontal Disease on Our Aging Population, " presented at the National Institutes of Health Conference on Aging, Louisville, Ky., 1975.
16. Kelly, J. E., and VanKirk, L. E., "Periodontal Disease in Adults: United States 1960-62, " PHS publication No. 10 (Washington, D. C.: U.S. Government Printing Office, 1965).
17. Keyes, P. H., et al., "The Use of Phase-Contrast Microscopy and Chemotherapy in the Diagnosis and Treatment of Periodontal Lesions—An Initial Report (I), " *Quintessence lnternat. 1:5I, 1978.*
18. _____ "The Use of Phase-Contrast Microscopy and Chemotherapy in the Diagnosis and Treatment of Periodontal Lesions—An Initial Report (II), *Quintessence lnternat. 2:69, 1978.*
19. Lee, H., et al., "Experimental Gingivitis, " *Man. J. Periodont.* 36;177, 1965.
20. Loesche, W. J., "Chemotherapy of Dental Plaque Infections, " *Oral Sci. Rev.* 9:63, 1976.
21. Pennel, B. M., and Keagle, J. G., "Predisposing Factors in the Etiology of Chronic Inflammatory Periodontal Disease, " J. *Periodont. 48:517, 1977.*
22. *Periodontal Disease and Oral Hygiene Among Children,* DHEW publication No. (HSM) 72-1060 (Washington, D. C.: Department of Health, Education, and Welfare, 1972).
23. Ramfjord, S. P., "Surgical Pocket Therapy," *Int. Dent. J.* 27;263, 1977.
24. Ramfjord, S. P., et al., "Longitudinal Study of Periodontal Therapy, " J. *Periodont. 44:66, 1973.*
25. Ranney, R. R., "Pathogenesis of Periodontal Disease: Position Report and Review of Literature, " in *International Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich.: University of Michigan, 1977).
26. Rosling, B., et al., "The Effect of Systemic Plaque Control on Bone Regeneration in Infrabony Pockets, " J. *Clin. Periodont,* 3:38, 1976.
27. _____ "The Healing Potential of the Periodontal Tissues Following Different Techniques of Periodontal Surgery in Plaque-Free Dentitions, " J. *Clin. Periodont.* 36:233, 1976.
28. Rovin, S., "A Curriculum for Primary Care Dentistry, " *J.E. D.* 41:176, 1977.
29. Sheiham, A., "Prevention and Control of Periodontal Disease, " in *International Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich,: University of Michigan, 1977).

30. Soransky, S. S., "Microbiology of Periodontal Disease—present Status and Future Considerations, " J. Periodotlt. 48:497, 1977.
31. Suomi, J. D., et al., "The Effect of Controlled Oral Hygiene Procedures on the Progression of Periodontal Disease in Adults: Results After Third and Final Year, " J. *Periodont.* 42:152, 1971.
32. Tanzer, J. M., "Microbiology of Periodontal Disease: Position Report and Review of Literature, " in *International Conference on Research in the Biology of Periodontal Disease* (Ann Arbor, Mich.: University of Michigan, 1977).
33. U.S. Department of Health, Education, and Welfare, "Edentulous Persons, United States, " National Center for Health Statistics, series 10, No. 89, 1971.
34. Zander, H. A., and Poison, A. M., "Present Status of Occlusion and Occlusal Therapy in Periodontics, " J. *Periodont.* 48:540, 1977.

Commentary

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INTRODUCTION

Periodontal disease is ubiquitous, affecting 80 to 90 percent of the adult population. It may range from simple gingivitis to advanced destructive periodontitis in which there is destruction of the supporting tissues around the teeth, resulting in tooth loss.

Treatment of early, or mild, periodontal disease is usually simple, short, and successful. Treatment of advanced periodontitis, though more involved and protracted, has a high success rate. Further, treatment is based on the long-term experience of many expert clinicians and observers, supported by sound clinical research.

