

# Using Research for Clinical Decision-Making: Elements of a Research Report

*This course is no longer offered for Continuing Education credit.*

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**Intended Audience:** Dentists, Dental Hygienists, Dental Assistants, Dental Students, Dental Hygiene Students, Dental Assistant Students

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**Disclaimer:** Participants must always be aware of the hazards of using limited knowledge in integrating new techniques or procedures into their practice. Only sound evidence-based dentistry should be used in patient therapy.

## **Introduction**

This course describes the parts of a research report and the information that should be contained within each section. This will guide practitioners in their review of research articles so that they can identify the specific research questions/hypotheses being explored and what was discovered about them. These skills will help oral health professionals decide whether or not to incorporate these research findings into their patient therapy and practice procedures.

## **Conflict of Interest Disclosure Statement**

- Dr. Ann McCann has done consulting work for P&G.
- Dr. Emet Schneiderman reports no conflicts of interest associated with this course.

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## Overview

Decisions made by oral health professionals concerning patient therapy or oral health products should be based on research findings. For example, is the basis for completing periodontal debridement (a) root smoothness or (b) absence of bleeding upon probing at a follow-up appointment? Research supports the latter criteria (b).<sup>1</sup> Should a practitioner recommend a particular dentifrice because the product advertisement claims that it contains an effective anticaries agent? Research studies must demonstrate the efficacy of the anticaries product before the practitioner decides to recommend it to patients. Research reports are the basis for evidence-based decision-making in clinical practice. This continuing education course will serve as the first of two articles on how to use published research for making decisions about patient care.

## Learning Objectives

**Upon completion of this course, the dental professional should be able to:**

- State the sources that should be used to access the dental literature, including MEDLINE/PubMed, online databases, and dental libraries.
- Identify the sections of the research report that most scientific journals use.
- Describe the characteristics of an Abstract in a well-written research article.
- Define the main components of the Introduction section of a research report.
- List the items commonly described in the Methods and Materials section in research reports.

- Explain how the researcher should present the interpretation of the results in the Discussion section.
- Explain how the Summary and Conclusions section should relate to the hypothesis/research question and findings of the study.

## Dental Literature

To find out what therapy or products are supported by research, the dental healthcare provider must rely on the dental literature. This represents the body of knowledge about dentistry and dental hygiene that is contained in journals, books, reports, and other written sources. Important research, properly conducted, will generally be found in the scientific literature. This is because reputable scientists and companies seek outside/independent review of their research and products and submit their research findings for publication in respected scientific journals. Keep in mind the process of conducting research and publishing the findings often takes several years.

Dental healthcare professionals should be familiar with the areas of the literature that relate to their practice and should review appropriate journals on a routine basis. Practitioners interested in reviewing a particular subject can search MEDLINE, which contains citations and summaries or abstracts of all biomedical journal articles since 1966.<sup>2</sup> The full text of these articles is also available for many biomedical and dental journals. Full-featured versions of MEDLINE are typically available at dental and medical libraries. PubMed, a free version of MEDLINE, is readily available to practitioners with Internet access.

Scopus is a useful search tool available at libraries. Another freely available resource is the Cochrane Reviews. These are systematic reviews of evidence-based patient care. The American Dental Association maintains an up-to-date online database specifically on evidence-based dental care. Finally, Google Scholar is also a powerful tool for researching the scientific literature.

## The Research Report

A research report is a technical article that communicates the results of original investigations.

The report should be concise, clear, and objective. Most journals require a format that includes the sections listed below. Each of these sections is hot-linked to the corresponding section of an actual published article.

- The Abstract
- The Introduction
- The Materials And Methods
- The Results
- The Discussion
- The Summary And Conclusions
- The References

### The Abstract

The **Abstract**, presented at the beginning of an article, should be a short summary (100 to 250 words) of the problem statement, methods used, results, and conclusions.<sup>3</sup> Some journal editors request that the abstract be “the paper in miniature,” completely self-contained. A recent trend is the “structured abstract” that has a heading and section for each of the above listed areas.

**Below is an example of the *Abstract* section:**

#### **The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>**

##### **Abstract**

The effects of stabilized 0.454% stannous fluoride dentifrices on supragingival plaque, gingival inflammation, and gingival bleeding were studied in 549 adult male and female subjects who completed a six-month, double blind clinical study. Following an oral prophylaxis, subjects were randomly assigned to brush with one of the following dentifrices: (1) 0.454% SnF<sub>2</sub> stabilized with 2.08% sodium gluconate, (2) 0.454% SnF<sub>2</sub> stabilized with 4.16% sodium gluconate, (3) an experimental dentifrice, or (4) 0.243% NaF control dentifrice. Follow-up examinations were conducted at 3 and 6 months. Compared to the control dentifrice

at 6 months, stannous fluoride dentifrices stabilized with 2.08% or 4.16% sodium gluconate significantly reduced gingivitis by 18.8% and 18.0%, respectively. There were no statistically significant differences between the two stabilized SnF<sub>2</sub> groups with respect to their beneficial effects on gingival health. Gingival bleeding was also reduced, relative to the control dentifrice, for both stabilized SnF<sub>2</sub> dentifrices. However, these differences were not statistically significant at p = 0.05. The stabilized SnF<sub>2</sub> dentifrices were not significantly different from the control dentifrice in their effects on supragingival plaque.

No significant differences in adverse oral soft tissue effects were observed between the test and control groups. As expected, accumulation of extrinsic tooth stain increased in the stabilized SnF<sub>2</sub> groups. However, the difficulty in removing accumulated dental stain was similar between the control and stabilized SnF<sub>2</sub> dentifrices. Since use of SnF<sub>2</sub> dentifrices has been reported to produce tooth stain, gingivitis examinations were done with and without custom-made tooth covers to evaluate the potential for examiner bias. Comparable gingivitis and gingival bleeding benefits were observed when the evaluations were conducted with or without the tooth covers.

