

AD-A076 564

COOPER LABS INC CEDAR KNOLLS NJ

F/G 6/5

A CLINICAL COMPARISON OF THE EFFECTIVENESS OF CONVENTIONAL DENT--ETC(U)

MAY 79 L MENAKER , T WEATHERFORD

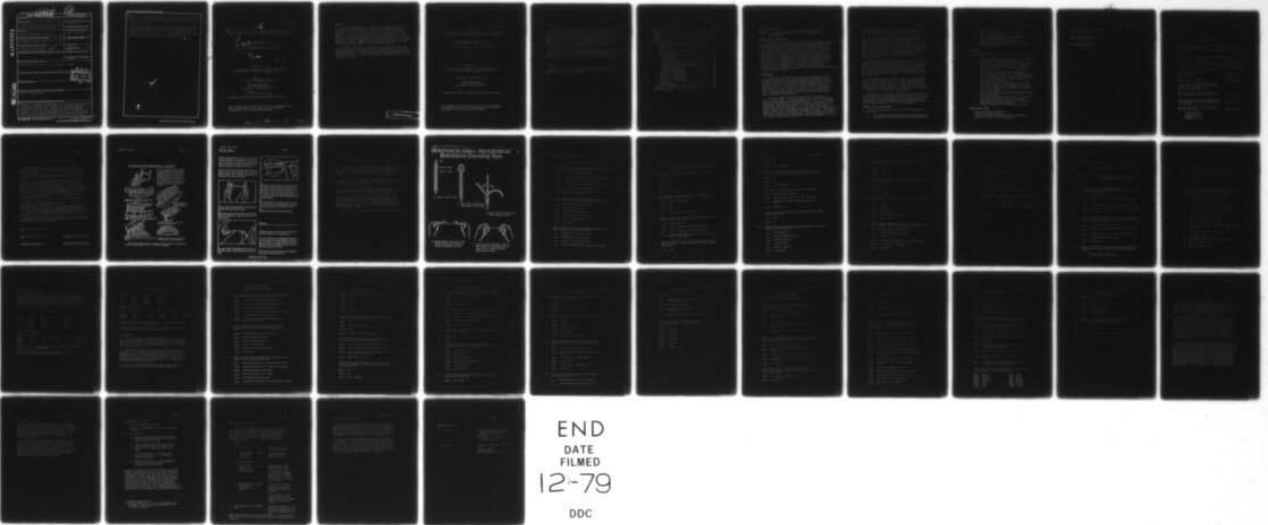
DAMD17-78-C-8084

UNCLASSIFIED 1

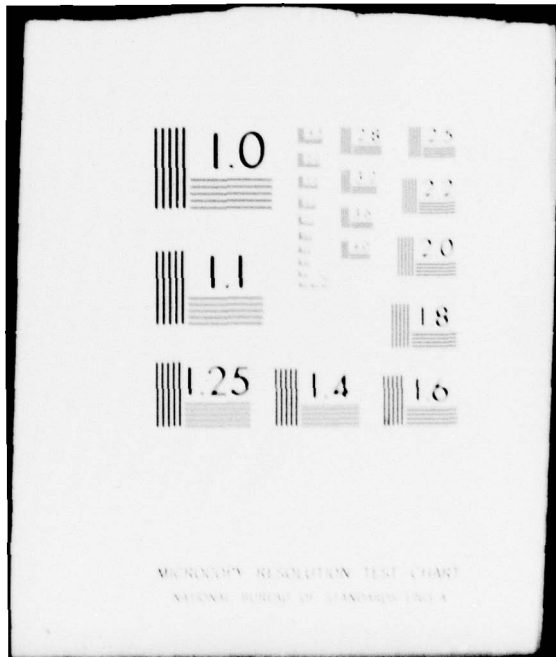
NL

| OF |

AD
A076564



END
DATE
FILMED
12-79
DDC



12

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

1. REPORT NUMBER One		2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) A Clinical Comparison of the Effectiveness of Conventional Dental Floss and a Coated, Elastomeric Dental Ribbon		5. TYPE OF REPORT & PERIOD COVERED Final Report	
7. AUTHOR(s) Lewis Menaker, D.M.D., Sc.D. Thomas Weatherford, D.V.M., D.M.D., M.S.		8. CONTRACT OR GRANT NUMBER(s) DAMD 17-78-C-8084	
9. PERFORMING ORGANIZATION NAME AND ADDRESS University of Alabama School of Dentistry Birmingham, Alabama 35294		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS	
11. CONTROLLING OFFICE NAME AND ADDRESS Cooper Laboratories, Inc. <i>source</i> 110 East Hanover Avenue Cedar Knolls, New Jersey 17927		12. REPORT DATE May 1979	
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) <i>Alabama Univ. in Birmingham School of D.</i>		13. NUMBER OF PAGES 45	
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited		15. SECURITY CLASS. (of this report)	
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE	
18. SUPPLEMENTARY NOTES			
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Floss, Clinical, Dental			
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A study was conducted to determine the clinical effectiveness of a coated, elastomeric dental ribbon as a suitable substitute for conventional dental floss. Thirty seven healthy volunteer patients with at least 28 teeth and no overt oral pathoses participated. After a screening examination and a cleaning, baseline data was collected for gingivitis and plaque accumulation. Using a computer generated randomization table, each patient			

AD A 076564

DDC FILE COPY

DDC RECEIVED NOV 14 1979

394252 over SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

went through a three week period using no floss, conventional floss or the coated elastomeric ribbon. Gingivitis and plaque scores were collected after each treatment period and statistically analyzed.

The range of treatment means was in all cases less than half the minimum standard deviation of the individual groups being compared and analysis of variance produced F ratios well below the 95% confidence level. It is concluded that no differences exist between floss and elastomeric tape for plaque removal and/or the ability to control gingivitis.

↖

Accession For	
NTIS GRA&I	<input checked="" type="checkbox"/>
DDC TAB	<input type="checkbox"/>
Unannounced	<input type="checkbox"/>
Justification	
By _____	
Distribution/	
Availability Codes	
Dist	Avail and/or special
A	

14
REPORT #1

6

A Clinical Comparison of the Effectiveness of Conventional Dental Floss and a Coated, Elastomeric Dental Ribbon.

10

Lewis Menaker, D.M.D., Sc.D.
Thomas Weatherford, D.V.M., D.M.D., M.S.
University of Alabama School of Dentistry

11

May 79

12 472

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

15

Contract No. DAMD 17-78-C-8084

394 252 Cooper Laboratories
110 E. Hanover Avenue
Cedar Knolls, New Jersey 17927

9 Final rept.

Approved for public release; distribution unlimited

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

394 252 79 11 09 078

Abstract:

A study was conducted to determine the clinical effectiveness of a coated, elastomeric dental ribbon as a suitable substitute for conventional dental floss. Thirty seven healthy volunteer patients with at least 28 teeth and no overt oral pathoses participated. After a screening examination and a cleaning, baseline data was collected for gingivitis and plaque accumulation. Using a computer generated randomization table, each patient went through a three week period using no floss, conventional floss or the coated elastomeric ribbon. Gingivitis and plaque scores were collected after each treatment period and statistically analyzed.