The criteria for a clinical investigation to be considered as having scientific merit are the following: ı) the use of reliable and standardized measurements; 2) adequate controls, particularly in clinical trials; 3) presentation of **data in a form allowing appropriate statistical analysis; and a) submission of reports to peer review** by publication in scientific journals. Studies not adhering to these standards are not scientifically valid, and their results must be considered anecdotal. Scheffler and Rovin's study of the Keyes technique in 18 dental practices in the Washington, D. C., area does not adhere to these standards.

However, there is in the scientific literature abundant well-documented evidence that plaque removal and subsequent control arrests or reverses gingivitis and early periodontitis. Since the Keyes technique relies principally on plaque removal and control, it is not a new technique at all, for plaque removal and control are exactly what all dentists who treat periodontal disease do as the initial and basic part of their therapy.

For hundreds of **years,** periodontal treatment has been based on the removal of hard and soft deposits from tooth surfaces. This therapy **has** been quite effective. However, cases of advanced periodontal disease may require the use of surgical procedures for the proper debridement of inaccessible microbial masses and calculus. The depths of periodontal pockets or other difficult to reach places cannot be thoroughly cleansed unless exposed surgically. Indeed, root surfaces with periodontal pockets deeper than 5 mm may still harbor significant numbers of micro-organisms despite careful scaling by skilled operators ***(12).*** A further beneficial effect of the surgical approach may be to reduce pocket depth, thus making formerly inaccessible areas accessible for the patient to exercise plaque control.

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A study of the result of conventional therapy was reported by Hirschfeld and Wasserman in **1978 (l). This study involved 600 patients, most of whom had advanced periodontal disease. All these patients had been referred to a periodontal specialist for care because they were in imminent danger of losing teeth. All 600 received conventional periodontal treatment, which for many included surgery** when indicated; and all then had followup care for 15 to ***50*** years (with a mean duration of observation of 22 years). Eighty-three percent of these patients lost only O to 3 teeth. The fact that these patients with advanced disease lost so few teeth during that long time span demonstrates the success of conventional periodontal therapy. However, a small subgroup of ***25*** patients (4.2 percent) in this study lost more than 10 teeth in the 22-year followup period. Recent evidence from other studies suggest that this subgroup of patients probably had a more aggressive or rapidly progressing form of adult periodontitis.

It should be noted that the Hirschfeld and Wasserman study did not include patients with simple gingivitis or early periodontitis; the study examined only the results of conventional treatment of patients with advanced periodontal disease. No similar conclusions regarding the effectiveness of the Keyes technique in the treatment of advanced periodontal disease can be drawn from the study by Scheffler and Rovin for two reasons. One, the authors provide no useful information indicating the severity of the patients' disease, and two, their study is of such short duration that it is valueless for judging the long-term effect of the Keyes technique on advanced periodontal disease.

There are other careful long-term studies which have demonstrated the long-term success of conventional treatment: Ramjford, et al. (7), Knowles, et al. (3), Lindhe and Nyman (4), and Nyman and Lindhe (6). These studies followed the patients for periods of time up to **10 years** after treatment. Treatment was careful preparation of the patient by scaling, plus motivation and training in oral hygiene. Surgery was indicated because of the severity of the patients' periodontal disease.

All of these studies constitute strong evidence that conventional periodontal therapy, including surgery and proper maintenance by the dentist and the patient, can stop the progress of advanced periodontal destruction and maintain the dentition in the majority of cases.

When comparing these well-designed studies of conventional treatment that have been reported in the scientific literature to the study of the Keyes technique by Scheffler and Rovin, one must point out that the Keyes technique involves the same antimicrobial approach as conventional therapy. However, Keyes only rarely accepts the use of surgery to gain access to more deeply involved areas. His method is to flush such areas with salt solutions, which, he states, is sufficient to kill pathogenic bacteria. Whether salt solutions actually achieve this goal is not clear at this time. Thus, it is premature to suggest that this treatment regimen alone should be used in human patients as a replacement for techniques that have been documented to control periodontal diseases.

DIAGNOSIS OF PERIODONTAL DISEASE AND MONITORING OF DISEASE ACTIVITY

The Keyes technique employs a diagnostic test that has not yet been validated as a measure of disease activity, namely, phase-microscopic examination of wet samples of material scooped out of periodontal pockets. Implicit in reliance on this test are at least two unproved assumptions: 1) that the microbiologic samples taken are representative of the microbiota (bacterial population) in the worst-diseased sites, and 2) that the test is diagnostic of disease activity and can also be used to monitor the effects of treatment.

