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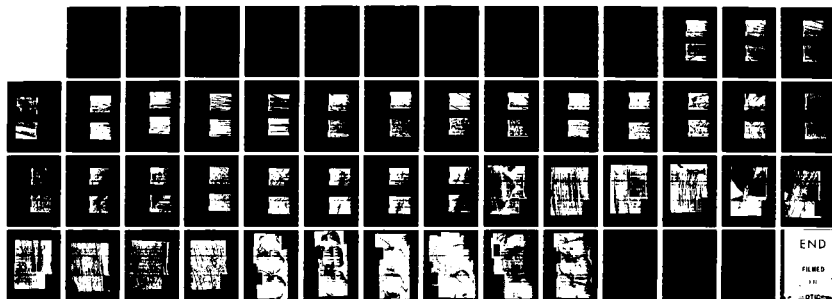
USE AND EFFECTIVENESS OF A COATED ELASTOMERIC DENTAL
RIBBON COMPARED TO C. (U) COOPER LABS INC CEDAR KNOLLS
NJ C GARBER ET AL. OCT 80 DAMD17-78-C-8084

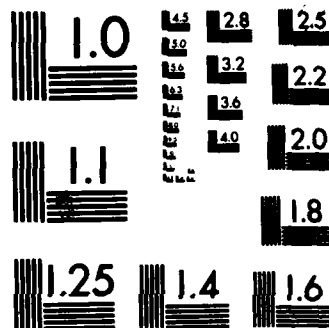
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REPORT #3

USE AND EFFECTIVENESS OF A COATED, ELASTOMERIC
DENTAL RIBBON COMPARED TO CONVENTIONAL DENTAL
FLOSS. Characterization of Dental Floss:
Before, During and After Use

Charles Garber, Ph. D.
Gary J. Shemaka, B.S.*

Structure Probe, Inc., Metuchen, New Jersey 08840
*Cooper Research Center, Mountain View, California 94043

October, 1980

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

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER Three	2. GOVT ACCESSION NO. AD-A130759	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) USE AND EFFECTIVENESS OF A COATED, ELASTOMERIC DENTAL RIBBON COMPARED TO CONVENTIONAL DENTAL FLOSS. Characterization of Dental Floss: before , During and After Use		5. TYPE OF REPORT & PERIOD COVERED Final, October, 1980
7. AUTHOR(s) Charles Garber, Ph.D. *Gary J. Shemaka, B.S.		6. PERFORMING ORG. REPORT NUMBER
9. PERFORMING ORGANIZATION NAME AND ADDRESS Structure Probe, Inc., Metuchan, New Jersey 08840 - *Cooper Research Center, Mountain View, CA. 94043		8. CONTRACT OR GRANT NUMBER(s) DAMD 17-78-C-8084
11. CONTROLLING OFFICE NAME AND ADDRESS Cooper Laboratories, Inc. Research & Development Division Cedar Knolls, N.J. 07927		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
14. MONITORING AGENCY NAME & ADDRESS (If different from Controlling Office)		12. REPORT DATE October, 1980
		13. NUMBER OF PAGES 53
		15. SECURITY CLASS. (of this report)
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited.		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Dental Floss, Scanning Electron Microscope		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) 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 compare the effectiveness of various types of floss. It has been suggested that unwaxed 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.

Dr. Paul Jaffe, ^{has been developed} with the cooperation of Cooper Laboratories, Inc. has developed a new dental ribbon consisting of a polyester film coated with a tacky adhesive. Employing the expertise of Structure Probe, Inc., the current study was designed to observe the performance of this new product in comparison to two conventional thread products. By direct observation with the scanning and transmission electron microcopies we hoped to understand their mode of cleansing action and structural deterioration during use in the oral cavity.

Overall the unwaxed thread floss best illustrated its performance in the oral cavity. Free-flying fibers rubbed, pinched, and entrapped material along and between individual filaments. The waxed thread floss performed the same way but to a lesser extent. Due to the waxy layer, the movement of individual fibers were limited and the amount of inter-fiber space reduced. However, this waxy coating kept the thread intact during positioning and the amount of fraying was reduced in comparison to its unwaxed counterpart. This waxy layer was visually smoother after use. Some material remained on the tooth after flossing with waxed floss but one could not distinguish whether it was residual wax or missed bacterial growth.

Jaffe Dental Ribbon showed little deterioration during usage. Before use, the abrasive particles were completely embedded and well distributed in the adhesive layer. After use, these particles projected out of the film as they rubbed and disrupted interproximal deposits. The ribbon positioned well due to its flat elongated configuration. Unlike its thread counterparts, no fraying or breakage was observed.

Upon reviewing the procedures for this study we found that SEM results of actual floss samples before and after were best contrasted with air dried samples rather than gluteraldehyde fixed samples. The fixed specimens showed little change due to either chemical degradation or experimental sample heterogeneities. SEM examination of replica models gave some detail of structure and performance but a study of more replicas would be needed before a judgement could be made for superiority. Like the actual samples, it was difficult to discriminate the thread waxy coat or the ribbon adhesive layer from the material being removed. For the TEM work, only the dry samples could be studied. In spite of numerous attempts, suitable sections could not be obtained. It was suspected that areas containing debris material were not sufficiently stable in the electron beam.