The range of treatment means was in all cases less than half the minimum standard deviation of the individual groups being compared and analysis of variance produced F ratios well below the 95% confidence level. It is concluded that no differences exist between floss and elastomeric tape for plaque removal and/or the ability to control gingivitis.

PRECEDING PAGE BLANK

REPORT #1

A Clinical Comparison of the Effectiveness of Conventional
Dental Floss and a Coated, Elastomeric Dental Ribbon

Lewis Menaker, D.M.D., Sc.D.
Thomas Weatherford, D.V.M., D.M.D., M.S.

University of Alabama School of Dentistry

May, 1979

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

Contract No. DAMD 17-78-C-8084

Cooper Laboratories
110 E. Hanover Avenue
Cedar Knolls, New Jersey 17927

Approved for public release; distribution unlimited

The findings in this report are not to be construed as
an official Department of the Army position unless so
designated by other authorized documents.

Summary:

A study was conducted to determine the clinical effectiveness of a coated, elastomeric dental ribbon as a suitable substitute for conventional dental floss. Thirty seven healthy volunteer patients with at least 28 teeth and no overt oral pathoses participated. After a screening examination and a cleaning, baseline data was collected for gingivitis and plaque accumulation. Using a computer generated randomization table, each patient went through a three week period using no floss, conventional floss or the coated elastomeric ribbon. Gingivitis and plaque scores were collected after each treatment period and statistically analyzed.

The range of treatment means was in all cases less than half the minimum standard deviation of the individual groups being compared and analysis of variance produced F ratios well below the 95% confidence level. It is concluded that no differences exist between floss and elastomeric tape for plaque removal and/or the ability to control gingivitis.

Forward:

In conducting the research described in this report, the investigators adhered to the guidelines for human subjects as set forth by the Institutional Review Board for Human Use at the University of Alabama in Birmingham.

Table of Contents

	Page
Cover Page	1
Abstract	3
Title Page	4
Summary	5
Forward	5
Table of Contents	6
Body of the Report	7
Statement of the Problem	7
Background	7
Patient Selection Criteria	8
Study Plan	9
Patient Data Forms	9
Screening Form	11
History Form	12
Plaque and Gingivitis Scoring Form	13
Informed Consent Form	14
Brushing and Flossing Instructions	15
Pre-test Questionnaire	19
Post-test Questionnaire	24
Results - Clinical Data	28
Discussion - Clinical Data	29
Results - Questionnaire	30
Discussion - Questionnaire	39
Conclusion	40
Recommendations	40
Appendix A - Product Safety Data Report	41
Distribution List	46

Body of the Report:

Title: A Clinical Comparison of the Effectiveness of Conventional Dental Floss and a Coated, Elastomeric Dental Ribbon

Statement of the Problem:

The regular use of dental floss to remove interproximal plaque accumulations is an important factor in controlling dental disease. The use of conventional floss in a mobile, military environment is difficult, due to the bulky nature of the product and availability in the field. The development of a substitute for dental floss that would encourage interproximal cleaning on a regular basis, under field conditions, would be of positive benefit to the military. Inclusion of such a product in packaged rations would make floss available to all military personnel on a regular basis and in a convenient form. This study was designed to test the efficacy of a single unit, elastomeric floss substitute that can be included in packaged military rations. The material is protected by a paper covering, has excellent environmental stability and is inexpensive to produce. The dental ribbon is coated with a mild cleansing agent that may offer certain advantages over conventional floss.

Background:

Dental floss is used as an adjunct to toothbrushing for the control of plaque and the prevention of dental disease. The literature contains many reports suggesting and supporting the use of dental floss as one method of removing plaque from interproximal surfaces. Although these papers suggest that floss is beneficial, very few reports are available which compare the effectiveness of various types of floss. It has been suggested that unwaxed floss is superior to waxed floss in the ability to remove interproximal plaque; however, these claims have never been conclusively substantiated.

The first record of floss use goes back to 1819 when Dr. L. Parmly wrote: "The third part is the waxen silken thread, which, though simple, is the most important. It is to be passed through the interstices of the teeth, between their gums, to dislodge that irritating matter which no brush can remove and which is the real source of disease." In later years silk became a scarce commodity and was replaced by a synthetic substitute called nylon. Nylon floss had several advantages over silk. The abrasion resistance of nylon, when drawn over rough surfaces, is greater than that of silk and it has greater elasticity than silk, allowing it to pass through close places and over rough surfaces with less

filament breakage. Virtually all floss available today is made with nylon and the basic physical characteristics have gone unchanged since nylon floss was first developed.

In a 1949 survey by Wisan and Bruebbel, it was shown that only 18.2 percent of the population questioned used dental floss frequently. A more recent estimate is that only 24 percent of the population uses dental floss. It is clear then that the need to use dental floss is poorly correlated with its use by the general population. The mass appeal of dental floss depends on its simplicity of use. Most patients give up flossing because it is inconvenient and awkward to use. A dental floss that is more effective, convenient, and easy to use would result in a greater proportion of the population executing this important oral hygiene function on a regular basis.

The physical characteristics of floss have essentially remained unchanged since it was introduced in 1819. The numerous micro-filaments making up the floss act to dislodge plaque deposits found between the teeth. To be effective the floss must have the ability to flatten out and gently pass under the sulcus at the interproximal margin. When the micro-filaments become damaged when passing over restorations or between tight contacts, the floss frays and eventually breaks.

A floss that does not fray, is gentle to the gingiva, covers a large surface area of the tooth, and easily fits between tight contacts would be a significant improvement over all other available types of floss. This study was designed to test such a product. It was designed to measure not only plaque removal and gingival health, but also subjective responses by the patient to the product.

The product is a novel, elastomeric ribbon coated with a tacky surface, a paper liner has been added to both sides of the ribbon. After the paper covering is removed, the material is stretched until resistance is felt and used like conventional floss. A summary of clinical use and safety of the product components is contained in Appendix A.

Patient Selection Criteria:

The following criteria were used in selecting patients in the study.

1. All patients should be adults 18 years or older.
2. Subjects with an existing medical condition should

- be excluded.
3. Subjects should have at least 16 interproximal areas in their mouth.
 4. None of the subjects should be pregnant.
 5. None of the subjects should demonstrate any gross pre-existing oral pathology.
 6. Patients with fixed bridges or similar prosthesis will be excluded from this study.
 7. Patients should be willing to sign an informed consent document.

Study Plan:

The following study plan was developed for use in the clinical trial.

1. At least thirty six subjects meeting the selection criteria were used in this study.
2. Each subject completed a pre-test questionnaire and received a dental prophylaxis. Following this, instruction was given on the correct execution of the Bass brushing technique using an Oral B-40 toothbrush.
3. The subjects were then randomly divided into three groups; brushing using conventional floss (J & J unwaxed), brushing using elastomeric ribbon, and brushing alone. Appropriate instruction on the proper use of both types of floss was given prior to dismissal.
4. After three weeks, the patients returned for plaque and gingivitis measurements. They were then given a prophylaxis and assigned to another test group. Appropriate instruction was given prior to dismissal.
5. At each measurement interval, the group using the elastomeric ribbon was asked to complete a brief, use questionnaire.
6. The study was terminated when each subject completed participation in each of the three experimental cycles as well as the three week baseline data collection period.
7. Data was analyzed using Analysis of Variance.