Are the Samples Representative?

The basis of choosing the sites for sampling of subgingival plaque has not been clearly defined by Keyes, apart from a statement that "particular effort is made to obtain samples from deeper subgingival spaces that are difficult for the patient to clear (sic)" (2). That the samples are representative is an unwarranted assumption, because there is a dramatic variation in the bacterial population from site to site within the same individual, from supragingival (above the gum margin) sites to subgingival (below the gum margin) sites, from diseased sites to healthy sites, and between sites with different forms of periodontal disease ***(5,8,9,10).*** Therefore, there is no basis for using a sample of bacteria from one area as an indication of the bacterial population of the plaque from a patient's mouth.

Is the Test Diagnostic of Disease Activity?

Any proposed diagnostic test must be validated. The one used in the Keyes technique has not been. Keyes' claim that the state of disease activity can be determined by examining the proportion of motile forms on a microscopic slide is not substantiated by scientific evidence. Research on the possible existence of such a relationship is just now being invited in a "Request for Proposals" issued by the National Institutes of Health (RFP No. NIH-NIDR-81- 3R).

However, there is at this time a limited amount of established knowledge about the relationship of motile organisms and periodontal disease. That phase microscopy could be sensitive to all forms of active periodontal destruction is doubtful. For example, in the case of periodontosis, an actively progressive periodontal disease that causes major destruction of bone surrounding the teeth in young individuals, there are few motile organisms even though the disease is progressing at a rate generally considered to be much faster than that of adult periodontitis. The organism that has been shown to be uniquely and closely associated with this condition is not motile.

Thus, it seems clear that to date there is no convincing rationale for the use of phase microscopy for either of the two uses suggested by Keyes.

THE USE OF SALT, HYDROGEN PEROXIDE, SODIUM BICARBONATE, AND TETRACYCLINE AS THERAPEUTIC AGENTS IN THE CONTROL OF PERIODONTAL DISEASE AND THE USE OF PHASE MICROSCOPY AS A PATIENT MOTIVATOR

A widespread group of therapeutic modalities is employed in the Keyes technique. One modality is scaling, which as stated above has been shown to be effective in controlling periodontal disease. In addition, Keyes advocates local applications of concentrated salt solutions and/or pastes of sodium chloride, magnesium chloride, hydrogen peroxide, and often the systemic administration of tetracycline (an antibiotic) under certain conditions. At present, tetracycline has been shown to be needed in only a small number of cases which responded poorly to routine therapy. The use of this drug in about half of the patients treated by the Keyes followers in Scheffler and Rovin's Washington area study is totally unjustified. Furthermore, no evidence is available which suggests that the local applications of salt solutions or pastes or hydrogen peroxide reduce the rate of periodontal destruction, prevent the recurrence of active periodontal lesions in a treated patient, or add anything to the existing regime of periodontal therapy.

Keyes and followers assert that phase microscopy has value in motivating a patient to perform proper oral hygiene. This assertion is based on the assumption that patients are more willing to follow the dentist's directions to clean their mouths properly when shown the living bacteria which can be scraped off their teeth.

However, the American Society of Preventive Dentistry, which in the 1960's spearheaded an effort to use phase microscopy to motivate patients, found that the technique does not provide a better approach to patient motivation than traditional modes of hygiene instruction.

ECONOMIC PERSPECTIVES

CBAS and **CEAS of medical-dental procedures are essentially accounting procedures carried out to determine if a** given program, or in this case a treatment regimen, is worth the effort. These analytic techniques have become increasingly sophisticated in the last 5 years (11,13). CBA relates the total costs of receiving such treatment to the total benefits, while CEA compares the costs of one treatment modality to those of another, or to a group of alternative treatments, having established that all of the treatments meet a minimum acceptable level of effectiveness.