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REPORT #3

USE AND EFFECTIVENESS OF A COATED, ELASTOMERIC
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Cooper Laboratories
110 E. Hanover Avenue
Cedar Knolls, New Jersey 17927

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SUMMARY

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.

Dr. Paul Jaffe, with the cooperation of Cooper Laboratories, has developed a new dental ribbon consisting of a polyester film coated with a tacky adhesive. Employing the expertise of Structure Probe, Inc., the current study was designed to observe the performance of this new product in comparison to two conventional thread products. By direct observation with the scanning and transmission electron microcopies we hoped to understand their mode of cleansing action and structural deterioration during use in the oral cavity.

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BODY OF-THE REPORT:

Title: Characterization of Dental Floss: Before, During, and After Use.

STATEMENT OF THE PROBLEM:

The regular use of dental floss to remove interproximal plaque accumulations is an important factor in controlling dental disease. Employing the scanning and transmission electron microscopes, this study was an attempt to compare and contrast the performance of three types of dental floss. By direct observation, it was our objective to see not only how the various types of floss changed during use but also give some insight into the mechanism of plaque pick-up.

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.

Dr. Paul Jaffe, with the cooperation of Cooper Laboratories, has developed a new dental ribbon consisting of a polyester film coated with a tacky adhesive. Employing the expertise of Structure Probe, Inc., the current study was designed to observe the performance of this new product in comparison to two conventional thread products.

METHODS AND MATERIALS

A. Personnel

Mr. Joseph Alexander, M.S.
Dr. Charles Garber, Ph.D.
Ms. Cheryl Husack, B.S.
Ms. Robin Mintz, R.D.H.
Mr. Gary Shemaka, B.S.

B. Sample Selection

G. Shemaka and J. Alexander volunteered their dentition for the replica studies. Due to the high viscosity of the replica polymer and a need to carefully position the floss before and after use, the mandibular anterior teeth were selected as a study site. Wet and dry floss samples were provided by the same subjects. To assure an adequate amount of plaque,

samples were taken from around the mandibular pre-molars and molars. All clinical materials were positioned and taken by a registered dental hygienist.

C. Floss Material

1. Oral-B Unwaxed Thread Floss
2. Johnson & Johnson Waxed Thread Floss
3. Jaffe Dental Ribbon

D. SEM Replica Studies

1. Preparation of Negative Replicas

The negative replicas were made using a specially prepared silicone polymer replicating system. This particular polymerized system was set-up in 30 to 60 seconds.

2. Preparation of Positive Replicas

The positive replicating material was melted carefully against the negative, in order to avoid or minimize replicating artifacts such as air bubbles. Each set of positives was examined optically before SEM examination to assure the final quality of the replicas.

3. Microscopy

The SEM used for this study was the JEOL Model #JSM-U3, sold in the United States by JEOL (USA), Inc., Medford, Maine. The instrument was also equipped with a television rapid scan which made it possible to visually "search" over larger distances of positive replica. In addition, this particular SEM has been modified with a special low magnification/low distortion coil, so that there is virtually no distortion visible in the montages, and the individual fields fit together in a distortion-free manner.

E. Transmission and Scanning Electron Microscopy on Before and After Floss Products

1. Sample Preparation

Samples were put alone into dry vials, and into vials containing an 8% aqueous solution of "electron microscopy" grade gluteraldehyde. There was some concern about what the gluteraldehyde might do to either the wax (on the Waxed Floss) or the adhesive (on Jaffe Dental Ribbon).

For the SEM work, the "dry" samples were mounted on a standard SEM mount, metallized with a 200-300 angstrom layer of 60% gold/40% lead alloy, and photographed. The gluteraldehyde-treated samples were permitted to air dry-mounted, and processed in the same way.

For the TEM work, the "dry" samples were used. The wet (gluteraldehyde-treated) samples would have required an alcohol dehydration, and a simple test showed that alcohol was dissolving the tape's adhesive. Hence, the decision was made to work with the dry samples only.

The preparation procedure used for the dry samples was as follows:

- a) Vapor stained with OsO_4 for 12 hours
- b) Gold coated (encapsulated) entire circumference of floss
- c) Sample embedded in Epon 812 epoxy for longitudinal staining
- d) Diamond knife thin-sectioning as longitudinal sections

2. Electron Microscopy

The SEM work was done on a JEOL Model JSM-U3 SEM.

The TEM work was done on an RCA EMU 4-B.