Results from this study support that 0.454% stabilized stannous fluoride dentifrices can provide an important adjunct to the prevention and control of gingivitis when used in combination with regular personal oral hygiene procedures and professional care.<sup>3</sup>

### The Introduction

The **Introduction** section should define the purpose of the investigation and review the literature that is relevant to the study. The purpose should include the research question(s) that will be answered by the investigation or the hypothesis(es) that will be tested. An example of a research question is: “Does the use of prizes and rewards improve the behavior of children in the dental office?” A hypothesis

is a statement that predicts the relationship between two or more variables,<sup>5</sup> such as: “The use of an ultrasonic scaling instrument for calculus removal results in a greater reduction in periodontal pocket depth than hand scaling instruments.” In this case, the two variables are (1) type of scaling instrument and (2) pocket depth. The literature review should include the theoretical basis for the research, the current knowledge available on the research question and current gaps in knowledge.<sup>3</sup>

**Below is an example of the *Introduction* section:**

### **The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>**

#### **Introduction**

The anticaries effects of stannous fluoride have been known for over thirty years.<sup>1</sup> Due to its antimicrobial properties, stannous fluoride has also been examined for its effects on plaque and gingivitis; however, efficacy against these conditions has not been as clearly defined.<sup>2,3</sup> Over the past 20 years, the plaque and gingivitis effects of stannous fluoride have been studied in seven clinical trials involving six or more months of topical application.<sup>4-10</sup> This work covered a variety of oral care formulations, clinical populations, and methodologies. In several of the studies, significant reductions in gingivitis and gingival bleeding were reported following the extended use of stannous fluoride. In a study evaluating the effect of fluoride mouth rinses on caries, gingivitis, and salivary *S. mutans* levels in caries prone adults, Klock et al.<sup>4</sup> showed that after one year, subjects using a stannous fluoride rinse had about 50% fewer bleeding sites than subjects using a sodium fluoride rinse. This difference was statistically significant at  $p = 0.05$ . After two years, subjects in the stannous fluoride group continued to have less than half as many bleeding sites as those in the sodium fluoride group; however, the

difference was no longer statistically significant. The authors attributed the lack of statistical significance in the second year of the study to the loss of subjects from one to two years. Boyd et al.<sup>5</sup> demonstrated that subjects using a 0.4% stannous fluoride gel with “highly available Sn<sup>2+</sup>” ion, significantly reduced gingivitis and gingival bleeding following nine months of twice-daily application. Similar beneficial effects on gingival health were observed following the extended use of 0.4% stannous fluoride gels by Derkson et al.<sup>6</sup> who demonstrated a reduction in gingivitis on the periodontium of overdenture abutment teeth, and by Tinanoff et al.<sup>7</sup> who demonstrated reductions in gingivitis and gingival bleeding in subjects with fixed or removable dental prostheses. Zimmermann et al.<sup>8</sup> reported that following seven months of use, an amine fluoride/stannous fluoride mouth rinse significantly reduced gingivitis and gingival bleeding.

In contrast to the clinical trials demonstrating antigingivitis effectiveness, Leverett et al.<sup>9</sup> and Wolff et al.<sup>10</sup> reported the results of stannous fluoride studies, which failed to detect reductions in gingivitis. In the Leverett study, students rinsing daily (on school days only) with a 0.1% stannous fluoride solution had consistently lower gingivitis scores at all examination points than students rinsing with a 0.05% sodium fluoride solution; however, this difference was modest in magnitude (less than 10%) and was not statistically significant. Results from this study suggest that intermittent daily dosing of a 0.1% stannous fluoride solution may not be sufficiently frequent enough to observe a gingivitis effect. In Wolff et al., close inspection of the results suggest that failure of subjects to comply with the brushing instructions for the stannous fluoride gels may have contributed to the negative results for gingivitis. Examination of the percentage of subjects self-reporting compliance in this trial reveals that by the end of the study (18 months), 33% of the subjects in the stannous fluoride group reported not using the test product, or using it less frequently than once a day. In contrast, only about 20% of the

subjects in both the placebo and sodium fluoride groups reported this level of usage.

Further complicating the clinical situation is stannous fluoride's relative lack of stability in aqueous environments where hydrolysis and oxidation of the stannous ion is favored.<sup>2,3,11-13</sup> One approach which has proven successful in stabilizing stannous fluoride is the use of non-aqueous gel formulations. These products, which are available commercially, have been clinically shown to possess antigingivitis efficacy. However, a limitation of the stannous fluoride gels is that they do not provide the cleaning and aesthetic benefits associated with conventional dentifrices and, therefore, require the adjunctive use of such dentifrices.<sup>10</sup> This could potentially lead to poor compliance as patients' oral hygiene regimens become increasingly complicated as a result of their having to apply the stannous fluoride gel following brushing with a conventional dentifrice. It is reasonable to assume that in such a situation, the product, which will see a decline in use over time, would be the stannous fluoride gel. Therefore, it would be advantageous to develop conventional dentifrice products which stabilized stannous fluoride to the degree required to inhibit gingivitis.

This double-blind clinical study was designed to assess the clinical effects of products containing 0.454% stannous fluoride stabilized in conventional dentifrice formulations on gingivitis, gingival bleeding, plaque, stain, and microbiological parameters. The effects of the stabilized stannous fluoride dentifrices on the microbiological parameters are published separately.

### **The Materials and Methods**

The **Materials and Methods** section should provide a detailed description of the materials and procedures used to conduct the investigation in order to assure the possibility of replication for future studies.<sup>3</sup> The items described should include: subjects of the study (i.e., patients, extracted teeth, experimental animals); their characteristics (i.e., mean age, sex ratio, etc.); the method for obtaining the

sample; sample size; the procedures used to assign subjects to treatment groups; data collection instruments; the statistical tests used; and, in the case of human subjects, methods used to protect their rights. This generally includes obtaining permission to do the study from an appropriate institutional review board (IRB). A justification for the sample size, often based on a power analysis, may also be included.