Patient Data Forms:

- Screening Form (see Figure 1)
- History Form (see Figure 2)
- Plaque and Gingivitis Scoring Form (see Figure 3)
- Informed Consent Form (see Figure 4)

Brushing and Flossing Instructions:

(see Figure 5)

Pre-Test Questionnaire:

(see Figure 6)

Post-Test Questionnaire:

(see Figure 7)

Figure 1: Screening Form

FLOSS STUDY

October - December, 1978

Name _____ Age _____ Sex _____
Social Security Number _____ Phone: Home _____
Work _____

Home Address _____

Is your general health good? Yes ___ No ___

List any general health problems _____

Are you taking antibiotics? Yes ___ No ___

Are you pregnant? Yes ___ No ___

Is your dental health good? Yes ___ No ___

Do you have 20 or more natural teeth,
including four molars, without bands,
crowns, and/or bridges?
(If not sure, let us check)

Are you willing to floss daily during
the study (approximately 9 weeks)? Yes ___ No ___

Are you willing to omit flossing, but
not brushing, during one 3 week period
of the study? Yes ___ No ___

Can you come for a 30 minute exam on
the following days: Yes ___ No ___

- October 9 or 10
- October 30 or 31
- November 20 or 21
- December 11 or 12

UNIVERSITY OF ALABAMA SCHOOL OF DENTISTRY

PATIENT'S NAME: _____ AGE: _____ SEX: _____ RACE: _____

INFORMANT: _____ DATE: _____ CLINIC NO.: _____

CLOSEST RELATIVE: _____ PHONE: _____

PAST MEDICAL HISTORY

NO	YES	COMMENTS
<input type="checkbox"/> Care of physician? (who, why)	<input type="checkbox"/>	
<input type="checkbox"/> Serious illnesses?	<input type="checkbox"/>	
<input type="checkbox"/> Serious injuries?	<input type="checkbox"/>	
<input type="checkbox"/> Hospital admissions?	<input type="checkbox"/>	
<input type="checkbox"/> Operations? (what, when, where)	<input type="checkbox"/>	
<input type="checkbox"/> Transfusions? (why, when)	<input type="checkbox"/>	
<input type="checkbox"/> Pregnancies? (past, present)	<input type="checkbox"/>	
<input type="checkbox"/> Allergies? (food, drugs, other)	<input type="checkbox"/>	
<input type="checkbox"/> Present medications (kinds, dosage)	<input type="checkbox"/>	
<input type="checkbox"/> Illicit drugs (quality, quantity)	<input type="checkbox"/>	
<input type="checkbox"/> Alcohol (quality, quantity)	<input type="checkbox"/>	
<input type="checkbox"/> Tobacco (quality, quantity)	<input type="checkbox"/>	

LAST PHYSICAL EXAMINATION: _____ DATE: _____ WHY: _____

REVIEW OF SYSTEMS

NEG	POS	COMMENTS	NEG	POS	COMMENTS
CARDIOVASCULAR:			ENDOCRINE:		
<input type="checkbox"/> Angina pectoris	<input type="checkbox"/>		<input type="checkbox"/> Diabetes	<input type="checkbox"/>	
<input type="checkbox"/> Myocardial infarction	<input type="checkbox"/>		<input type="checkbox"/> Adrenal disorders	<input type="checkbox"/>	
<input type="checkbox"/> Congenital heart defect	<input type="checkbox"/>		<input type="checkbox"/> Thyroid disorders	<input type="checkbox"/>	
<input type="checkbox"/> Rheumatic fever	<input type="checkbox"/>		<input type="checkbox"/> Parathyroid disorders	<input type="checkbox"/>	
<input type="checkbox"/> Rheumatic heart disease	<input type="checkbox"/>		<input type="checkbox"/> Steroids	<input type="checkbox"/>	
<input type="checkbox"/> Murmurs	<input type="checkbox"/>		<input type="checkbox"/> Other:	<input type="checkbox"/>	
<input type="checkbox"/> Hypertension	<input type="checkbox"/>		HEMATOPOIETIC		
<input type="checkbox"/> Stroke	<input type="checkbox"/>		<input type="checkbox"/> Anemia	<input type="checkbox"/>	
<input type="checkbox"/> Other:	<input type="checkbox"/>		<input type="checkbox"/> Bleeding disorders	<input type="checkbox"/>	
RESPIRATORY			<input type="checkbox"/> Anticoagulants	<input type="checkbox"/>	
<input type="checkbox"/> Tuberculosis	<input type="checkbox"/>		<input type="checkbox"/> Leukemia	<input type="checkbox"/>	
<input type="checkbox"/> Emphysema	<input type="checkbox"/>		<input type="checkbox"/> Other:	<input type="checkbox"/>	
<input type="checkbox"/> Asthma	<input type="checkbox"/>		NEUROLOGIC:		
<input type="checkbox"/> Shortness of breath	<input type="checkbox"/>		<input type="checkbox"/> Paralysis	<input type="checkbox"/>	
<input type="checkbox"/> Dyspnea on exertion	<input type="checkbox"/>		<input type="checkbox"/> Epilepsy	<input type="checkbox"/>	
<input type="checkbox"/> Orthopnea	<input type="checkbox"/>		<input type="checkbox"/> Convulsions	<input type="checkbox"/>	
<input type="checkbox"/> Edema	<input type="checkbox"/>		<input type="checkbox"/> Psychiatric treatment	<input type="checkbox"/>	
<input type="checkbox"/> Other:	<input type="checkbox"/>		<input type="checkbox"/> Faints/Spells	<input type="checkbox"/>	
MUSCULOSKELETAL:			<input type="checkbox"/> Tranquilizers	<input type="checkbox"/>	
<input type="checkbox"/> Arthritis	<input type="checkbox"/>		<input type="checkbox"/> Other:	<input type="checkbox"/>	
<input type="checkbox"/> Bone Disorders	<input type="checkbox"/>		GASTROINTESTINAL/LIVER		
<input type="checkbox"/> Fractures	<input type="checkbox"/>		<input type="checkbox"/> Ulcers	<input type="checkbox"/>	
<input type="checkbox"/> Muscular Disorders	<input type="checkbox"/>		<input type="checkbox"/> Bleeding	<input type="checkbox"/>	
<input type="checkbox"/> Other:	<input type="checkbox"/>		<input type="checkbox"/> Hepatitis	<input type="checkbox"/>	
GENITOURINARY:			<input type="checkbox"/> Jaundice	<input type="checkbox"/>	
<input type="checkbox"/> Kidney Infections	<input type="checkbox"/>		<input type="checkbox"/> Cirrhosis	<input type="checkbox"/>	
<input type="checkbox"/> Venereal disease	<input type="checkbox"/>		<input type="checkbox"/> Other:	<input type="checkbox"/>	
<input type="checkbox"/> Other:	<input type="checkbox"/>				

Student: _____ Date: _____ Instructor: _____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Index	Date	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	
B M L																																		P1	
B M L																																		G1	

Record # _____ Patient _____

Figure 4: Informed Consent Form

INFORMED CONSENT - FLOSS STUDY

You are being asked to participate in a study of the effectiveness of a new type of dental floss in the removal of and/or prevention of the formation of dental plaque (germs around the teeth).