RESULTS

Results are illustrated in photocopied Figures 1-41. The only set of photographs were forwarded to Colonel William R. Posey at the U.S. Army Dental Research Unit at Fort Detrick, Maryland. They are indexed as follows:

<u>Figure Number</u>	<u>Content</u>
1-4	Unfixed samples of unwaxed floss before and after use
5-8	Gluteraldehyde fixed after use samples of unwaxed floss before and after use
9-12	Unfixed samples of waxed floss before and after use
13-16	Gluteraldehyde fixed samples of waxed floss before and after use
17-20	Unfixed samples of Jaffe Dental Ribbon before and after use
21-25	Gluteraldehyde fixed samples of Jaffe Dental Ribbon before and after use
26, 27, 36	SEM Replica of unwaxed floss before use
28, 29, 37	SEM Replica of unwaxed floss after use
30, 31, 38	SEM Replica of waxed floss before use
32, 33, 39	SEM Replica of waxed floss after use
40	SEM Replica of Jaffe Dental Ribbon before use
34, 35, 41	SEM Replica of Jaffe Dental Ribbon after use



CONVENTIONAL FLOSS
UNWAXED, UNFIXED
100X

Fig. 1



Fig. 2



678 1 1979
 Con. Floss -
 Unwaxed and
 Unfixed
 1 - A-2702

BEFORE

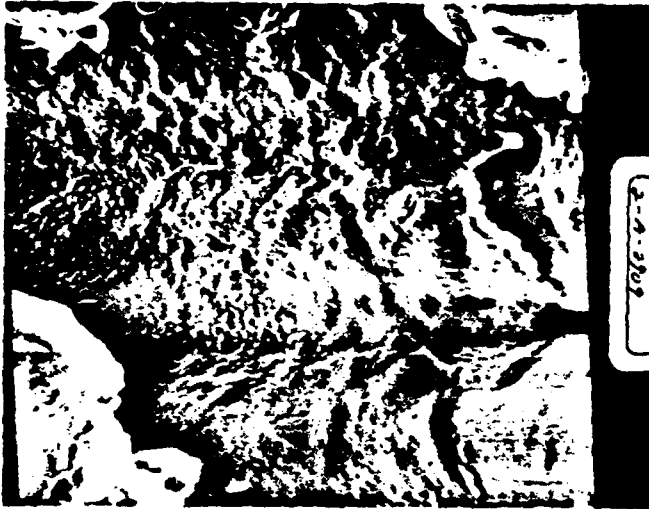


678 1 1979
 Con. Floss -
 Unwaxed and
 Unfixed
 1 - A-2702

AFTER

CONVENTIONAL FLOSS
 UNWAXED, UNFIXED
 1000X

Fig. 3



STANDARD PHOTOGRAPHIC CO.
CON. PHOTO
NUMBER 1001
2-8-39

AFTER



STANDARD PHOTOGRAPHIC CO.
CON. PHOTO
NUMBER 1001
2-8-39

6/6 1 1979

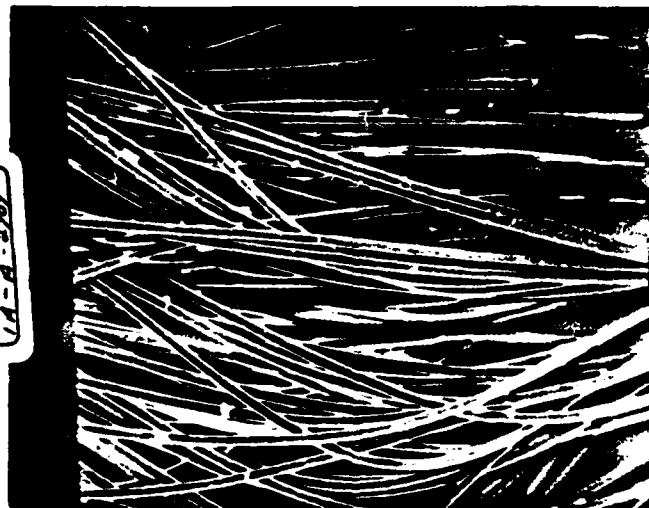
BEFORE

CONVENTIONAL FLOSS
UNWAXED, UNFIXED
3000X

Fig. 4

BEFORE

CONV. FLOSS - I
UNWAXED - GLUTERALDEHYDE
FIXED
100X
1A-A-2392

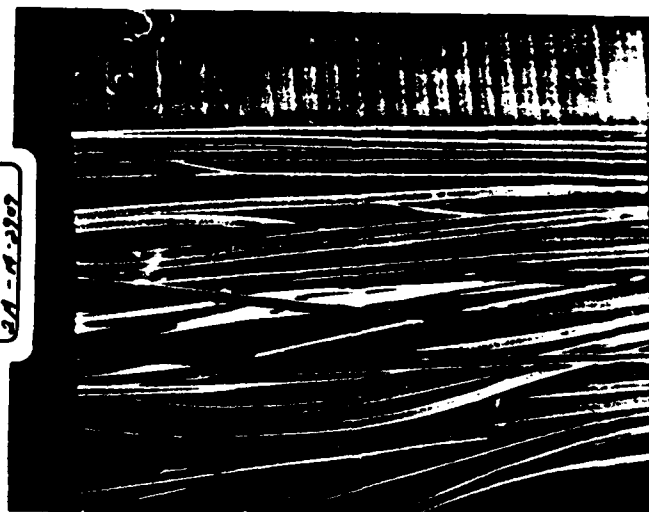


CONVENTIONAL FLOSS
UNWAXED, GLUTERALDEHYDE FIXED,
AIR DRIED
100X

Fig. 5

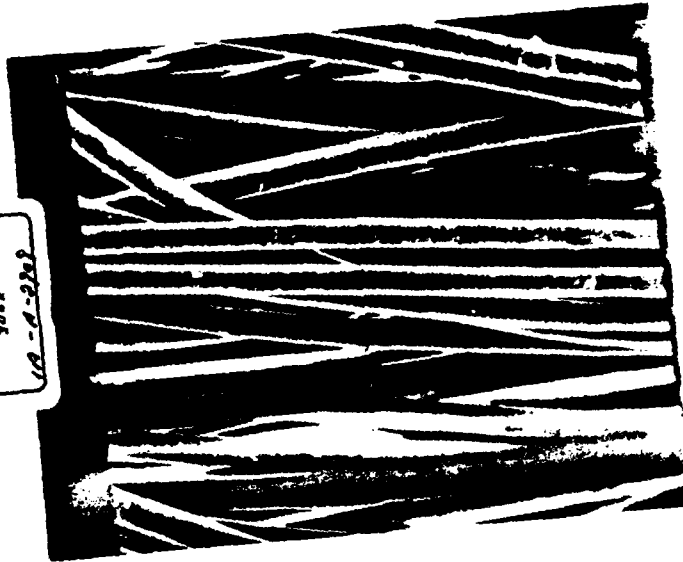
AFTER

CONV. FLOSS - I
UNWAXED - GLUTERALDEHYDE
FIXED
100X
2A-A-2392



BEFORE

666 11 2 1979
 Con. Floss -
 Unwaxed
 Floss
 300K
 2A-A-2207



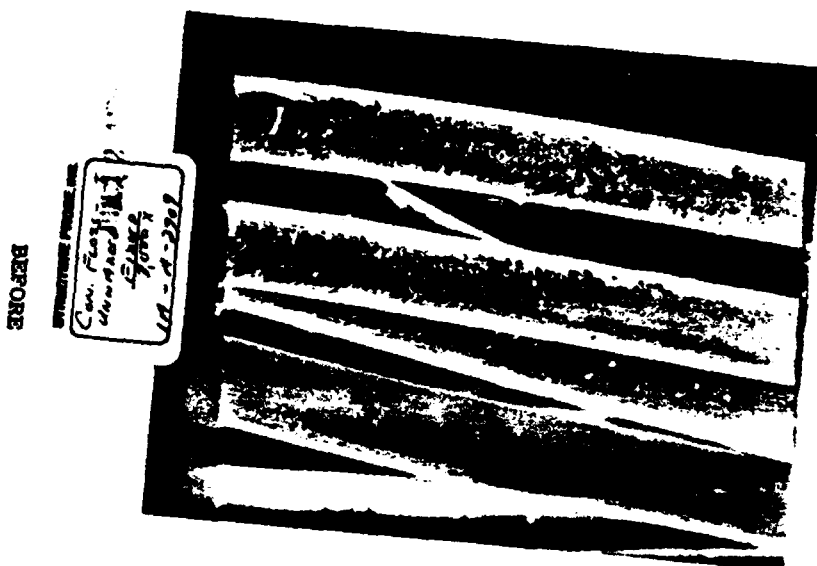
CONVENTIONAL FLOSS
 UNWAXED, GLUTARALDEHYDE FIXED,
 AIR DRIED
 300X

Fig. 6

AFTER

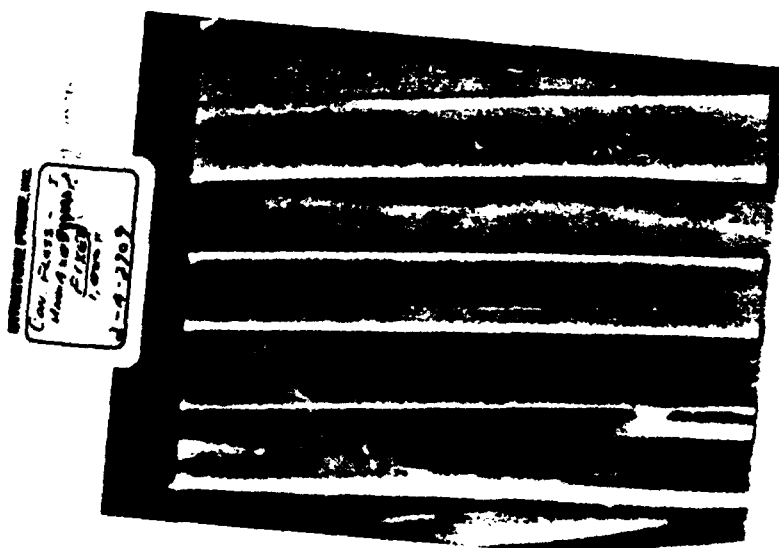
666 11 2 1979
 Con. Floss -
 Unwaxed
 Floss
 300K
 2A-A-2207