**Below is an example of the *Materials and Methods* section:**

#### **The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>**

##### **Materials and Methods**

###### *Study Design*

Six-hundred and twenty healthy adult volunteers from the greater Indianapolis metropolitan area were accepted as subjects for this six-month, double-blind, placebo controlled, parallel group, single center clinical trial. To participate in the study, subjects had to have at least 16 natural teeth, including 4 molars, and five gingival bleeding sites at the initial examination. Subjects were excluded if they had rampant caries, advanced periodontal disease, chronic dental neglect which required prompt treatment or serious medical conditions as determined by the investigator. Subjects were also excluded if they had taken antibiotics within seven days of the start of the study. Pregnant women were not entered into the study.

After baseline examinations to determine initial levels of gingivitis, plaque accumulation, extrinsic dental stain, and oral soft tissue status, subjects were separated by gender and stratified with respect to their baseline gingivitis scores. Within strata, subjects were assigned to treatment groups by random permutations of four. Following the initial examinations, all subjects received

intraoral photographs and had an alginate impression of the mandibular and maxillary arches taken. The impressions were used to produce models for the construction of stain masking tooth covers. Following this procedure, all subjects received a thorough oral prophylaxis and a supply of their assigned test dentifrice. Each subject was provided with six 4.6 ounce plain white tubes containing one of the following dentifrices: (1) 0.243% sodium fluoride dentifrice (control), (2) 0.454% SnF<sub>2</sub> dentifrice stabilized with 1.5% SnCl<sub>2</sub> and 2.08% sodium gluconate (lowGluc stabilized stannous fluoride), (3) 0.454% SnF<sub>2</sub> stabilized with 1.5% SnCl and 4.16% sodium gluconate (highGluc stabilized stannous fluoride), and (4) experimental dentifrice. The dentifrices were packaged in uniquely labeled identical white tubes to ensure that neither the examiners nor subjects knew the identity of the dentifrices throughout the course of the trial.

Dentifrice use instructions were given to each subject verbally and in writing at the time of product distribution. These instructions were for the subject to use their assigned dentifrice according to their own individual habits. Subjects were also instructed to use only their assigned dentifrice and no other toothpastes or mouth rinses. Subjects did not receive a new toothbrush at the start of the study. Rather they were told to use their existing toothbrushes and to replace them from commercial sources as they normally would.

Subjects returned for examinations after three and six months of dentifrice use. At these examinations, gingival inflammation and gingival bleeding, plaque accumulation, extrinsic dental stain, and oral soft tissue status were recorded. Supragingival plaque was sampled at baseline and after three and six months. At the six-month examination, tooth covers, previously fabricated for each subject and covering the tooth to the cervical margin, were employed to evaluate the potential for examiner bias resulting from stannous fluoride staining. To construct the tooth covers, dark gray plastic sheets were

vacuumformed onto full-arch models and then carefully trimmed around the cervical areas of the teeth. This produced a “cover” which obscured the teeth from view, but still permitted access for conducting gingivitis examinations. In order to determine the effort expended by the dental hygienists to remove stain at the end of the study, questionnaires were completed by the hygienist at the conclusion of each subject’s prophylaxis. The data collected on the questionnaires included the time it took to scale and polish each subject as well as the severity and ease of removal of each subject’s accumulated stain. A complete schedule of study visits and corresponding clinical measurements is shown in Figure 1.

|           | 3 Months             | 3 Months         | Exit Study       |
|-----------|----------------------|------------------|------------------|
| Screening | Baseline Exam        | 3-Month Exam     | 6-Month Exam     |
|           | Plaque Sampling      | Plaque Sampling  | Plaque Sampling  |
|           | Oral Soft Tissue     | Oral Soft Tissue | Oral Soft Tissue |
|           | Stain                | Stain            | Stain            |
|           | Plaque               | Plaque           | Plaque           |
|           | Gingivitis           | Gingivitis       | Gingivitis       |
|           | Prophylaxis          |                  |                  |
|           | Product Distribution |                  |                  |

**Figure 1.** Schedule of Study Visits and Clinical Examinations

#### Conduct of Clinical Examinations

Oral examinations were conducted under dental clinic conditions employing good oral illumination, compressed air, mouth mirrors, and periodontal probes.

#### Oral Soft Tissue Health

To monitor oral soft tissue health, comprehensive visual-tactile examinations of the oral mucosa were conducted to detect pathoses that could possibly be related to dentifrice use. Structures examined included the gingival, hard and soft palate, oropharynx, buccal mucosa, tongue, floor of the mouth, labial mucosa, and lips.

### Gingivitis and Gingival Bleeding

Gingivitis was measured using the Gingival Index developed by Loe and Silness.<sup>14</sup> This index measured the qualitative changes in the gingival tissue adjacent to the mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and mesiolingual surfaces of all natural teeth, excluding third molars, for a total of 168 potential sites. After drying the teeth and gingival areas with a stream of air, a score was assigned to each site according to the following criteria:

|    |  |
|----|--|
| 0= | Normal gingiva (no inflammation)   |
| 1= | Mild inflammation evidenced by a slight change in color, slight edema, but no bleeding on probing              |
| 2= | Moderate inflammation evidenced by redness, edema, glazing and bleeding on probing                             |
| 3= | Severe inflammation evidenced by marked redness and edema. Ulceration with a tendency to spontaneous bleeding. |

For gingivitis, results are reported as the mean GI score for each surface averaged across all teeth evaluated. For bleeding, results are reported as the number of sites bleeding on probing or bleeding spontaneously (grades 2 or 3).