You are asked to participate because you are an adult with most of your natural teeth and apparently are in good health.

If you decide to participate, you must come for four examinations and three cleanings of your teeth. Each of these will require approximately 30 minutes. A removable stain to disclose plaque will be applied. You will be asked to brush and floss during the study period of about 10 weeks using the materials provided and the exams will measure their effectiveness in removing plaque. You will also be asked to fill out an initial and a final questionnaire.

You may have any necessary dental treatment except tooth cleanings during the study.

You should report to us any antibiotics taken during the study.

You will be paid \$75 at the conclusion of the study provided you miss no appointments.

Your decision not to participate in the study or to withdraw after the study starts will not prejudice your future relations with the University of Alabama School of Dentistry.

If you have any questions, we expect you to ask us. If you have additional questions later, Dr. Menaker can be reached at 934-5424.

You are making a decision whether or not to participate. Your signature indicates you have decided to participate after having read the information above.

Date

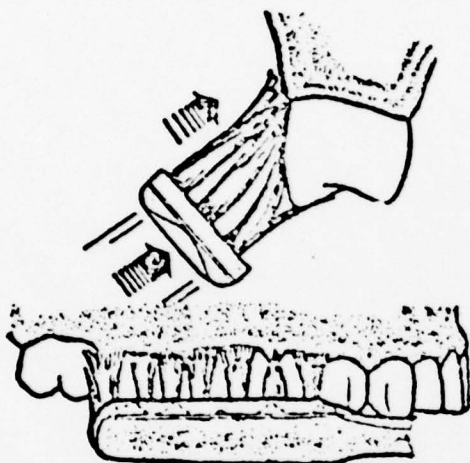
Time

Signature of Witness

Signature

Signature of Investigator

A PROPER TOOTHBRUSHING METHOD



Brush only 3 or 4 teeth at one time with a back-and-forth "wiggle" motion.

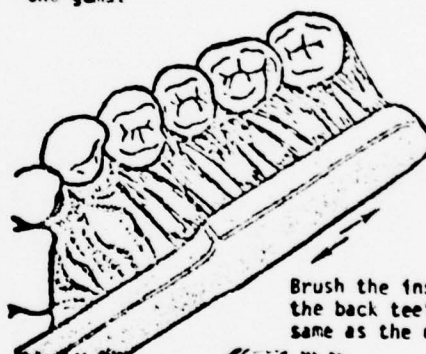


Push the bristles down into the grooves on the chewing surface then brush back-and-forth.



Use the end or tip of the brush to clean the corners.

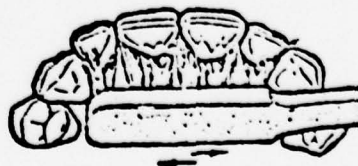
Use a "soft" brush with a flat brushing surface. Place the brush on the tooth at an angle toward the gums where the tooth meets the gums. Push the brush against the tooth to help the bristles spread out. Gently "wiggle" the brush without removing it from the tooth. The bristles should be half on the tooth and half on the gums. This will clean the tooth, the space between the tooth and gums and provide stimulation to the gums.



Brush the inside of the back teeth the same as the outside.



Brush the inside of the front teeth with the tip of the brush.



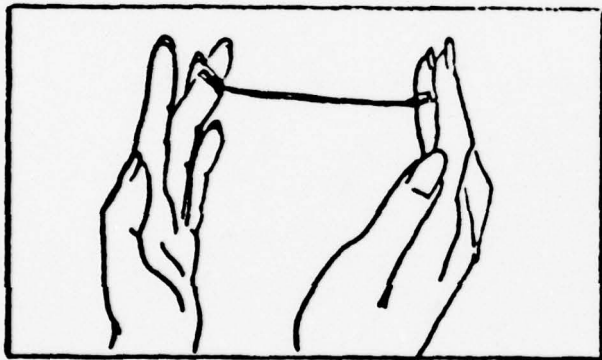
Sometimes you can place the brush flat on the inside if you have a wide jaw.

Your dentist or dental hygienist should determine the best method of toothbrushing for you. The above method is one that is frequently recommended.

Using Floss

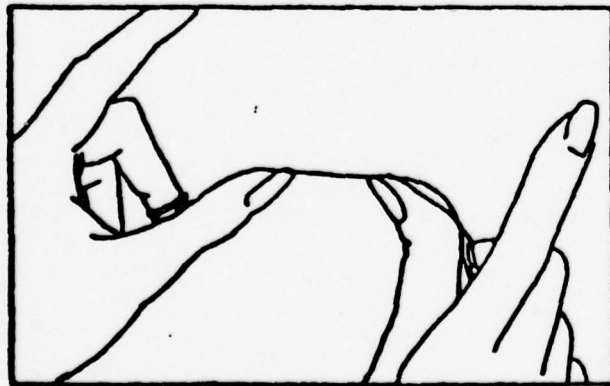
Flossing removes plaque and debris from between the teeth especially near the gum line. It's important that you use floss to clean these areas thoroughly because tooth decay and gum disease often start in these areas where your toothbrush can't reach.

Flossing is a skill that can be developed with a little practice. Don't be discouraged with your first flossing attempt; after a few days flossing you will take only a few minutes of your time.

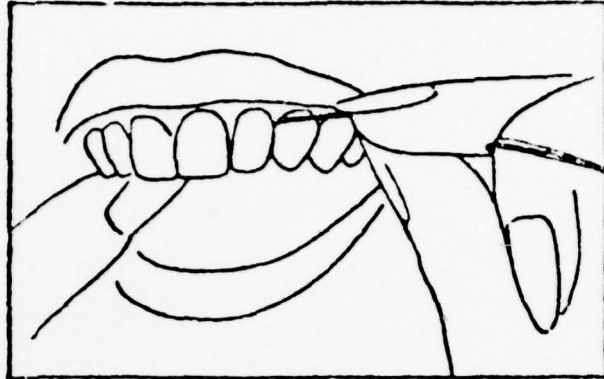


1. Break off about 18 inches of floss and wind most of it around one of your middle fingers.

2. Wind the rest around the same finger of the opposite hand. This finger can "take up" the floss as it becomes soiled.



3. Use your thumbs and forefingers with an inch of floss between them to guide the floss between your teeth.



4. Holding the floss tightly (there should be no slack), use a gentle sawing motion to insert the floss between your teeth. Never "snap" the floss into the gums! When the floss reaches the gum line curve it into a C-shape against one tooth and gently slide it into the space between the gum and the tooth until you feel resistance.