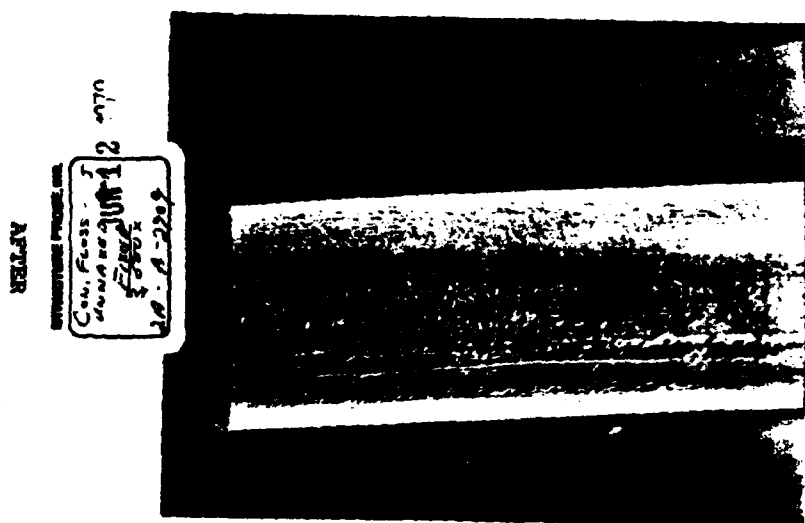


BEFORE

CONVENTIONAL FLOSS
UNWAXED, GLUTERALDEHYDE FIXED,
AIR DRIED
1000X
Fig. 7



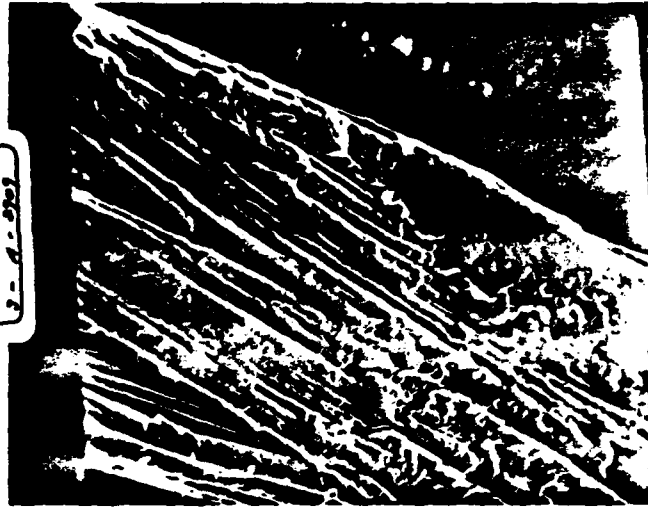
AFTER



CONVENTIONAL FLOSS
UNWAXED, GLUTARALDEHYDE FIXED,
AIR DRIED
3000X
Fig. 8

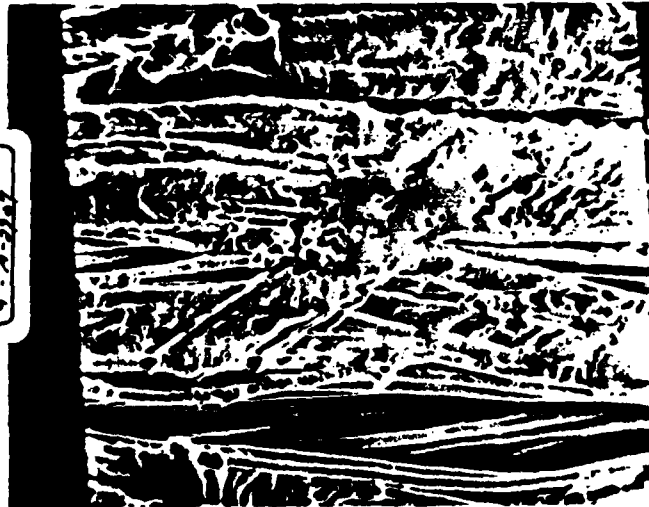
BEFORE

CONVENTIONAL FLOSS
Cav. Floss -
Waxed Floss
100X
4-A-2242



AFTER

CONVENTIONAL FLOSS
Cav. Floss -
Waxed Floss
100X
4-A-2242



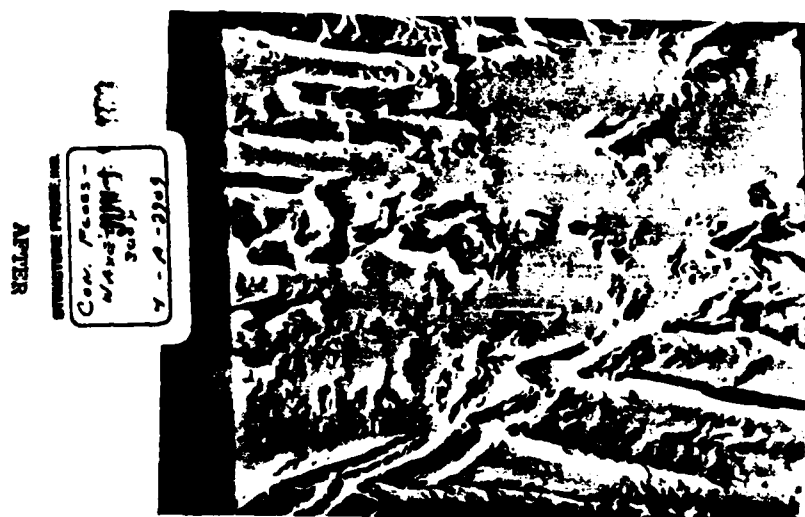
CONVENTIONAL FLOSS
WAXED, UNFIXED
100X
Fig. 9