### Plaque

Plaque was measured using the P1I Index described by Silness and Loe.<sup>15</sup> After drying the teeth and gingival areas with a stream of air, undisclosed plaque was measured on the mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and mesiolingual surfaces of all teeth (except third molars) for a total of 168 potential sites (6 sites per tooth). A score was assigned to each surface according to the following criteria:

|    |  |
|----|--|
| 0= | No plaque in the cervical area   |
| 1= | A film of plaque adhering to the free gingival margin or the adjacent cervical area of the tooth. The plaque is not visible to the naked eye and is only recognized by running a probe across the surface. |
| 2= | Moderate accumulation of plaque on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye   |
| 3= | Abundance of plaque on the gingival margin and adjacent tooth surface, filling the gingival sulcus.  |

An average plaque score was obtained for each subject at each examination by summing the scores and dividing by the number of sites graded for that subject.

### Dental Stain

Extrinsic dental stain was scored on the facial and lingual surfaces of all natural teeth (excluding third molars) resulting in a total of 56 possible sites. The stain was graded by first assigning an intensity score (0-3 scale) for a surface and then estimating the area covered on that surface to the nearest five percent.<sup>16</sup> The intensity score was multiplied by the area covered for each site graded, summed for each subject, and divided by the number of sites graded for that subject.

### Statistical Analysis

Covariance analyses<sup>17</sup> were performed on the plaque, gingivitis, gingival bleeding, and dental stain scores using the baseline score as covariate. All statements of significance were based on alpha = 0.05, two-tailed test, and all percent reductions were calculated versus the sodium fluoride control. Significance testing among the four treatment groups was performed using Student-Newman-Keuls multiple comparison techniques as described by Snedecor.<sup>18</sup>

## The Results

The **Results** should present the findings of the study related to each research question or hypothesis without explanation.<sup>3</sup> A summary of the numerical findings or data should be presented in tables, while figures should provide a pictorial representation of the data in graphs, illustrations, photographs, and micrographs (photos of objects seen through a microscope). Table 1 often summarizes the baseline characteristics (descriptive statistics) of the sample. In a randomized controlled trial, such as the dentifrice example here, this table is important in demonstrating the equivalence of the experimental groups in their baseline characteristics. Data in subsequent tables usually address the main research hypotheses. The text describes the most important findings.

**Below is an example of the Results section:**

## The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>

### Results

Of the 620 subjects entered into the study, 542 were available for the three-month examination and 549 were available for the final six-month examination. These sample sizes represent the total for the four treatment groups studied. The presentation of results that follow excludes the scores for the experimental dentifrice group which had no bearing on the stannous fluoride comparisons. For the remaining groups, 463 subjects were included in the baseline examination, 412 subjects were included in the three-month examination, and 416 subjects were included in the final six-month examination.

The baseline demographics for those subjects who completed the three-and six-month examinations are given in Table 1. The means of the clinical baseline scores measured for these same subjects are given in Table 2. At both three and six months, there were no statistically significant differences among treatment groups with respect to baseline age, gender, plaque, stain, gingivitis, and gingival bleeding scores.

**Table 1. Initial Demographic Balance for Subjects Completing the Indicated Portion of**

|  | Treatment                 | N   | Sex  |        | Age (years) |       |
|--|---------------------------|-----|------|--------|-------------|-------|
|  |                           |     | Male | Female | Mean        | Range |
| Subjects   | Control                   | 153 | 45   | 108    | 32.34       | 18-64 |
| Starting   | lowGluc SSF <sup>a</sup>  | 157 | 50   | 107    | 33.22       | 18-68 |
| Study  | highGluc SSF <sup>b</sup> | 153 | 50   | 103    | 34.14       | 19-67 |
|  |                           |     |      |        |             |       |
| Subjects   | Control                   | 135 | 39   | 96     | 32.77       | 19-64 |
| Completing   | lowGluc SSF               | 141 | 47   | 94     | 33.79       | 18-68 |
| 3 Months   | highGluc SSF              | 136 | 48   | 88     | 34.51       | 19-67 |
|  |                           |     |      |        |             |       |
| Subjects   | Control                   | 136 | 41   | 95     | 32.62       | 19-64 |
| Completing   | lowGluc SSF               | 140 | 44   | 96     | 33.79       | 18-68 |
| 6 Months   | highGluc SSF              | 140 | 49   | 91     | 34.55       | 19-67 |
| <sup>a</sup> 0.454% stannous fluoride stabilized with 2.08% sodium gluconate<br><sup>b</sup> 0.454% stannous fluoride stabilized with 4.16% sodium gluconate |                           |     |      |        |             |       |



**Table 2. Initial Balance for Gingivitis, Gingival Bleeding, Plaque, and Stain for Subjects Completing the Indicated Portion of the Study**