5. While holding the floss tightly against the tooth, move the floss away from the gum by scraping the floss up and down against the side of the tooth.

6. Repeat this method on the rest of your teeth.

Hints

Establish a regular time and pattern for flossing, so you won't miss any of your teeth, any day.

You may experience some bleeding and soreness the first few times you floss. As the plaque is broken up and the bacteria is removed, healing of the gums begins and bleeding will stop. If it does not do so in a few days, contact your dentist.

Remember to be gentle when inserting floss between your teeth and under the gum line.

Figure 5: Legend

STRETCHABLE INTERDENTAL CLEANSING TAPE

Oral hygiene doesn't end with your toothbrush. There are certain places in your mouth that toothbrushes can't reach -- between the teeth. To reach these spaces you need dental floss. Like the toothbrush, floss must be used correctly in order to be effective as an oral hygiene device.

You are about to see a new and different floss designed to clean the in-between areas of your mouth. It's different because it stretches in a unique way. Once you pull it open, it stays there.

In addition, the stretchable ribbon is coated with a tacky cleansing agent. The surface is protected by a paper covering that must be removed before using the floss.

To use the stretchable tape, locate the break mark on the strip. Hold the strip with both hands near the break mark and twist, using a slight pulling motion. To separate the paper from the ribbon, pull downward with one hand and work the paper free. Once the paper is removed, grasp the tape firmly at both ends and pull smoothly until firm resistance is felt.

The tape is now ready to use -- just like dental floss.

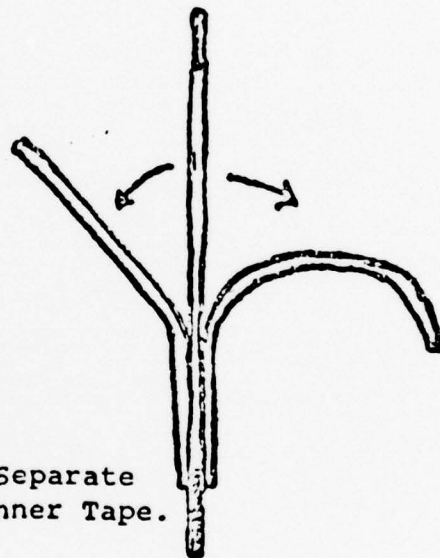
Directions for Use of the Interdental Stretchable Cleansing Tape



Tab

Coated Tape

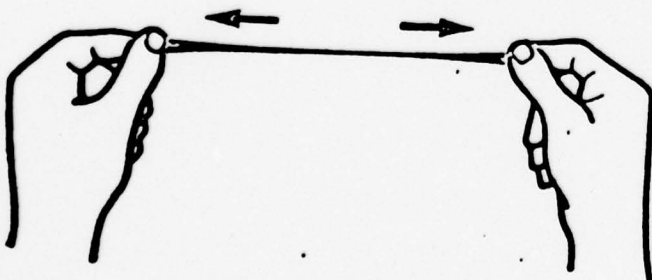
Paper Liners



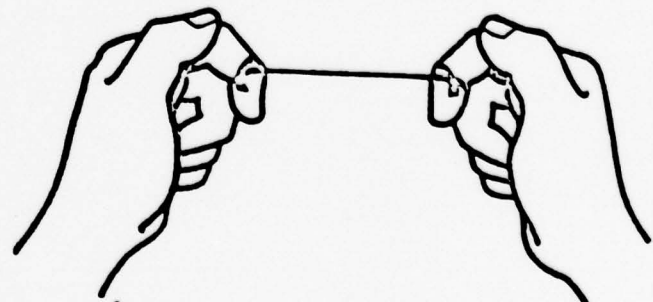
1. Locate Colored Tab.

2. Bent Tab to Separate and Expose Inner Tape.

3. Peel Back and Completely Remove Paper Liners.



4. Grasp Ribbon where the tabs Overlap and Pull Smoothly Until Resistance is Felt.



5. Starting From One End, Wind a Small Amount of Ribbon Around Your Index Fingers and Use Like Dental Floss.

Figure 6: Pre-test Questionnaire

PRE-TEST QUESTIONNAIRE

1. What statement best describes your attitude toward practicing oral hygiene (check only one).
 - I want to avoid big dental bills
 - Good oral hygiene keeps your breath fresh
 - I want to keep my mouth healthy
 - It's a habit I developed as a child
 - I don't want to have dentures
 - In the long run, oral hygiene doesn't make any difference

2. What statement best describes your reason for practicing oral hygiene measures (check only one)
 - Remove annoying food debris
 - Keep my teeth white
 - Remove harmful bacteria
 - Keep my gums firm and healthy
 - Control dental plaque
 - Don't know

3. What statement best described your regular, daily hygiene routine (check only one)
 - Brushing usually once a day
 - Brushing after every meal
 - Brushing morning and night
 - Regular brushing plus flossing every day

3. (Continued)

- Regular brushing with occasional flossing
- Occasional brushing with occasional flossing

4. What type of toothbrush do you prefer to use (check only one).

- Hard
- Medium
- Soft
- Don't care

5. In general, how would you rate your regular oral hygiene habits (check only one)

- Better than average
- Good
- Poor
- Sporadic but suits my needs

6. What statement best describes your experience with dental floss (check only one).

- Never used it
- Use it regularly at least once a day
- Use it occasionally to remove food
- Used it regularly at one time but now only when I feel like it

7. Have you ever been given formal instruction by a dental hygienist or dentist on how to brush (check only one).

- Yes

7. (Continued)

- No
- Don't remember

8. Has the use of dental floss ever been recommended to you by a dentist or hygienist (check only one).

- Yes
- No
- Don't remember

9. The purpose of flossing is to (check only one).

- Keep the gums healthy
- Remove plaque where the brush can't go
- Remove food debris caught between the teeth
- Don't know

10. Do you now use dental floss on a regular, daily basis (check only one).

- Yes
- No

11. Probably the reason why few people regularly use dental floss is (check only one).

- Too expensive
- Hard to carry with you
- Too hard to use
- Doesn't work
- Hurts to use it
- No opinion

12. Do you have a preference for tape floss over thread (check only one).

- Yes
- No
- No opinion

13. Have you ever tried using a floss holder or threader (check only one).

- Yes
- No
- No opinion

14. Which kind of dental floss is best for you (check only one).

- Waxed
- Unwaxed
- The cheapest
- They are all the same
- Don't know

15. What statement best describes why you would discard your present toothbrush (check only one).

- I got tired of looking at it
- The bristles got all matted
- I lost it
- My dentist recommended a different brush
- I found one I liked better
- No opinion

16. The most effective program of oral hygiene is (check only one).

- Regular brushing after every meal
- Brushing twice a day
- Brushing at least once a day and avoiding sweets
- Brushing twice a day plus daily flossing
- Brushing plus the Water Pic every day
- Flossing and the Water Pic every day

17. If the average roll of dental floss is 50 yards, how long should the roll last (check only one).

- | | | |
|-----------------------------------|--|-------------------------------------|
| <input type="checkbox"/> 6 months | <input type="checkbox"/> 2 months | <input type="checkbox"/> 1 month |
| <input type="checkbox"/> 3 months | <input type="checkbox"/> 2 weeks or less | <input type="checkbox"/> No opinion |

Figure 7: Post-test Questionnaire

STRETCHABLE INTERDENTAL CLEANSING TAPE

INSTRUCTIONS: After answering the questions below, insert the folded questionnaire into the postage-paid envelope and mail.

