Tetracycline Fibers Plus Scaling and Root Planing Versus Scaling and Root Planing Alone: Similar Results After 5 Years

Thomas G. Wilson, Jr., Michael K. McGuire,† Gary Greenstein,‡ and Martha Nunn§*

THIS PAPER PRESENTS 5-YEAR data pertaining to a subgroup of patients from a previous investigation who were treated with scaling and root planing plus tetracycline fibers. The parent study demonstrated that 6 months after therapy, scaling and root planing plus tetracycline fiber therapy was significantly better at reducing probing depth and gaining clinical attachment than scaling and root planing alone. However, the long-term data presented here show a regression from the original gains in clinical attachment levels in the fiber group. Ultimately, the use of fibers provided no significant advantage with regards to probing depth reduction or clinical attachment gain. Within the power of this study, which would have required 1.78 mm of change in clinical attachment to show a difference, there was no significant difference between the treatments at 5 years. This study underscores the need for additional long-term evaluation of this mode of therapy. *J Periodontol 1997;68:1029–1032.*

Key Words: Follow-up studies; planing; scaling; tooth root; tetracycline/therapeutic use; periodontal attachment.

Tetracycline impregnated fiber‖ is a controlled release local delivery device which has recently become commercially available. This device allows controlled release of tetracycline into the periodontal pocket to prolong drug activity. The elastic fiber consists of ethylene vinyl acetate polymer and is impregnated with tetracycline hydrochloride. The fiber is placed into a periodontal pocket where it slowly releases tetracycline. This product has been tested in a number of controlled clinical trials ranging in length from 42 days to 12 months.[1–9] In 1985 Goodson et al. compared the effect of fiber placement and root planing on several putative periodontal pathogens and reported no statistically significant difference between treatment methods.[9] Subsequently, others compared the effects of tetracycline fibers and root planing versus root planing alone and measured several clinical parameters including probing depths and clinical attachment levels.[4–6] In this regard, Heijl and coworkers found no significant difference between treatment methods.[4] Similarly, Drisko et al. found statistical but no clinically significant differences 1 year after therapy when scaling and root planing alone was compared to scaling and root planing plus fiber placement.[6] On the other hand, Newman and coworkers, 6 months after therapy, reported a significant advantage when patients underwent scaling and root planing plus fiber therapy.[5] To date, the longest published follow-up of patients in controlled studies treated with impregnated fibers has been 1 year. The purpose of this paper is to report 5-year results from a subgroup of patients from the study by Newman et al.[5]

MATERIALS AND METHODS

Original Group

The protocol for the original study was previously published.[5] Clinical methods for the study may be summarized as follows: 113 patients from 7 private periodontal practices throughout the United States were treated either with tetracycline fibers plus root planing or root planing alone. To qualify for the study, patients had to have 2 non-adjacent sites in separate quadrants that required periodontal treatment. These patients were in supportive peri-

*Private practice, Dallas, TX.
†Private practice, Houston, TX.
‡Private practice, Freehold, NJ.
§Department of Biostatistics and Dental Public Health Sciences, University of Washington, Seattle, WA.
‖Actisite, Procter & Gamble, Cincinnati, OH.

odontal treatment (SPT) and had probing depths of 5 to 8 mm at baseline when measured with an automated periodontal probe.[¶] They also must have bled upon probing at the previous SPT visit and at the baseline SPT visit upon plaque sampling. Patients were excluded from the study based on medical criteria or for any of the following reasons: 1) systemic antibiotics were used for 7 days or longer in the previous 3 months; 2) manifested clinical signs of candidiasis; 3) used a 0.12% chlorhexidine mouth rinse routinely; 4) periodontal surgery in the previous 4 months; 5) restorative dental work performed on either of the study teeth in the previous 4 months; or 6) a tooth was extracted adjacent to either of the study teeth in the previous 4 months.

The original clinical examinations were performed 5 years ago by blinded, calibrated operators other than the therapists. Two of the authors of this paper (TGW and MKM) were the original therapists for their subgroups and performed the closed subgingival scaling and root planing and fiber placement. Original test sites were randomly selected and, where possible, control sites were selected based on similar probing depths and tooth types. The following clinical parameters were sequentially measured: gingival recession; probing depths using a chairside computer-interfaced controlled force (20g) periodontal probe and measured to the nearest 0.2 mm; and bleeding on probing. Clinical attachment levels were then calculated. Probing depth, bleeding upon probing, and clinical attachment levels were measured at baseline and at 1, 3, and 6 months.

Subgroup

A subgroup consisting of a total of 26 patients from the original 113 patients was followed for 5 years. These patients came from 2 of the original 7 centers that had an interest in further evaluation of the study patients. Each patient had one site treated with scaling and root planing alone and another treated with scaling and root planing plus a tetracycline fiber. Five years after the original study, patients were re-evaluated using the same clinical measurements gathered in the original investigation.