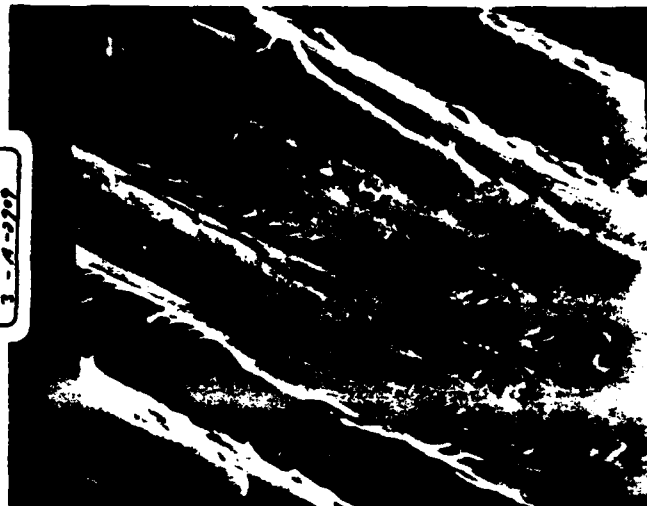
BEFORE

CONVENTIONAL FLOSS
WAXED, UNFIXED
300X

Fig. 10



AFTER



6066-B-3
 Gen. Alge
 Waver
 1000X

BEFORE



6066-B-4
 Gen. Floss
 Waver
 1000X

AFTER

CONVENTIONAL FLOSS
 WAVED, UNFIXED
 1000X

Fig. 11

BEFORE

66A 11 NOV 1979
3000X
3 - A - 2202
CONV. FLOES -
WATER -
3000X



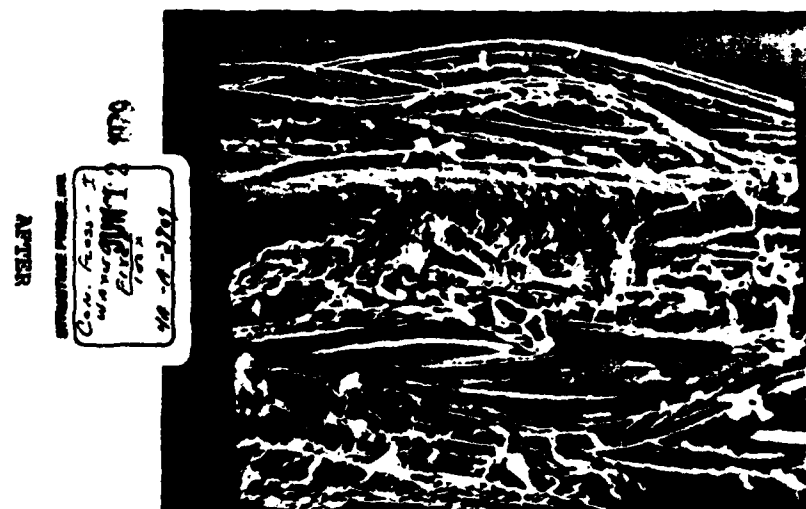
CONVENTIONAL FLOES
WAXED, UNFIXED
3000X

Fig. 12

AFTER

66A 11 NOV 1979
3000X
3 - A - 2202
CONV. FLOES -
WATER -
3000X





CONVENTIONAL FLOSS
WAXED, GLUTARALDEHYDE
FIXED, AIR DRIED
100X

Fig. 13



CONVENTIONAL FLOSS
WAXED, GLUTERALDEHYDE