1. What was your very first reaction to seeing a demonstration of the stretchable dental cleaning tape (choose only one).
 - Looked interesting enough to try
 - Looked like a major improvement over dental floss
 - Looked more difficult to use than dental floss
 - Looked like it wouldn't work as good as floss
 - No opinion

2. After using the stretchable tape for a few weeks, what statement best describes your feelings about the product (choose only one).
 - I liked it better the more I used it
 - Liked it at first but found it was too hard to use
 - It seems to be a lot easier to use than floss
 - I like dental floss better
 - No opinion

3. Circle the number of those statements below which reflect your feelings towards the stretchable dental ribbon.
 1. It doesn't fray like floss

3. (Continued)

2. It's easier to use than floss
3. It doesn't make my gums bleed when I use it
4. It does a better job than regular floss
5. It's more convenient to carry away from home
6. No opinion

4. The following statements may reflect your reaction to the use of the stretchable dental cleaning tape. Circle those statements which, based on your experience with the tape, you feel are true.

1. The tape doesn't stretch far enough
2. The coating comes off on my teeth
3. The strip tends to break when I use it
4. It takes too many strips to floss my teeth
5. The tape gets twisted on itself when I use it
6. It cuts my gums when I use it
7. Tape doesn't stretch far enough
8. It won't get in between certain teeth
9. The tape doesn't feel like it's cleaning like it should
10. It tends to stick to itself too much
11. Too hard to pull open
12. Package is bulky and difficult to carry
13. Not as easy to use as floss
14. The strip is too long

4. (Continued)

- 15. Too hard to get the paper off
- 16. Can't hold it in my fingers
- 17. Tastes funny

5. What statement best describes your reaction to the stretchable dental cleaning tape (check only one).

- I liked the idea but it was just about as good as regular floss
- I had difficulty using it at first but now prefer it to regular floss
- It makes the job of flossing a lot easier
- The stretchable tape is too difficult to use compared to regular floss
- It's a good idea but it just doesn't work
- No opinion
- The stretchable material felt softer and gentler in my mouth
- Regular dental floss may be hard to use, but I think it cleans better

6. Select TWO words from the list below that you feel best describes the stretchable tape.

- | | | | |
|--------------------------|---------|--------------------------|------------|
| <input type="checkbox"/> | Awkward | <input type="checkbox"/> | Convenient |
| <input type="checkbox"/> | Easy | <input type="checkbox"/> | Novelty |
| <input type="checkbox"/> | Sticky | <input type="checkbox"/> | Quick |
| <input type="checkbox"/> | Logical | <input type="checkbox"/> | Soft |
| <input type="checkbox"/> | Better | <input type="checkbox"/> | Clean |
| <input type="checkbox"/> | Handy | <input type="checkbox"/> | Sensible |
| <input type="checkbox"/> | Messy | <input type="checkbox"/> | Gentle |

7. I would have liked the stretchable tape better if:

- It was flavored

Results - Clinical Data:

Gingivitis and plaque scores for each tooth were averaged for each patient. This data was then entered for each of the four treatments: base line data (B), no floss (N), conventional floss (F) and elastomeric tape (T). A simple one way analysis of variance was accomplished with tape vs. conventional floss and then against all four treatments. The results are shown below in Tables 1 and 2.

Table 1 - Plaque*

Group	Mean	StD (corr)	StD/mean
B	1.074	0.598	0.56
N	1.119	0.535	0.48
T	0.930	0.516	0.55
F	0.884	0.627	0.71

Analysis of Variance

Source	Sum of Sqs	d.f.	mean sq.	F ratio	Cum Prop
Between	1.41	3	0.47	1.4	F(3,120)
Within	46.93	144	0.33		
Total	48.34	147			0.75

*Sample size: 37 subjects, 28 teeth, 3 surfaces scored for plaque times four treatments.

Raw scores are averaged over tooth surface so that each entering measure represents 84 observations.

Table 2 - Gingivitis*

Group	Mean	StD (corr)	StD/mean
B	1.497	0.405	0.27
N	1.470	0.391	0.27
T	1.414	0.355	0.25
F	1.422	0.331	0.23

Analysis of Variance

Source	Sum of Sqs.	d.f.	Mean Sq.	F Ratio	Cum Prop
Between	0.18	3	0.06	0.4	F(3,120)
Within	19.91	144	0.14		0.25
Total	20.09	147			

*Sample size: 37 subjects, 28 teeth, 3 surfaces scored for gingivitis times four treatments.

Raw scores are averaged over tooth and surface so that each entering measure represents 84 observations.

Discussion:

Since the range of treatment means is in all cases less than half the minimum StD of the individual groups compared and analysis of variance produces F ratios well below 95% confidence (25 to 75%), it seems unrewarding to sort these data out in greater detail.

While observations of plaque and gingivitis each fall into few discrete classes and are perhaps somewhat subjective (suggesting use of non-parametric statistics), the use of averages over 28 to 84 surfaces and treatment of such means as single observations in computing degrees of freedom seems very conservative and should justify the use of analysis of variance and related statistics.

It must be concluded from these data that there are no significant differences between the treatment groups.

Results Questionnaires

PRE-STUDY QUESTIONNAIRE

1. What statement best describes your attitude toward practicing oral hygiene (check only one).

91.9 I want to keep my mouth healthy
5.4 It's a habit I developed as a child
2.7 I want to avoid big dental bills
0.0 Good oral hygiene keeps your breath fresh
0.0 I don't want to have dentures
0.0 In the long run, oral hygiene doesn't make any difference

2. What statement best describes your reason for practicing oral hygiene measures (check only one)

32.4 Keep my gums firm and healthy
24.3 Remove harmful bacteria
24.3 Control dental plaque
10.8 Keep my teeth white
8.1 Remove annoying food debris
0.0 Don't know

3. What statement best described your regular, daily hygiene routine (check only one)

43.2 Regular brushing plus flossing every day
43.2 Regular brushing with occasional flossing
10.8 Brushing morning and night
2.7 Brushing usually once a day
0.0 Brushing after every meal
0.0 Occasional brushing with occasional flossing

Results Questionnaire

4. What type of toothbrush do you prefer to use (check only one)
- 54.1 Medium
- 43.2 Soft
- 2.7 Hard
- 0.0 Don't care
5. In general, how would you rate your regular oral hygiene habits (check only one)
- 64.9 Good
- 35.1 Better than average
- 0.0 Poor
- 0.0 Sporadic but suits my needs
6. What statement best describes your experience with dental floss (check only one)
- 54.1 Use it regularly at least once a day
- 21.6 Use it occasionally to remove food
- 18.9 Used it regularly at one time but now only when I feel like it
- 5.4 Never used it
7. Have you ever been given formal instruction by a dental hygienist or dentist on how to brush (check only one)
- 86.5 Yes
- 13.5 No
- 0.0 Don't remember