Statistical Analysis

The response of each patient to scaling and root planing in the control sites was compared to the response of scaling and root planing plus fiber placement (test sites) in the same patient. In other words, all treatment comparisons were performed as within-subject comparisons, so the individual served as his/her own control.

The results after 6 months and 5 years with regards to probing depth reduction and clinical attachment gain for test and control sites were compared on analysis of covariance with baseline scores as the covariant. The statistical model included terms for study center, subject within center, baseline score, treatment, and the treatment-by-center interaction. The treatment-by-center interaction term provided a test for heterogeneity of treatment effects across centers. If this term was not significant, it was assumed that results were consistent across centers, and the interaction term was pooled into the error term.

[¶]The Florida Probe, Florida Probe Corporation, Gainesville, FL.

Table 1. Baseline Values for All Sites in the Subgroup (n = 26)

Parameter	Scaling and Root Planing	Scaling and Root Planing + Fiber
Probing depth (mm)	6.45 (SD = 0.70) (range 5.4 to 8.6)	6.32 (SD = 0.80) (range 4.6 to 8.2)
Recession (mm)	1.15 (SD = 1.85) (range −3.0 to 6.0)	1.42 (SD = 1.53) (range −2.0 to 4.0)
Attachment level (mm)	7.80 (SD = 2.01) (range 4.2 to 13.0)	7.75 (SD = 1.97) (range 4.2 to 11.0)

RESULTS

Thirty of the original 36 patients from the two offices involved in the original study were available for re-evaluation. Four patients moved out of state and could not be contacted, and 2 of the patients died. Four of the 30 patients presenting for the 5-year re-evaluation had lost study or control teeth and were exited from the data used to compile results. Since the original data collection, this group had lost a total of 6 study teeth as a result of advancing periodontal disease. Four of the lost teeth were treated with fiber plus scaling and root planing and 2 had received scaling and root planing alone.

Table 1 demonstrates that at baseline, sites in each treatment group were similar in terms of probing depths, recession, and clinical attachment levels. Clinical changes following treatment are shown in Table 2 and Figures 1, 2, and 3. Within-patient comparisons of the 2 treatment methods demonstrated that probing depth reduction was significantly greater at 6 months (1.53 mm vs. 0.87 mm; P value = 0.002) for fiber-treated sites, but there was no significant difference in probing depth reduction between the 2 groups at 5 years (P value = 0.397). With regards to change in recession, there was no significant difference between the 2 groups at 6 months, but there was a marginally significant difference between the groups at 5 years (P value = 0.05). The fiber-treated group showed greater recession at 5 years than the group treated with scaling and root planing only. At 6 months, the fiber-treated group had marginally greater gains in clinical attachment (1.18 mm vs. 0.59 mm) than the group with scaling and root planing (P value = 0.085), but there was no significant difference of clinical attachment gains 5 years after therapy (P value = 0.470). It was noted that treatment effect between offices did not differ significantly in any of the analyses. After 5 years, scaling and root planing resulted in a 1.2 mm gain of clinical attach-

Table 2. Overall Clinical Results

	Scaling and Root Planing	Scaling and Root Planing + Fiber	Difference Between Groups
Covariance-adjusted probing depth reduction from baseline			
6 months (n = 27, MSE = 0.48)	0.87 mm (SD = 0.193) (range −0.93 to 2.57)	1.53 mm (SD = 0.193) (range 0.23 to 3.83)	0.66 mm (P = 0.002)
5 years (n = 26, MSE = 2.08)	1.61 mm (SD = 0.409) (range −1.46 to 4.14)	1.96 mm (SD = 0.409) (range −0.74 to 4.86)	0.35 mm (P = 0.397)
Covariance-adjusted recession reduction from baseline			
6 months (n = 27, MSE = 0.77)	−0.23 mm (SD = 0.241) (range −2.38 to 0.71)	−0.40 mm (SD = 0.241) (range −1.74 to 0.54)	0.17 mm (P = 0.490)
5 years (n = 26, MSE = 1.45)	−0.58 mm (SD = 0.650) (range −5.10 to 1.40)	−1.23 mm (SD = 0.650) (range −4.90 to 1.60)	0.65 mm (P = 0.067)
Covariance-adjusted attachment gain from baseline			
6 months (n = 27, MSE = 1.48)	0.59 mm (SD = 0.331) (range −0.81 to 2.96)	1.18 mm (SD = 0.331) (range −0.15 to 3.44)	0.59 mm (P = 0.085)
5 years (n = 26, MSE = 4.54)	1.09 mm (SD = 0.593) (range −3.77 to 3.40)	0.66 mm (SD = 0.593) (range −7.25 to 5.23)	0.43 mm (P = 0.470)