|            | Treatment                 | N   | Gingival Index Score |       | Gingival Bleeding Sites |       |
|------------|---------------------------|-----|----------------------|-------|-------------------------|-------|
|            |                           |     | Mean                 | SEM*  | Mean                    | SEM   |
| Subjects   | Control                   | 153 | 0.6968               | 0.018 | 18.67                   | 1.138 |
| Starting   | lowGluc SSF <sup>b</sup>  | 157 | 0.6742               | 0.018 | 17.64                   | 1.181 |
| Study      | highGluc SSF <sup>c</sup> | 153 | 0.6953               | 0.020 | 18.23                   | 1.311 |
|            |                           |     |                      |       |                         |       |
| Subjects   | Control                   | 135 | 0.6938               | 0.019 | 18.43                   | 1.166 |
| Completing | lowGluc SSF               | 141 | 0.6846               | 0.019 | 18.35                   | 1.290 |
| 3 Months   | highGluc SSF              | 136 | 0.6961               | 0.021 | 18.07                   | 1.393 |
|            |                           |     |                      |       |                         |       |
| Subjects   | Control                   | 136 | 0.7125               | 0.019 | 19.58                   | 1.252 |
| Completing | lowGluc SSF               | 140 | 0.6758               | 0.019 | 17.84                   | 1.282 |
| 6 Months   | highGluc SSF              | 140 | 0.6941               | 0.020 | 17.87                   | 1.320 |
|            |                           |     | Plaque Index         |       | Stain Index             |       |
|            | Treatment                 | N   | Mean                 | SEM*  | Mean                    | SEM   |
| Subjects   | Control                   | 153 | 0.9534               | 0.031 | 2.82                    | 0.317 |
| Starting   | lowGluc SSF <sup>b</sup>  | 157 | 1.0268               | 0.031 | 3.41                    | 0.356 |
| Study      | highGluc SSF <sup>c</sup> | 153 | 0.9711               | 0.037 | 3.25                    | 0.374 |
|            |                           |     |                      |       |                         |       |
| Subjects   | Control                   | 135 | 0.9305               | 0.032 | 2.63                    | 0.292 |
| Completing | lowGluc SSF               | 141 | 1.0270               | 0.033 | 3.36                    | 0.373 |
| 3 Months   | highGluc SSF              | 136 | 0.9643               | 0.040 | 3.18                    | 0.409 |
|            |                           |     |                      |       |                         |       |
| Subjects   | Control                   | 136 | 0.9542               | 0.033 | 2.90                    | 0.324 |
| Completing | lowGluc SSF               | 140 | 1.0300               | 0.034 | 3.47                    | 0.376 |
| 6 Months   | highGluc SSF              | 140 | 0.9620               | 0.039 | 3.11                    | 0.387 |

\* SEM is the standard error of the mean  
<sup>b</sup> 0.454% stannous fluoride stabilized with 2.08% sodium gluconate  
<sup>c</sup> 0.454% stannous fluoride stabilized with 4.16% sodium gluconate

The three-and six-month covariance-adjusted mean gingivitis scores and corresponding percent reductions between control and treatment groups are given in Table 3. Relative to the control group, statistically significant reductions in gingivitis of 14.6% and 16.7% were observed at three months for the lowGluc and highGluc stabilized

stannous fluoride dentifrices, respectively. At six months, relative to the control group, statistically significant reductions in gingivitis of 18.8% and 18.0% were seen for the lowGluc and highGluc stabilized stannous fluoride dentifrices, respectively. No significant differences in gingivitis effects were observed between the two stannous fluoride dentifrices.

**Table 3. Covariance-Adjusted Three and Six Month Gingivitis Results**

| Exam Time  | Treatment    | N   | Mean Gingival Index Scores | Percent Reduction |
|--|--------------|-----|----------------------------|-------------------|
| 3 Months*  | Control      | 135 | 0.4809                     | —                 |
|  | lowGluc SSF  | 141 | 0.4108                     | 14.6              |
|  | highGluc SSF | 136 | 0.4005                     | 16.7              |
| Covariance Adjusted Error Mean Square = 0.0271. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test.<br>*No tooth covers employed at this examination.    |              |     |                            |                   |
| Exam Time  | Treatment    | N   | Mean Gingival Index Scores | Percent Reduction |
| 6 Months**   | Control      | 136 | 0.4523                     | —                 |
|  | lowGluc SSF  | 140 | 0.3672                     | 18.8              |
|  | highGluc SSF | 140 | 0.3707                     | 18.0              |
| Covariance Adjusted Error Mean Square = 0.0359. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test.<br>**Tooth covers were employed at this examination. |              |     |                            |                   |

The three-and six-month covariance-adjusted mean gingival bleeding scores and corresponding percent differences between control and treatment groups are given in Table 4. After three months of use, the lowGluc and highGluc stabilized stannous fluoride dentifrices reduced gingival bleeding, relative to the control group, by 27.9% and 20.2%, respectively. Following six months of use, the lowGluc and highGluc stabilized stannous fluoride dentifrices reduced gingival bleeding, relative to the control group, by 30.5% and 23.1%, respectively. However, these differences were not statistically significant at alpha = 0.05.

**Table 4. Covariance-Adjusted Three and Six Month Gingival Bleeding Results**

| Exam Time  | Treatment    | N   | Mean Gingival Bleeding Scores | Percent Reduction |
|--|--------------|-----|-------------------------------|-------------------|
| 3 Months   | Control      | 135 | 6.59                          | —                 |
|  | lowGluc SSF  | 141 | 4.75                          | 27.9              |
|  | highGluc SSF | 136 | 5.26                          | 20.2              |
| Covariance Adjusted Error Mean Square = 36.3277. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                               |                   |
| Exam Time  | Treatment    | N   | Mean Gingival Index Scores    | Percent Reduction |
| 6 Months   | Control      | 136 | 6.06                          | —                 |
|  | lowGluc SSF  | 140 | 4.21                          | 30.5              |
|  | highGluc SSF | 140 | 4.66                          | 23.1              |
| Covariance Adjusted Error Mean Square = 45.3027. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                               |                   |

Three- and six-month covariance-adjusted plaque scores are given in Table 5. At both three and six months, non-significant reductions in plaque scores, relative to the control group, were observed for both the lowGluc and highGluc stabilized stannous fluoride dentifrices.

**Table 5. Covariance-Adjusted Three and Six Month Plaque Index Results**

| Exam Time   | Treatment    | N   | Mean Plaque Scores | Percent Reduction |
|---|--------------|-----|--------------------|-------------------|
| 3 Months  | Control      | 135 | 0.8245             | —                 |
|   | lowGluc SSF  | 141 | 0.7712             | 6.5               |
|   | highGluc SSF | 136 | 0.7610             | 7.7               |
| Covariance Adjusted Error Mean Square = 0.0998. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                    |                   |
| Exam Time   | Treatment    | N   | Mean Plaque Scores | Percent Reduction |
| 6 Months  | Control      | 136 | 0.7339             | —                 |
|   | lowGluc SSF  | 140 | 0.7148             | 2.6               |
|   | highGluc SSF | 140 | 0.7223             | 1.6               |
| Covariance Adjusted Error Mean Square = 0.0799. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                    |                   |

Three- and six-month covariance-adjusted stain scores are presented in Table 6. Clinically measured stain was significantly increased for the stannous fluoride groups at both the three- and six-month examinations.