Scheffler and Rovin do not present a complete picture of costs and benefits nor of the costs of alternative treatments. Although they discuss alternative surgical and nonsurgical techniques, they do not present the types of data necessary to compare these alternatives with the Keyes technique.

The only costs that Scheffler and Rovin present are certain average variable labor and capital costs of dental office visits. Even these figures are inconclusive. The authors' data are not clear and do not specify whether all of the dentists were providing the same mix of dental services. Their cost estimates might differ considerably if periodontists or general practitioners proficient in periodontal surgery were included in the data sample.

A more glaring deficiency, which the authors have acknowledged by disclaimer, is the lack of any estimates of patient opportunity costs, both in the dental office visits and in home oral hygiene. Generally speaking, patient opportunity costs would capture the value of resources consumed by the patient in addition to dental office charges. These costs would include transportation costs to visit the dentist, time spent in home oral hygiene, etc. They would also include dentist opportunity costs, e.g., the cost of training personnel to carry out the Keyes regimen.

SUMMARY

Researchers can point to mounting evidence that dentistry is gaining the scientific knowledge that will provide the public some measures for the prevention and management of periodontal disease. Dentistry has repeatedly demonstrated its willingness to support major public health efforts. Dental researchers and practitioners have actively participated in the development of the scientific base, clinical applications, and promotion of measures to control dental caries through the use of fluoride and, more recently, sealants. Now the dental research community is seeking to conquer caries totally by developing a caries vaccine. Research towards this goal is being carried out at a number of research centers, supported cooperatively by universities and the National Institutes of Health.

While our scientific knowledge base for periodontal disease may lag behind that for caries, significant advances have been made in the last decade and a half by a diverse and dedicated group of scientists and concerned clinicians.

We understand and sympathize with the goal of Dr. Keyes and coworkers as well as Drs. Scheffler and Rovin to provide better, simpler and less expensive therapy to all periodontal patients, because this is a goal shared by all individuals in periodontal research. However, the standard for acceptance of therapy cannot

become enthusiastic advocacy, popular appeal, and press releases, but must be carefully controlled clinical and laboratory testing. Acceptance of the former as standards would be as a sharp step backward for the dental profession and for the public.

REFERENCES

1. Hirschfeld, L., and Wasserman, D., "A Long-Term Survey of Tooth Loss in 600 Treated Periodontal Patients," J. Periodont. 49:225, 1978.
2. Keyes, P. H., et al., "The Use of Phase-Contrast Microscopy and Chemotherapy in the Diagnosis and Treatment of Periodontal Lesions—An Initial Report (I)," Quintessence Internat. 1:51, 1978.
3. Knowles, J. W., et al., "Results of Periodontal Treatment Related to Pocket Depth and Attachment Level: Eight Years," J. Periodont. **50:225,** 1979.
4. Lindhe, J., and Nyman, S., "The Effect of Plaque Control and Surgical Pocket Elimination on the Establishment and Maintenance of Periodontal Health: A Longitudinal Study of Periodontal Therapy in Cases of Advanced Periodontitis," J. *Clin, Periodont. 2:67, 1975.*
5. Listgarten, M. A., and Hellden, L., "Relative Distribution of Bacteria at Clinically Healthy and Periodontally Diseased Sites in Humans," J. Clin. *Periodont. 5:115, 1978,*
6. Nyman, S., and Lindhe, J., "A Longitudinal Study of Combined Periodontal and Prosthetic Treatment of Patients With Advanced Periodontal Disease," J. *Periodont, 50:163, 1979.*
7. Ramfjord, S. P., et al., "Longitudinal Study of Periodontal Therapy," J. *Periodont. 44:66, 1973.*
8. Slots, J., "Subgingival Microflora and Periodontal Disease," J, *Clin. Periodont. 6:351, 1979.*
9. Socransky, S. S., "Microbiology of Periodontal Disease—Present Status and Future Considerations," J. *Periodont, 48:497, 1977.*
10. Syed, S. A., and Loesche, W. J., "Bacteriology of Human Experimental Gingivitis: Effect of Plaque Age," *Infect. and Immun. 21:821, 1978.*
11. Thompson, M., *Benefit-Cost Analysis* for *Program Evaluation* (Beverly Hills, Calif.: Sage Press, 1980).
12. Waerhaug, J., "Healing of the Dento-Epithelial Junction Following Subgingival Plaque Control, II: As Observed on Extracted Teeth," J. *Periodent. 49:119, 1978.*
13. Warner, K., and Luce, B., *Cost-Benefit and Cost-Effectiveness Analysis in Health Care: Principles, Practice and Potential* (Ann Arbor, Mich.: Health Administration Press, in press, *1981).*