FIXED, AIR DRIED
300X

Fig. 14





BEFORE

CONVENTIONAL FLOSS
WAXED, GLUTARALDEHYDE
FIXED, AIR DRIED
1000X

Fig. 15



AFTER



BEFORE

JAFFE DENTAL RIBBON

UNFIXED
100X

Fig. 17

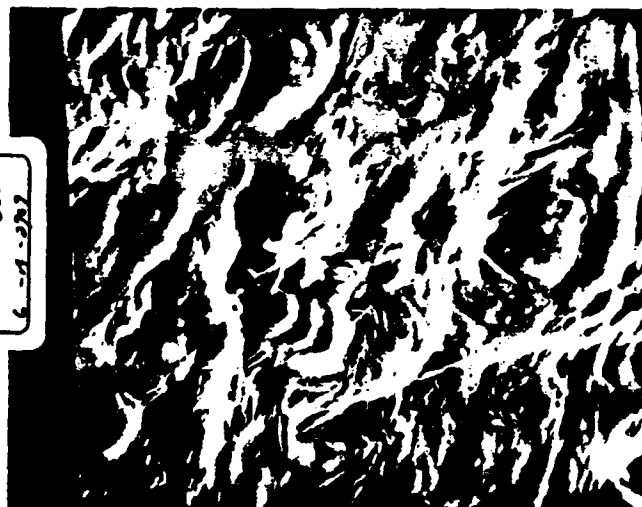


AFTER



1086-B-5
JUN 2 1966
JUN 2 1966
JUN 2 1966

BEFORE



1086-B-6
JUN 2 1966
JUN 2 1966
JUN 2 1966

AFTER

JAFFE DENTAL RIBBON

UNFIXED

300X

Fig. 18



6/19 21 JUN 12 1979
 Jaffe Dental Ribbon
 100X
 6A-A-2202

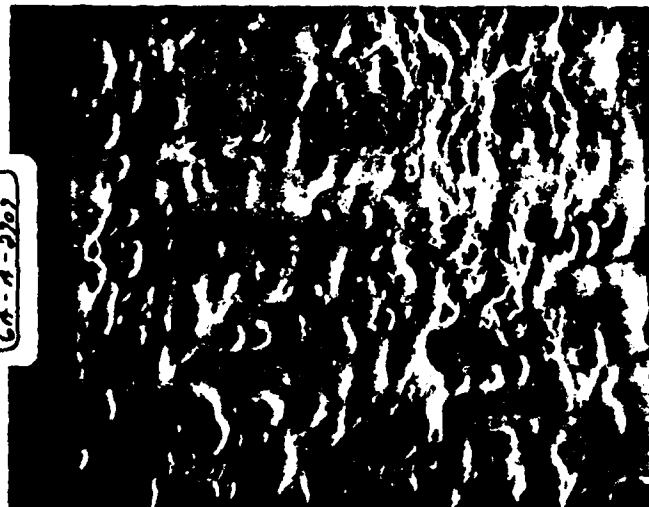
BEFORE

JAFFE DENTAL RIBBON

GLUTERALDEHYDE FIXED,

AIR DRIED
 100X

Fig. 21



6/19 21 JUN 12 1979