**Table 6. Covariance-Adjusted Three and Six Month Stain Index Results**

| Exam Time  | Treatment    | N   | Mean Stain Scores |
|--|--------------|-----|-------------------|
| 3 Months   | Control      | 135 | 2.30              |
|  | lowGluc SSF  | 141 | 3.94              |
|  | highGluc SSF | 136 | 4.28              |
| Covariance Adjusted Error Mean Square = 15.5491. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                   |
| Exam Time  | Treatment    | N   | Mean Stain Scores |
| 6 Months   | Control      | 136 | 2.58              |
|  | lowGluc SSF  | 140 | 4.70              |
|  | highGluc SSF | 140 | 4.95              |
| Covariance Adjusted Error Mean Square = 20.9946. Means within brackets are not significantly different at alpha = 0.05 using the 2-tailed Student-Newman-Keuls test. |              |     |                   |

There were no significant differences with respect to clinical stain between the two stannous fluoride groups. The six-month hygienist stain assessment, ease of stain removal, and total post-study prophylaxis times are shown in Tables 7a, 7b, and 7c, respectively.

**Table 7. Hygienist Stain Rating (7a), Ease of Stain Removal (7b), and Timed Prophylaxis (7c)**

| Table 7a. Hygienist Stain Rating   |    |                             |
|--|----|-----------------------------|
| Treatment  | N  | Average Stain Rating        |
| Control  | 84 | 1.25                        |
| lowGluc SSF  | 84 | 2.21                        |
| highGluc SSF   | 84 | 2.20                        |
| <small>For stain rating, scores ranged from 0 to 6 in increments of 1 where 0 = none; 2 = slight; 4 = moderate; 6 = severe.<br/>                     Analysis of variance conducted using a model that contained hygienist, treatment, and hygienist by treatment as factors. Means within brackets are not significantly different by the Student-Newman-Keuls test at alpha = 0.05.</small>                            |    |                             |
| Table 7b. Ease of Stain Removal  |    |                             |
| Treatment  | N  | Ease of Stain Removal       |
| Control  | 68 | 1.78                        |
| lowGluc SSF  | 80 | 2.16                        |
| highGluc SSF   | 77 | 2.38                        |
| <small>For ease of stain removal, scores ranged from 1 to 5 where 1 = easy; 2 = moderately easy; 3 = average; 4 = moderately difficult; 5 = difficult.<br/>                     Analysis of variance conducted using a model that contained hygienist, treatment, and hygienist by treatment as factors. Means within brackets are not significantly different by the Student-Newman-Keuls test at alpha = 0.05.</small> |    |                             |
| Table 7c. Timed Prophylaxis  |    |                             |
| Treatment  | N  | Prophylaxis Time in Minutes |
| Control  | 84 | 26.79                       |
| lowGluc SSF  | 84 | 31.18                       |
| highGluc SSF   | 84 | 28.86                       |
| <small>Analysis of variance conducted using a model that contained hygienist, treatment, and hygienist by treatment as factors. Means within brackets are not significantly different by the Student-Newman-Keuls test at alpha = 0.05.</small>  |    |                             |

Hygienists reported observing significantly more stain for the stannous fluoride groups relative to the control group, though the absolute magnitude of the stain was rated as “slight” for both stannous fluoride groups. With respect to ease of stain removal, hygienists reported a slight increase in effort progressing from the control (1.78) to the lowGluc (2.16) and highGluc (2.38) stabilized stannous fluoride groups. The difference between the control and lowGluc stabilized stannous fluoride groups was not statistically significant. However, the difference between the control and highGluc stabilized stannous fluoride groups was statistically significant. Differences in the mean prophylaxis times between the control and stabilized stannous

fluoride dentifrice groups were less than five minutes and were not statistically significant.

Examinations of the oral mucosa after three and six months revealed no unexpected or clinically serious adverse reactions to any of the test dentifrices.

## The Discussion

The **Discussion** section presents the researcher’s interpretation of the results. These interpretations should be discussed as probabilities rather than fact, using phrases such as “results indicate...” or “this finding suggests...” etc. The researcher should provide several explanations for the results, any results that differ from what was expected, the limitations of the research, and comparisons with other investigations.<sup>3</sup> Differences in findings from previous research warrant a consideration of possible reasons. The researcher should also discuss the value of the investigation, including the implications of the findings to professional practice. If possible, the researcher should generalize or speculate about how the findings can be applied to a larger group or population of people. The findings have much more value if they can be applied to a larger group than the sample used in the study. For example, the research finding that a group of dental hygienists stayed in a practice setting longer when they had more autonomy for decision-making about patient care has more value for the profession when it can be applied to all dental hygienists in the United States.

**Below is an example of the Discussion section:**

### The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>

#### Discussion

A six-month, double-blind clinical study was conducted to evaluate the effect on gingivitis,

relative to a sodium fluoride control, of two dentifrices containing 0.454% SnF<sub>2</sub> stabilized with different levels of sodium gluconate. To be eligible for the study, subjects had to have a minimum of five sites which bled (individual sites with a score of 2 or 3) during the Gingival Index examination. This restriction was intended to enable recruitment of a clinical population which exhibited mild to moderate levels of gingivitis. As can be seen from the baseline data, the gingivitis and gingival bleeding scores for the treatment groups at the start of the trial were approximately 0.7 and 18, respectively. This confirms that qualifying criteria of five bleeding sites were successful in selecting a clinical population with the targeted level of gingivitis. For perspective, subjects in the present study had approximately 10% of their gingival sites bleed upon probing, whereas in a recent survey of oral health in employed U.S. adults, it was observed that about 6% of gingival sites bled upon probing.<sup>19</sup>

At the start of, and throughout the course of the study, groups were well-balanced with respect to all clinical parameters and demographic characteristics. Review of the results show that the gingivitis scores of the stannous fluoride groups were significantly lower than the control group at both the three- and six-month examinations. However, there were no significant differences between the two stannous fluoride dentifrices with respect to gingivitis. This suggests that both stabilization systems were equally effective at delivering therapeutic levels of stannous fluoride during tooth brushing.