Results Questionnaire

8. Has the use of dental floss ever been recommended to you by a dentist or hygienist (check only one)
- 83.8 Yes
16.2 No
0.0 Don't remember
9. The purpose of flossing is to (check only one)
- 70.3 Remove plaque where the brush can't go
27.0 Remove food debris caught between the teeth
2.7 Keep the gums healthy
0.0 Don't know
10. Do you now use dental floss on a regular, daily basis (check only one)
- 56.8 Yes
43.2 No
11. Probably the reason why few people regularly use dental floss is (check only one)
- 68.6 Too hard to use
20.0 No opinion
8.6 Hurts to use it
2.9 Hard to carry with you
0.0 Too expensive
0.0 Doesn't work
12. Do you have a preference for tape floss over thread (check only one)
- 43.2 No opinion

Results Questionnaire

13. Have you ever tried using a floss holder or threader (check only one)
- 81.1 No
- 16.2 Yes
- 2.7 No opinion
14. Which kind of dental floss is best for you (check only one)
- 43.2 Waxed
- 35.1 Unwaxed
- 16.2 Don't know
- 2.7 The cheapest
- 2.7 They are all the same
15. What statement best describes why you would discard your present toothbrush (check only one)
- 43.2 The bristles got all matted
- 24.3 My dentist recommended a different brush
- 21.6 I found one I liked better
- 8.1 No opinion
- 2.7 I got tired of looking at it
- 0.0 I lost it
16. The most effective program of oral hygiene is (check only one)
- Brushing twice a day plus daily
- Regular brushing after every meal

Results Questionnaire

16. (Continued)

- 2.7 Brushing at least once a day
 and avoiding sweets
- 0.0 Brushing twice daily
- 0.0 Brushing plus the Water Pic
 every day
- 0.0 Flossing and the Water Pic every
 day

17. If the average roll of dental floss is
50 yards, how long should the roll last
(check only one)

- 51.4 3 months
- 13.5 6 months
- 13.5 1 month
- 13.5 No opinion
- 5.4 2 months
- 2.7 2 weeks or less

Results Questionnaire

Final Test Questionnaire

STRETCHABLE INTERDENTAL CLEANSING TAPE

1. What was your very first reaction to seeing a demonstration of the stretchable dental cleaning tape (check only one)
 - 78.4 Looked interesting enough to try
 - 16.2 Looked more difficult to use than dental floss
 - 5.4 No opinion
 - 0.0 Looked like a major improvement over dental floss
 - 0.0 Looked like it wouldn't work as good as floss

2. After using the stretchable tape for a few weeks, what statement best describes your feelings about the product (check only one)
 - 48.7 I like dental floss better
 - 24.3 Liked it at first but found it was too hard to use
 - 16.2 I liked it better the more I used it
 - 8.1 It seems to be a lot easier to use than floss
 - 2.7 No opinion

3. Circle the number of those statements below which reflect your feelings towards the stretchable dental ribbon
 - 36.7 It doesn't fray like floss
 - 24.5 No opinion

Results Questionnaire

3. (Continued)

- 16.3 It doesn't make my gums bleed when I use it
- 10.2 It does a better job than regular floss
- 8.2 It's easier to use than floss
- 4.1 It's more convenient to carry away from home

4. The following statements may reflect your reaction to the use of the stretchable dental cleaning tape. Circle those statements which, based on your experience with the tape, you feel are true.

- 15.9 The tape gets twisted on itself when I use it
- 14.2 The strip tends to break when I use it
- 13.3 It tends to stick to itself too much
- 10.6 Not as easy to use than floss
- 9.7 It won't get in between certain teeth
- 8.0 The tape doesn't feel like its cleaning like it should
- 7.1 The coating comes off on my teeth
- 6.2 It takes too many strips to floss my teeth
- 5.3 It cuts my gums when I use it
- 4.4 The tape doesn't stretch far enough
- 1.8 Tape doesn't stretch far enough
- 1.7 Can't hold it in my fingers
- 0.9 The strip is too long

Results Questionnaire

4. (Continued)

- 0.9 Tastes funny
- 0.0 Too hard to pull open
- 0.0 Package is bulky and difficult to carry
- 0.0 Too hard to get the paper off

5. What statement best describes your reaction to the stretchable dental cleaning tape (check only one)

- 32.4 The stretchable tape is too difficult to use compared to regular floss
- 18.9 I liked the idea but it was just about as good as regular floss
- 13.5 Regular dental floss may be hard to use, but I think it cleans better
- 10.8 No opinion
- 10.8 The stretchable material felt softer and gentler in my mouth
- 8.1 It's a good idea but it just doesn't work
- 5.4 It makes the job of flossing a lot easier
- 0.0 I had difficulty using it at first but now prefer it to regular floss

6. Select TWO words from the list below that you feel best describe the stretchable tape

- | | | | |
|-------------|------------|------------|----------|
| <u>20.8</u> | Sticky | <u>5.4</u> | Easy |
| <u>20.3</u> | Awkward | <u>4.5</u> | Clean |
| <u>16.5</u> | Novelty | <u>2.9</u> | Better |
| <u>7.3</u> | Convenient | <u>1.5</u> | Quick |
| <u>6.6</u> | Messy | <u>1.5</u> | Sensible |
| <u>6.6</u> | Soft | <u>1.5</u> | Gentle |
| <u>5.7</u> | Handy | <u>0.0</u> | Logical |

Results Questionnaire

7. I would have liked the stretchable tape better if

50.0 Wasn't sticky

17.7 It came on a roll

17.7 Didn't stretch

14.7 It was flavored

8. Assuming on a scale of 1 to 10 that regular dental floss would be a 5, how would you rate the stretch tape (circle number)

1	2	3	4	5	6	7	8	9	10
Worse									Best
10.8	10.8	27.0	21.6	10.8	8.1	5.4	2.7	2.7	0.0

$x = 3.86$ S.D. = 1.95 Var. = 3.68

Discussion-Questionnaires

The subject population was recruited from the staff at the University of Alabama Medical Center. There were 24 females and 13 males whose mean age was 28.38 years. A pre-study questionnaire was handed out to all of the volunteers at the beginning of the study. A final questionnaire was issued to each subject after using the elastomeric ribbon for three weeks. (See page 8 and 9)

The pre-study questionnaire profiled the population to possess a better than average oral health education and habits. 96% of the population brush daily and 86.5% had received some past professional instructions on how to brush. All but one subject used either a medium or soft textured toothbrush and were highly motivated. 70.3% of the subjects recognized the need to floss where the toothbrush couldn't reach. A majority had received professional recommendation to floss and 57% of the population "flossed" on a regular daily basis. 43% used waxed floss and 35% used unwaxed floss. Most had no opinion as to a preference of tape floss over thread. Few had used either a floss holder or threader.

