

Acceptance Program
Guidelines

Dental Floss Or Other Interdental Cleaners

Council on Scientific Affairs

Dental Floss or Other Interdental Cleaners

Scope:

These guidelines apply to the design of clinical trials and other information needed to evaluate the safety and effectiveness of manual and powered devices and products intended for the removal of interproximal dental plaque.

I. SUBMISSION DIRECTIONS

1. General Information

- A Submissions are to be sent to the Council Office:
Director, Product Evaluations
Council on Scientific Affairs
American Dental Association
211 East Chicago Avenue
Chicago, Illinois 60611-2678
- B Submissions are to be sent in triplicate, along with a market sample of the product, i.e., packaged as marketed. The Council agrees to return the product sample within 6 months if requested. If possible, the submission should be less than 200 pages exclusive of appendices.
- C A manufacturer is advised that the review process is complex. Typically, notification of Council action may be expected 90 to 150 days from the receipt of a complete submission by the Council. More time may be required if additional information or clarification is needed from the manufacturer.
- D When a product is classified as "Accepted" the classification is for 3 years. Renewal of the classification will be considered by the Council upon request by the manufacturer.
- E Companies with Accepted products are subject to the conditions stated in the Agreement Governing Use of the ADA Seal of Acceptance.

2. Arrangement of a Submission

- A The submission is to be divided into sections and arranged in order as indicated in part II. Sections to be identified by tabs are designated by an asterisk (*).

II. INFORMATION TO BE SUBMITTED

1. **Cover Page**

A Name of company

B Product name

*2. **Table of Contents**

*3. **Company Information**

A Name of company (to be used in official list of Accepted Products)

B Address (to be used in listing)

C Phone number (to be used in listing)

D Fax number and e-mail address

E Names of owners, officers and other individuals authorized to furnish information to the Council and represent the firm in dealing with the Council including the main contact person. (Foreign manufacturers must have an office or branch located in the United States and the product must be available for purchase in the United States.)

F Names and qualifications of scientific personnel responsible for formulation and testing of the product in its manufacturing process.

*4. **Summary of Submission**

Comprehensive summary of the information submitted on safety and effectiveness.

*5. **Product Information**

A Name of product (to be used in listing)

B Claims of Efficacy

(i) The primary claims for the device in labeling and in advertising to the public should relate to reductions of plaque and gingivitis.

(ii) All claims of efficacy, including all health benefit claims and all claims which imply a health benefit (e.g., reduction in gingival inflammation), must be documented. These claims include "reduces gingivitis," "reduces gingival bleeding," "reduces risk of periodontal destruction," "reduces risk of attachment loss," and "reduces risk of tooth loss."

C Patent title(s) and patent number(s) relating to the product.

D Product description

- (i) List the materials used in the construction of the product.
- (ii) Principles of design.

E Instructions including indications and contraindications for use, warnings, limitations, etc.

F Labeling/packaging

G Promotional Materials

***6. Quality Control Procedures for the Manufacturing of the Product**

***7. Safety Data**

A Evidence must be provided that the components of the product are safe for use in the oral cavity. Compliance with applicable FDA standards should be provided (where appropriate).

B For dental floss, laboratory data should be provided on the tensile strength of the floss and resistance to shredding. Comparisons should be made between the tested product and currently Accepted products.

C For powered products and for manual products whose design or composition represent a significant departure from those in currently Accepted products, manufacturers must present adequate evidence from at least two clinical investigations to show that unsupervised use of the product by the average patient will not be harmful to hard or soft oral tissues or restorations. See sample protocol.

D For powered devices, the product must have been submitted to an examination by and met the requirements of an appropriate technical safety laboratory such as Underwriters Laboratories, Inc. This requirement may be waived for products operating from non-rechargeable batteries of low voltage.

***8. Efficacy Data — Clinical Data to Show Effectiveness**

A Clinical trials will not be necessary for manual products similar in design and composition to those previously Accepted by the Council.

B For powered products or for manual products whose design or materials represent a significant departure from those in currently Accepted products, manufacturers must present adequate evidence from at least two clinical investigations to show that the test product plus normal tooth brushing can be readily employed under unsupervised conditions by the average patient to reduce plaque and gingivitis beyond that obtained by normal tooth brushing alone. See sample protocol.

***9. Comprehensive Bibliography Concerning the Product**

***10. Copies of Most Significant Articles**

***11. Appendices**

Detailed description of test evaluation methods and any other defined areas.

III. REQUIREMENTS (PERFORMANCE CRITERIA) FOR CLASSIFICATION OF “ACCEPTED”

In the clinical evaluation, mean group plaque and gingivitis scores should demonstrate that the use of the test product and a toothbrush results in a statistically significant ($p \leq 0.05$) improvement in performance compared to a toothbrush used alone.

IV. STATEMENT

To be used for products accepted under these Guidelines.

“The ADA Council on Scientific Affairs’ Acceptance of (product name) is based on its finding that the product is effective for removing plaque between teeth and helping to prevent or reduce gingivitis, when used as directed.”