There was a clear trend toward reduced gingival bleeding for both the lowGluc and highGluc stabilized stannous fluoride dentifrices relative to the control group. This trend was strongest for the lowGluc stabilized stannous fluoride dentifrices where a statistically nonsignificant 30.5% reduction in gingival bleeding was seen. It should be noted that while this study was designed to have adequate statistical power for detecting significant differences between

treatment groups with respect to gingivitis, it was not sized to demonstrate that differences of a similar magnitude in gingival bleeding were statistically significant.

The significant reductions in gingivitis seen in this study for the stannous fluoride groups were not accompanied by corresponding decreases in plaque scores. There are a number of possible explanations for this observation. One possibility is that clinical assessments of plaque coverage may be affected by artifacts associated with stannous fluoride use. Tinanoff and Weeks<sup>20</sup> and Rykke et al.<sup>21</sup> have observed an increased deposition of the pellicle protein layer as a result of topical stannous fluoride use. Several authors have speculated that this “thickened” pellicle layer could complicate plaque area measurements.<sup>3,9,22</sup> It is possible that relative to other, non-stabilized stannous fluoride products, the increased bioavailability associated with the stabilized stannous fluoride dentifrices might confound plaque measurements to an even greater extent.

Another possible explanation for not observing plaque reductions is that stannous fluoride, through its inhibition of bacterial metabolism, improves gingival health by reducing plaque virulence.<sup>3,6,23</sup> Such a qualitative effect would not necessarily be expected to lead to a corresponding quantitative decrease in plaque.

As would be expected, the extended use of stannous fluoride dentifrices resulted in more extrinsic dental stain than the control group. To investigate whether tooth staining might result in examiner bias, subjects wore pre-fabricated, custom-made tooth covers at the six-month but not three-month examination. This allowed for a comparison of the observed stannous fluoride effects with and without the use of the covers. As can be seen from the three- and six-month efficacy results (Table III), the measured effectiveness for the stannous fluoride dentifrices were unaffected by the presence or absence of tooth covers. This indicates that during the assessment of gingivitis in this study, the presence of stain

did not bias the gingivitis examiner. The results from this trial are in agreement with a previously published study where tooth covers were employed during the gingivitis examination to mask antimicrobial stain.<sup>24</sup> The outcome of this trial suggested that well-trained examiners were capable of focusing on the criteria of the Gingival Index and not be influenced by the presence of stain.

In order to assess the possible impact of this increased staining on dental prophylaxes, the time and effort that was required for dental hygienists to complete each prophylaxis, as well as their assessment of the amount of stain present, was determined. Interestingly, the increased tooth staining associated with the use of the stannous fluoride dentifrices did not appear to translate into increased prophylaxis efforts on the part of the dental hygienists. This can be seen when the total prophylaxis times for the control and stabilized stannous fluoride groups are considered. It was found that mean prophylaxis times were increased by less than five minutes for subjects in the stannous fluoride groups. This increase was not statistically significant and was of a small enough magnitude to be considered relatively unimportant. Further illustrating the minor impact of the stain were the results from the dental hygienist questionnaires assessing both the coverage and difficulty in removing stain. When asked to rate the difficulty of removing stain (1 = easy, 2 = moderately easy, 3 = average, 4 = moderately difficult, 5 = difficult) hygienists reported their efforts in the “moderately easy” range for the control (1.78), lowGluc (2.16), and highGluc (2.38) stabilized stannous fluoride groups. Consistent with the clinical assessment, hygienists also reported observing increased stain for the stabilized stannous fluoride groups relative to the control group. However, to put this in perspective, it should be noted that when asked to estimate how much stain was present (0 = none, 2 = slight, 4 = moderate, 6 = severe), hygienists reported only a “slight” amount visible on the teeth of subjects in the stannous fluoride groups. As a whole, these

results indicate that from a professional standpoint, the increase in tooth stain associated with the use of stannous fluoride can be easily managed by employing standard oral prophylaxis techniques and effort.

Objective and subjective safety parameters assessed throughout this six-month study indicate that the stannous fluoride dentifrices were safe. No serious, or potentially serious, adverse effects were observed during the oral soft tissue examinations. Further, of the many minor, routine soft tissue conditions seen, the frequencies and nature of the observations were similar for all treatment groups.

In an effort to more closely approximate habitual brushing patterns, subjects entering the clinical trial were instructed to brush with their assigned dentifrice as they normally would. In addition, subjects were not given new toothbrushes at the start of the study and were instructed to replace their brushes from commercial sources at their own discretion. Subject interactions with the clinical site were kept to a minimum and restricted to their examinations and the reporting of any adverse events. As a result of this approach, the test dentifrices were used under conditions resembling conventional oral hygiene practices. Therefore, the gingival health improvements observed for the stannous fluoride dentifrices are likely directly representative of the benefits that would be seen for people in the general population who brushed with these dentifrices.

### **The Summary and Conclusions**

In the **Summary and Conclusions** section, the summary should briefly restate the problem, procedures, and findings.<sup>3</sup> The conclusions should relate to the research question or hypothesis and be based on the findings of the study. The researcher may also recommend areas for future study. Journals will often combine this section with the discussion.

**Below is an example of the *Summary and Conclusions* section:**

### The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>

#### Conclusions

The results of this double-blind clinical trial demonstrated that the use of stabilized 0.454% SnF<sub>2</sub> dentifrices over a six-month period resulted in statistically significant reductions in gingivitis relative to a fluoride-containing control dentifrice. Overall, the stannous fluoride dentifrices were very well tolerated and were devoid of any significant adverse effects on the oral soft tissues. Furthermore, the results suggest that when properly formulated, stannous fluoride is effective in reducing gingivitis.

