

## AUTHORS' RESPONSE TO COMMENTARY

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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 follow-up 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.