The results of the final questionnaire expressed an overall negative response to the elastomeric ribbon. 78.4% of the subjects were visually interested to experiment with it but preferred the thread floss after using it. The chief problems were in the tackiness of the ribbon and its difficulty in use. Half of the population felt the elastomeric ribbon could be improved without the sticky feature. Few objected to the stretching properties; however, some prefer it to be stronger. 36.7% of the population recognized the ribbon's non-fraying characteristics but found no advantage to its portability. On a scale from 1 to 10 with conventional thread floss at 5, the population mean score for the elastomeric ribbon was 3.84. (See page 30 through 38).

Conclusion

A study was conducted to determine the clinical effectiveness of a coated, elastomeric dental ribbon as a suitable substitute for conventional dental floss. Thirty seven healthy volunteer patients with at least 28 teeth and no overt oral pathoses participated. After a screening examination and a cleaning, baseline data was collected for gingivitis and plaque accumulation. Using a computer generated randomization table, each patient went through a three week period using no floss, conventional floss or the coated elastomeric ribbon. Gingivitis and plaque scores were collected after each treatment period and statistically analyzed.

The range of treatment means was in all cases less than half the minimum standard deviation of the individual groups being compared and analysis of variance produced F ratios well below the 95% confidence level. It is concluded that no differences exist between floss and elastomeric tape for plaque removal and/or the ability to control gingivitis.

Recommendations

1. Because there appears to be no difference for plaque removal and/or the ability to control gingivitis, the elastomeric ribbon appears to be a viable option for interproximal cleansing.
2. Due to objections to the stickiness of the elastomeric ribbon, a replacement adhesive with a lower level of tact (a ribbon with no adhesive) should be investigated.
3. The subject population found no advantage to the portability of the individual strips. Therefore, a return to a coiled or rolled configuration employing a single release liner should be re-investigated.
4. If a prototype is developed without an adhesive coating, the need for paper cover protection and after use waste would be eliminated.



HAZLETON
LABORATORIES AMERICA, INC.

8200 LEESBURG TURNPIKE, VIENNA, VIRGINIA 22182, U.S.A.

Appendix A Product Safety Data Report

Page 41

August 14, 1978

Mr. Joseph Alexander
Cooper Laboratories, Inc.
110 East Hanover Avenue
Cedar Knolls, New Jersey 07927

Dear Mr. Alexander:

As you requested, I have enclosed the pathology summary and histopathology incidence table for Hazleton Laboratories Project No. 2031-118, a Mucous Membrane Irritation Study in Hamsters with Stretchable Dental Tape Strips.

At necropsy, all cheek pouches were observed to be normal.

Should you have any questions or comments regarding this information, please do not hesitate to contact me. You should receive the final report by the end of the month.

Sincerely,

DAVID G. SEROTA, Ph.D.
Project Coordinator
Toxicology Department

DGS/pl
Enclosures

Appendix A - Continued

The interdental cleansing tape is a stretchable ribbon made from a polyester elastomer film. In it's present stage of development, the tape is protected with two release liners to maintain the integrity of an adhesive-polishing agent coating both sides. Outlined below is available information we have on the sub-components of the product, their toxicological and storage capacities.

The film is a Dupont product called Hytrel 5556. This material is a thermoplastic polyester elasomer whose numbers specify both its inherit hardness and viscosity in the molten state. Its hardness lays between hard rubber and less rigid plastic. It is based on 1,4 butanediol, terephthalic acid and poly-tetramethylene ether glycol, all of which are derived from petroleum. Toxicological data indicates its relative inertness in the animal model.

Appendix A - Continued

I. Polyester Elastomer Hytrel

*A.L.D. (rats) greater than 25.0 gm/Kg body weight

II. It Components

- a. Terephthalic acid LD50 (rats) greater than 6.4 gm/Kg body weight. It's composed 40.6% of the film.
- b. Polytetramethylene ether glycol A.L.D. (rats) greater than 11.0 gm/Kg body weight. It's composed 35.5% of the film.
- c. 1,4 butanediol L.D. 50 (rats) 1.78 gm/Kg body weight. It's composed 23.9% of the film.
- d. **Irganox 1098 L.D. 50 (rats) greater than 5.0 gm/Kg body weight. It's composed 0.2% of the film.

Dupont and Underwriter Laboratories have defined Hytrel's physical properties and its capacity to handle stress under various conditions. The 55D durometer elastomer has the best combination of both high and low temperature properties ranging from 51°C to 149°C. Combined are such features as resilience, high resistance to deformation under moderate strain conditions, outstanding flex-fatigue resistance, good abrasion resistance, retention of flexibility at low temperature and good retention of properties at elevated temperature.

* Assumed Lethal Dose

** Irganox 1098 is a product of Ciba-Geigy and is added to Ilytrel as an antioxidant, used for color stability

Appendix A - Continued

The tacky substance on both sides of the ribbon is a mixture of an adhesive and a polishing agent. The adhesive is a product of Avery International, who is involved with a number of health-related items. The material is a straight chain single acrylate copolymer. It has no cross linking and has met F.D.A. approval.

1. Dosage

A. Acute LD ₅₀	Rats	Greater than 10.0 gm/Kg body weight
B. Single Dose Skin Application for 24 hours	Rabbits	7.94 gm/Kg body weight (greatest dosage tested)

2. Dermal Irritation

A. Acute Irritation Test (Draize Scoring Criteria)	Rabbits	<u>Intact Skin</u> - mild irritants no edema at 24 hours. No irritants, no edema at 48 hours. <u>Abraded Skin</u> - mild irritant no edema at 24 hours, no irritants, no edema at 48 hours.
B. Repeated Insult Human Patch Test (Schwartz-Peck Scale)		12 out of 55 subjects showed some form of erythema during 15 repeated 24 hour exposure. All subjects show no sensitization to the adhesive when challenged after a 14 hour rest period.

3. Eye Conjunction Sac Rabbit Test

Average score of 11.7 on a scale of 110 at 24, 48 and hours with 100 microliter of undiluted adhesive.

*The adhesive is applied at 10 grains per 24 sq.inch. Therefore, a 3/16 inch x 4 inch strip would have 0.020 grams of adhesive.

Appendix A - Continued

Data has shown the adhesive to not be affected at with 50% humidity at 23°C for up to 2 years. Accelerated age testing of the material at 48°C and 71°C for three months have shown little effect. The acrylic polymer is already completely oxidized to the acid state making it non-reactant. The polishing agent is commercially known as "Gammadent". Chemically it is Calcium peroxide.

The paper release liner is a densified, semi-blank kraft paper. Its coating helps maintain the integrity of the adhesive. It is a food approved polymer called polysiloxane. It contains no tin but catalyzed with a small amount of platinum, will initiate an additive reaction, causing the silicon polymer to self cross link with one another. Couple this with a dense paper, a good barrier is established to protect the product.

Distribution List:

4 copies

HQDA (SGRD-AJ/Mrs. Madigan)
US Army Medical Research and
Development Command
SGRD-AJ,
Fort Detrick, Frederick,
Maryland, 21701

12 copies

Defense Documentation Center
(DDC)
ATTN: DDC-TCA
Cameron Station
Alexandria, Virginia 22314