#### The References

The **References** section is the acknowledgment and documentation of the work of other investigators, i.e., a list of sources cited in the paper. The author has an ethical obligation to carefully document the source of all information that is derived from the work of others. Failure to do so is considered plagiarism. Additionally, the accuracy of the references will be crucial to other individuals who are exploring similar areas of research. This should contain classic works related to the topic as well as the most current research.<sup>3</sup> Secondary sources, a summary of an investigation by someone other than the original author (such as in a textbook), should be avoided, since misinterpretations are more likely to occur.

A variety of reference formats are used by different journals, including how they are cited in the text (e.g., by superscripted number or author and date), how the references themselves are structured (e.g., placement of date), and the order in which they are listed in the reference section (e.g., by order of appearance in the text or alphabetically). A popular format used in dental and medical literature is that of the National Library of Medicine.<sup>6</sup> Another common format is that of the American Psychological Association or APA.<sup>7</sup>

Below is an example of the **References** section:

### The Clinical Effect of Dentifrices Containing Stabilized Stannous Fluoride on Plaque Formation and Gingivitis - A Six-Month Study with Ad libitum Brushing<sup>4</sup>

#### References

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## Conclusion

This continuing education course has described the parts of a research report and the information that should be contained within each section. This will guide oral health professionals in their review of research articles so that they can identify the specific research questions/hypotheses being explored and what was discovered about them. The next continuing education course in this series will explain how to evaluate the quality of research conducted as reported in a research report and how to interpret the findings. These skills will help oral health professionals decide whether or not to incorporate these research findings into their patient therapy and practice procedures.

## Course Test Preview

- 1. Which of the following is the most important reason to evaluate professional literature?**
  - a. To make sure it will satisfy continuing education requirement.
  - b. To facilitate reports to professional colleagues.
  - c. To enable the oral care provider to make decisions concerning patient care.
  - d. It is not necessary to evaluate the article if it appears in a peer-reviewed journal.
- 2. Which of the following is an accepted source of appropriate dental research literature?**
  - a. PubMed
  - b. MEDLINE
  - c. Dental Libraries
  - d. All of the above.
- 3. Which of the following is NOT a standard section title of a research report?**
  - a. Abstract
  - b. Discussion
  - c. Recommendations
  - d. References
- 4. Of the following statements, which of the following best describes an abstract?**
  - a. "The paper in miniature"
  - b. "The hypothesis"
  - c. "Follows the format of the journal editors"
  - d. "A short description of the problem"
- 5. A hypothesis is which of the following?**
  - a. A guess of the outcomes of the study.
  - b. A summary of possible results.
  - c. A statement that confirms another researchers study.
  - d. A statement that predicts a relationship between two or more variables.
- 6. In the Introduction section of the article, what research question was being addressed?**
  - a. What is the anticaries effect of 0.454% stannous fluoride dentifrice?
  - b. What is the effect of 0.454% stannous fluoride dentifrice on plaque formation?
  - c. What is the effect of 0.454% stannous fluoride dentifrice on gingivitis?
  - d. B and C
  - e. All of the above.
- 7. The major purpose of the detailed description of Material and Methods is which of the following?**
  - a. To give a better understanding to the reader of the details of the study.
  - b. To assure the possibility of replication for future studies.
  - c. To provide the results (data).
  - d. All of the above.
  - e. A and B



- 8. In the Material and Methods section of the article, which of the following dentifrices was used as the control?**
- a. 0.243% sodium fluoride dentifrice
  - b. 0.454% SnF<sub>2</sub> dentifrice stabilized with 1.5% SnC<sub>12</sub> and 2.08% sodium gluconate
  - c. 0.454% SnF<sub>2</sub> dentifrice stabilized with 1.5% SnC<sub>12</sub> and 4.16% sodium gluconate
  - d. An experimental dentifrice.
- 9. In the Material and Methods section of the article, what was recorded/evaluated at both the 3-and 6- month examinations?**
- a. Gingival inflammation
  - b. Plaque accumulation
  - c. Extrinsic dental stain
  - d. Oral soft tissue status
  - e. All of the above.
  - f. A, B, and C
- 10. The Results section should contain which of the following?**
- a. Unexplained finding related to the research questions or hypothesis.
  - b. Summary of numerical findings.
  - c. Tables, graphs, illustration, etc.
  - d. All of the above.
- 11. In the Results section of the article, dental hygienists reported observing significantly more stain for the control group relative to the stannous fluoride group.**
- a. True
  - b. False
- 12. In the Results section of the article, examinations of the oral mucosa after 3 and 6 months revealed no unexpected or clinically serious adverse reactions to any of the test dentifrices.**
- a. True
  - b. False
- 13. In the Discussion section of the article, which of the following reasons is(are) offered by the authors to explain why the significant decrease in gingivitis was NOT accompanied by a significant decrease in plaque deposits?**
- a. Stannous fluoride increases the deposition of the pellicle protein layer.
  - b. Stannous fluoride improves gingival health by reducing plaque virulence.
  - c. Stannous fluoride reduces gingivitis by its anti-inflammatory properties.
  - d. All of the above.
  - e. A and B
  - f. B and C
- 14. In the Discussion section of the article, the authors generalized the results of this study to what larger population?**
- a. All the US population.
  - b. All the US population who use a fluoridated dentifrice.
  - c. All the US population who use the stannous fluoride dentifrices described in the study.

- 15. In the Conclusions section of the article, the authors answer the research question about the effect of 0.454% stannous fluoride dentifrice on which condition(s)?**
- a. gingivitis
  - b. gingival bleeding
  - c. plaque
  - d. stain
  - e. microbiological parameters
  - f. A and B
  - g. A and C

## References

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