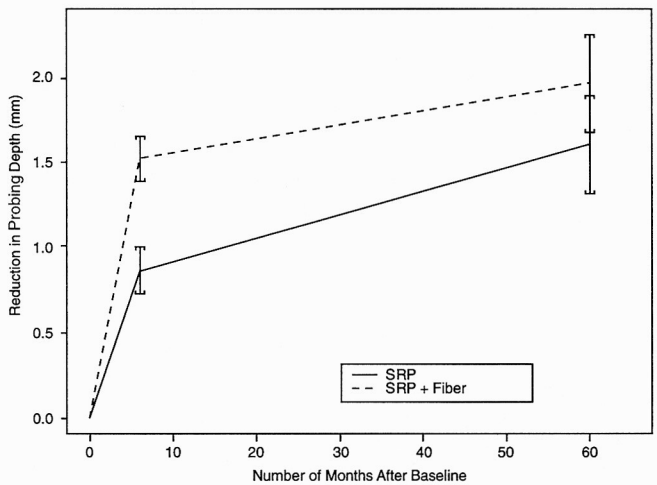

Figure 1. Average reductions in probing depth from baseline.

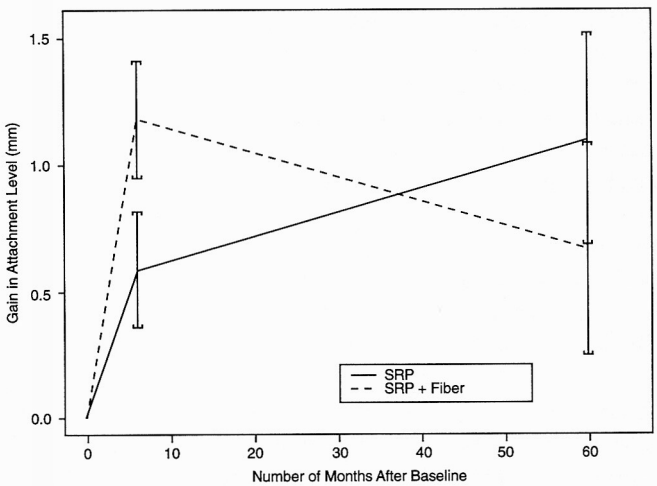

Figure 3. Average gain in clinical attachment from baseline.

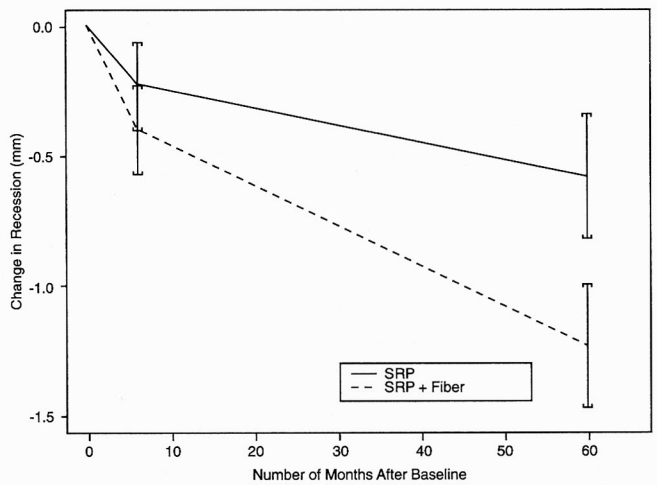

Figure 2. Average changes in recession from baseline.

ment, whereas combined therapy resulted in 0.6 mm gain of attachment (Table 2).

DISCUSSION

In a previous investigation, the efficacy of scaling and root planing plus tetracycline fiber therapy was compared to scaling and root planing alone in a group of maintenance patients who did not respond to periodic supportive periodontal therapy.[5] The 26 patients in the current study each had a tooth that was originally treated with scaling and root planing alone and a matched tooth in another area of the mouth that was treated with scaling and root planing plus fiber therapy. The subset of the 26 patients included in the present study had similar findings at 6 months as the entire set of 113 patients from the original study. This indicates that this is a representative sample of the original group studied. In the subset of 26 patients followed in this study, there was no statistical difference

between the two forms of therapy when probing depths and clinical attachment levels were measured. When the efficacy of scaling and root planing was compared to scaling and root planing plus fiber therapy (combined therapy), it was clear that the initial advantages associated with combined therapy were temporary in nature.