SAMPLE CLINICAL PROTOCOL

The following protocol is only one possible design to demonstrate safety and effectiveness of interproximal cleaning devices. Other well-controlled study designs following similar procedures would be acceptable. Additional information concerning clinical trials and clinical trial reporting can be obtained from the Council's Guidelines for Clinical Trial Protocols.¹ Manufacturers are invited to submit protocols for review before implementing a study.

Study Design

Patient Population

Control subjects will be randomly assigned a commercially available ADA Accepted toothbrush and test subjects will be randomly assigned the test product and the same ADA Accepted toothbrush. Sufficient subjects will be enrolled in the study so that at least 25 subjects in each group will complete the study. Control and test subjects should be homogeneous with respect to disease severity (e.g., mild to moderate gingivitis). A sufficient number of study sites in each patient should be examined during the study to determine the effectiveness of the interproximal cleansing device for teeth in anterior/posterior and maxillary/mandibular areas of the mouth.

At least 5 interproximal sites per patient in each of these site categories will allow for a minimum total of 125 maxillary anterior sites, 125 maxillary posterior sites, 125 mandibular anterior sites, and 125 mandibular posterior sites.

Study Protocol

Each subject will have a complete examination of the oral cavity to determine eligibility for the study. In general, subjects should be adults in good medical health with mouths free from major hard or soft tissue lesions. All clinical examinations will be performed by an investigator who has no knowledge of the oral hygiene devices used by the subjects. Clinical measurements will be taken at baseline (prior to the study), at 15 days, and at 30 days. If patients are instructed in product usage, this should be delineated in the protocol. Safety assessments will be made at each measurement period. Areas to be examined will be tongue, hard and soft palate, teeth, dental restorations, gingivae, mucobuccal folds, the inner surface of the cheeks and sublingual space areas. All areas will be assessed and reported as normal or abnormal, per patient. Evaluations will be performed by trained and calibrated investigators.

Patients should be instructed not to brush their teeth for 12–14 hours before each study visit so that overnight plaque formation can occur. Prior to brushing or use of the assigned interproximal cleaning device, plaque and gingival inflammation scores will be recorded. With the investigator out of the room, the subjects will be given 5 minutes to clean their teeth with the assigned oral hygiene device(s). The subjects will not have access to a mirror. After this oral hygiene period, the plaque scores will be assessed again to determine plaque removal efficacy. At each visit, scoring of supragingival plaque will be done at all study sites following use of an acceptable disclosing solution. It is suggested that an index such as the Turesky² modification of the Quigley–Hein plaque index be used.

Other suitable plaque indices may also be acceptable. The index used, the rationale for its use and any modification in the method of using it should be clearly explained. Separate plaque scores will be given for the interproximal papillae and gingival margins for both buccal/lingual and mesial/distal surfaces.

At each visit, scoring of gingival inflammation (gingivitis) will be done at all study sites. It is suggested that a method such as Löe & Silness³ be used. If a different index is used, its rationale should be provided. Additional assessments of interproximal health such as bleeding on provocation are recommended. Assessment of gingivitis should be done prior to the scoring of plaque to avoid masking the gingival inflammation with the disclosing agent.

Between the baseline and 30 days examination, each subject will be instructed to clean his/her teeth daily, using only the assigned products provided and a dentifrice provided. During the study, subjects should not use antimicrobial mouthrinses or other dental products that might affect plaque or gingivitis scores.

Compliance should be assessed by appropriate methods (e.g., patient-recorded oral hygiene logs). As an aid to establish compliance, toothbrushes and unused floss (or the test interproximal cleaning product/device) should be returned at the end of the study.

Data analysis

Within each group, means and standard deviations will be calculated for all clinical measurements and assessments for the entire dentition of each subject for specific selected sites (e.g., buccal/lingual interproximals), and anterior/posterior teeth. Percent reductions in plaque scores will be calculated by comparing pre-and post-oral hygiene values. Repeated measures multivariate analyses of variance (ANOVA) can be used to test for time- and device-dependent differences for all clinical assessments between the subject groups over the 3 visits. The effects of the oral hygiene devices in reducing baseline values of the plaque and gingivitis indices at the 15-day and 30-day visits can be assessed using appropriate nonparametric methods.

Safety Reporting

All patient reports of irritation will be recorded on an appropriate case report form. All changes noted during the oral examinations will also be recorded. The investigator(s) will record opinions of the relationship of the study products to each adverse reaction or change in the oral cavity. Any serious adverse experience will be reported to appropriate regulatory agencies. Safety evaluation data (normal vs. abnormal) will be analyzed by an acceptable non-parametric statistical test.

REFERENCES

1. ADA Council on Scientific Affairs. Acceptance Program Guidelines: Clinical Trial Protocols. Chicago: American Dental Association, 2003.
2. Turesky S, Gilmore ND, Glickman I. Reduced plaque formation by the chloromethyl analogue of Vitamin C. *J Periodontol* 1970; 41:41–43.
3. Løe H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontol Scand* 1963; 21:533–551.



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