AUTHORS' RESPONSE TO COMMENTARY

In his commentary, Dr. Formicola includes among the criteria for evaluating a scientific clinical investigation the use of adequate control groups, and he further states that studies without such controls must be considered "anecdotal. " A control group in a clinical study is generally defined as a group of patients which is comparable to the treatment group but which does not receive the therapy that is to be studied. However, the clinical studies of periodontal therapy that Dr. Formicola cites do not use control groups; instead, they report the impact of the application of one therapeutic modality or another. Thus, according to Dr. Formicola's commentary, these studies should be labeled "anecdotal. "

Actually, the lack of control groups is a fundamental problem found in most of the literature on periodontal disease. Specifically, there have been few controlled clinical studies in which a treatment group received periodontal procedures and a control group received no therapy at all. The one major study that did use a control group (4) dealt with the use of oral hygiene procedures only; it did not include surgical procedures. That investigation was cited in our case study, but not in Dr. Formicola's commentary.

There are no scientific studies which show that the surgical approach to treating periodontal disease is any better than the conservative approach used by clinicians for many years. Actually, a major recommendation in our case study is that such controlled clinical studies be carried out: "Our assessment of the literature on the effectiveness of periodontal surgery suggests that further long-term clinical studies are needed. Such studies would be quite useful if they were designed to compare the Keyes technique to periodontal surgery and included a control group which did not receive either treatment ."

In his commentary, Dr. Formicola spoke at great length about the Hirschfeld and Wasserman study (1) and suggested that it was an example of research with scientific merit. However, it should be noted that in this study, patient samples were not randomized nor selected on any statistical basis; there were no control groups; and the same dentists who performed the treatment also evaluated it. The Hirschfeld and Wasserman study was a retrospective analysis of treatment and was not predicated on a predetermined treatment modality. Moreover, there was no rating reliability between the evaluators. In fact, some of the patients were treated by different dentists at different points in time. Finally, no statistical tests were used to analyze the data.

However, even if we ignore these limitations, the evidence in the Hirschfeld and Wasserman study (1) points more to the retention of teeth without periodontal surgery than it does to retention with surgery. Of the ***600*** patients in the study, only 230 (39.3 percent) had periodontal surgery in the first place. According to Hirschfeld and Wasserman, most of the patients responded just as well without surgery as with it: ". . . in the great majority of cases surveyed, simple but thorough treatment in the form of subgingival scaling, occlusal adjustment, and fair to good home care seemed to reduce tooth loss." The investigators concluded: "The mortality of teeth which were treated with periodontal surgery was compared with that of teeth which did not have surgery. Tooth retention seemed more closely related to the case type than the surgery performed. "

Although Dr. Formicola implies otherwise, the Hirschfeld and Wasserman study cannot be considered anything other than what he terms "anecdotal, " for the reasons we have cited. Hirschfeld and Wasserman appropriately entitle their study a survey, "A Long-Term Survey of Tooth Loss in ***600*** Treated Periodontal Patients. " This label is not to denigrate their effort because the effort did provide useful and important information.

Many of the other clinical studies cited by Dr. Formicola are deficient because dentists who performed the surgical therapy also evaluated the results; independent evaluations were usually absent. The Ramfjord group of studies (3) had some standardization in that the same evaluators were used throughout, but even in these studies, it is not clear in some cases whether the

dentists who performed the evaluation did not also perform the surgery. An even more serious deficiency is the absence of a control group.