After 5 years, both groups continued to demonstrate increased probing depth reduction (see Table 2). The scaling and root planing group continued to gain clinical attachment (0.59 mm to 1.09 mm). In contrast, the gain of clinical attachment associated with combined therapy regressed and some clinical attachment initially gained was lost (1.18 mm to 0.66 mm).

Among the teeth that received combined therapy, around two-thirds of the pocket reduction can be accounted for by recession and one-third by gain of clinical attachment. In contrast, among the teeth that received scaling and root planing only, around one-third of the pocket reduction can be attributed to recession and two-thirds to gain of clinical attachment.

Retrospective assessment of the data does not provide an explanation as to why there is a greater loss of clinical attachment among teeth receiving combined therapy, since both the fiber-treated tooth and the control tooth in each patient's mouth underwent root planing. Similarly, there is no clear explanation as to why those areas that received the scaling and root planing alone continued to gain clinical attachment during the 5-year study.

One possible explanation for these discrepancies could be measurement error. However, examiners were blinded, clinically calibrated, and employed pressure-sensitive probes. A second possible explanation could be that the differences between the fiber-treated tooth and the control tooth per patient were quite large, and since the sample size was small, the data were somewhat skewed. Assessment of the ranges indicated that the changes with regards to probing depths and recession were similar (Table 2). However, the range of clinical attachment loss among fiber-treated teeth was much larger than among teeth receiving scaling and root planing alone (Table 2). A large loss of clinical attachment among fiber-treated teeth in a few patients may provide an explanation as to why teeth that were treated with scaling and root planing alone appeared to do better than the fiber-treated teeth during the 5-year monitoring period. Another reason for these discrepancies could be the difference in compliance with professional suggestions concerning personal oral hygiene and supportive periodontal therapy (SPT). However, no differences in oral hygiene efficacy, as measured by bleeding upon probing or compliance to suggested SPT, could be found between the test and control groups. Compliance to SPT, as measured by attendance, was high for both responders and non-responders (average percent compliance was 86.9% with a range of 54% to 100%).

During the 5 years covered by the study, 8 of the patients received treatment in addition to supportive periodontal therapy. Seven patients had closed subgingival scaling and root planing with local anesthesia, and 1 received bone grafts. All procedures involved both study and control teeth and were performed by the authors. When the subset of 18 patients who did not receive additional therapy was analyzed, there were still no statistical differences between the two forms of therapy when probing depths and clinical attachment levels were measured.

On the basis of the present clinical findings, further long-term study should be conducted to determine whether tetracycline fiber therapy is beneficial to actual tooth survival and which patients are most likely to benefit from this therapy. The lack of any significant results in the present study makes one question the usefulness of tetracycline fiber therapy in long-term therapy of periodontal diseases.

REFERENCES

1. Goodson J, Cugini M, Kent R, et al. Multi-center evaluation of tetracycline fiber therapy. I. Experimental design. *J Periodont Res* 1991; 26:361–370.
2. Goodson J, Cugini M, Kent R, et al. Multi-center evaluation of tetracycline fiber therapy. II. Clinical response. *J Periodont Res* 1991; 26:371–379.
3. Goodson J, Tanner A, McArdle S, Dix K, Watanabe S. Multi-center evaluation of tetracycline fiber therapy: III. Microbiological response. *J Periodont Res* 1991;26:440–451.
4. Heijl L, Dahlen G, Sundin Y, Wenander A, Goodson J. A 4 quadrant comparative study of periodontal treatment using tetracycline containing drug delivery fibers and scaling. *J Clin Periodontol* 1991;18: 111–116.
5. Newman M, Kornman K, Doherty F. A 6-month multi-center evaluation of adjunctive tetracycline fiber therapy used in conjunction with scaling and root planing in maintenance patients: Clinical results. *J Periodontol* 1994;65:685–691.
6. Drisko C, Cobb C, Killoy W, et al. Evaluation of periodontal treatments using controlled release tetracycline fibers: Clinical response. *J Periodontol* 1995;66:692–699.
7. Michalowicz B, Pihlstrom B, Drisko C, et al. Evaluation of periodontal treatment using controlled-release tetracycline fibers: Maintenance response. *J Periodontol* 1995;66:708–715.
8. Lowenguth R, Chin I, Caton J, et al. Evaluation of periodontal treatments using controlled-release tetracycline fibers: Microbiological response. *J Periodontol* 1995;66:700–707.
9. Goodson J, Offenbacher S, Farr D, Hogan P. Periodontal disease treatment by local drug delivery. *J Periodontol* 1985;56:265–272.

Send reprint requests to: Dr. Thomas G. Wilson, Jr., 8350 North Central Expressway, Suite M-2112, Dallas, TX 75206. Fax: 214/691-2228; e-mail: perio@onramp.net

Accepted for publication March 24, 1997.