Thus, none of the clinical studies which were cited by Dr. Formicola conforms to his own criteria for scientific merit. Unfortunately, the clinical studies which occupy the bulk of the periodontal literature lack scientific rigor. But these are the studies on which periodontal therapy is predicated. To repeat, the need for randomized controlled clinical studies of alternative treatments for periodontal disease is essential, so that effective periodontal treatments can be identified.

We find it disappointing that Dr. Formicola believes that cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) are "essentially accounting procedures, " despite the effort that OTA has made in explaining these concepts. According to OTA: "The terms CEA and CBA refer to formal analytical techniques for comparing the positive and negative consequences of alternative ways to allocate resources" (2), OTA found no consensus among analysts and practitioners as to a standard set of methods for CEA/CBA (2). Accounting procedures have little, if anything, to do with the analytical technique of CEA or CBA.

We conducted a CEA of the Keyes technique, but because there was no existing CEA of periodontal surgery, we could not compare the Keyes technique to the surgical alternative. We did find national data which show that surgery is much more expensive than the Keyes technique. Surgery on a single quadrant of the mouth costs the patient an average of at least $250, whereas six visits for the Keyes program cost about $150. Thus, even without including the cost of followup treatments after surgery, the cost to the patient is considerably higher when surgery is performed than when the Keyes technique is used. As Dr. Formicola points out, the costs of the Keyes technique would be different if periodontists performed it instead of general practice dentists. However, we see no reason to use the higher wages of periodontists in our calculations if general practice dentists can deliver the Keyes technique.

As we noted in our case study, owing to data limitations, our cost estimates did not include the opportunity costs of the patients' time. However, if we had been able to include opportunity costs in our calculations for both the Keyes technique and for the surgical alternative, the Keyes technique would appear to be even more cost effective. Surgery and its followup treatment require travel time to the dentist's office as well as home oral hygiene. The pain and suffering due to surgery also have an economic value, because patients are willing to take measures to avoid it. Finally, Dr. Formicola is incorrect in suggesting that the opportunity costs of the dentist time used for "training personnel to carry out the Keyes regimen" is omitted from our calculations. These costs, which are small in magnitude because the Keyes technique is quite simple, have already been included in the fees charged by the dentist.

Again, as we stated repeatedly in our paper, *the most important aspect of controlling periodontal disease is what the patient does for him or herself;* it is not what the dentist does to or for the patient. Even the best dental therapy will fail if the patient does not practice good oral hygiene. Unfortunately, as can be judged by the amount of periodontal disease that exists, many people on their own do a less than adequate job of oral hygiene. One alternative is to have the dentist or hygienist keep the patient's teeth free or relatively free of plaque by giving professional prophylaxes every 1 to 3 months. Since the cost of doing this for the adult population is prohibitive, alternative methods need to be developed.

We do not know at this time whether the Keyes program will prove to be an effective long-run method for controlling bacterially related periodontal disease. Our data, abstracted from dental records from 18 dental practices on 190 patients with over 800 visits for the Keyes technique, show a measurable and statistically significant improvement in five indicators of oral health, which is suggestive evidence that the Keyes program is of value to patients in the short term. We feel confident that the Keyes program shows enough promise to

warrant a long-term comprehensive investigation. If the Keyes program should prove effective in the long run, it could reduce the cost of controlling periodontal disease and perhaps allow the treatment of many more patients with periodontal disease, as well as reduce the amount of periodontal surgery and its costs.

REFERENCES

1. Hirschfeld, L., and Wasserman, D., "A Long-Term Survey of Tooth Loss in *600* Treated Periodontal Patients," *J. Periodont.* **49:225**, 1978.
2. Office of Technology Assessment, U.S. Congress, *The Implications of Cost-Effectiveness Analysis of Medical Technology,* GPO stock No. 052-003-00765-7 (Washington, D. C.: U.S. Government Printing Office, August 1980).
3. Ramfjord, S. P., et al., "Longitudinal Study of Periodontal Therapy," *J. Periodont.* **44:66**, *1973.*
4. Suomi, J. D., et al., "The Effect of Controlled Oral Hygiene Procedures on the Progression of Periodontal Disease in Adults: Results After Third and Final Year," *J. Periodont.* **42:152**, *1971.*

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