 Jaffe Dental Ribbon
 100X
 6A-A-2202

AFTER

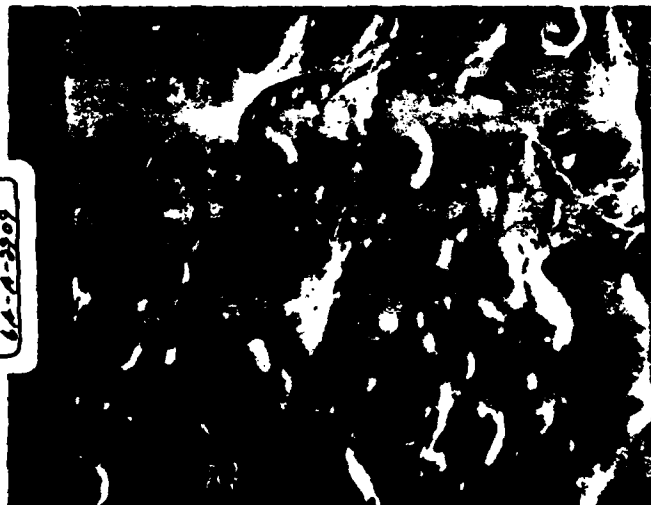


6066-P-45
N. 1
M. 1
A. 1
I. 1
A. 1
I. 1
A. 1
I. 1

BEFORE

JAFFE DENTAL RIBBON
GLUTERALDEHYDE FIXED,
AIR DRIED
300X

Fig. 22



6066-P-49
N. 1
M. 1
A. 1
I. 1
A. 1
I. 1
A. 1
I. 1

AFTER

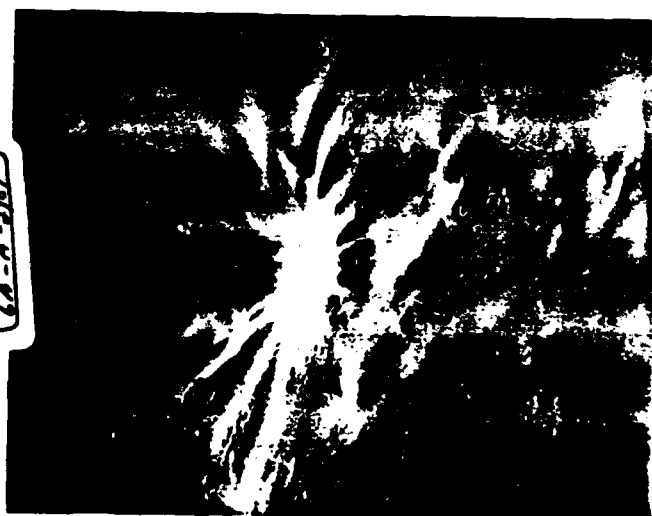


6-21-68
1 NOC 2000
very
mildly
exposed

BEFORE

JAFFE DENTAL RIBBON
GLUTERAIDEHYDE FIXED,
AIR DRIED
3000X

Fig. 24



6-21-68
1 NOC 2000
very
mildly
exposed

AFTER



JAFFE DENTAL RIBBON
 GLUTERALDEHYDE FIXED,
 AIR DRIED
 10,000X
 Fig. 25

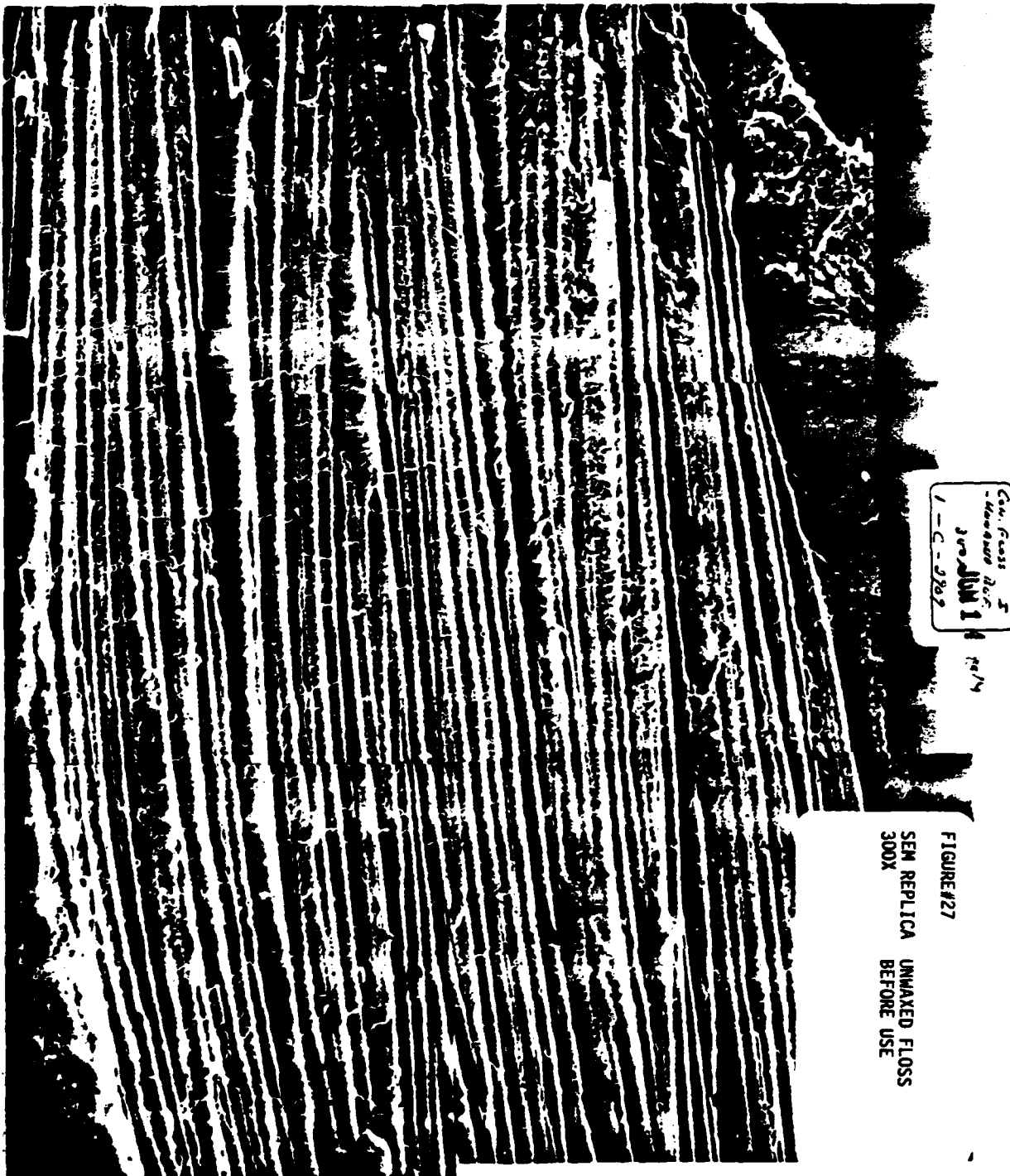


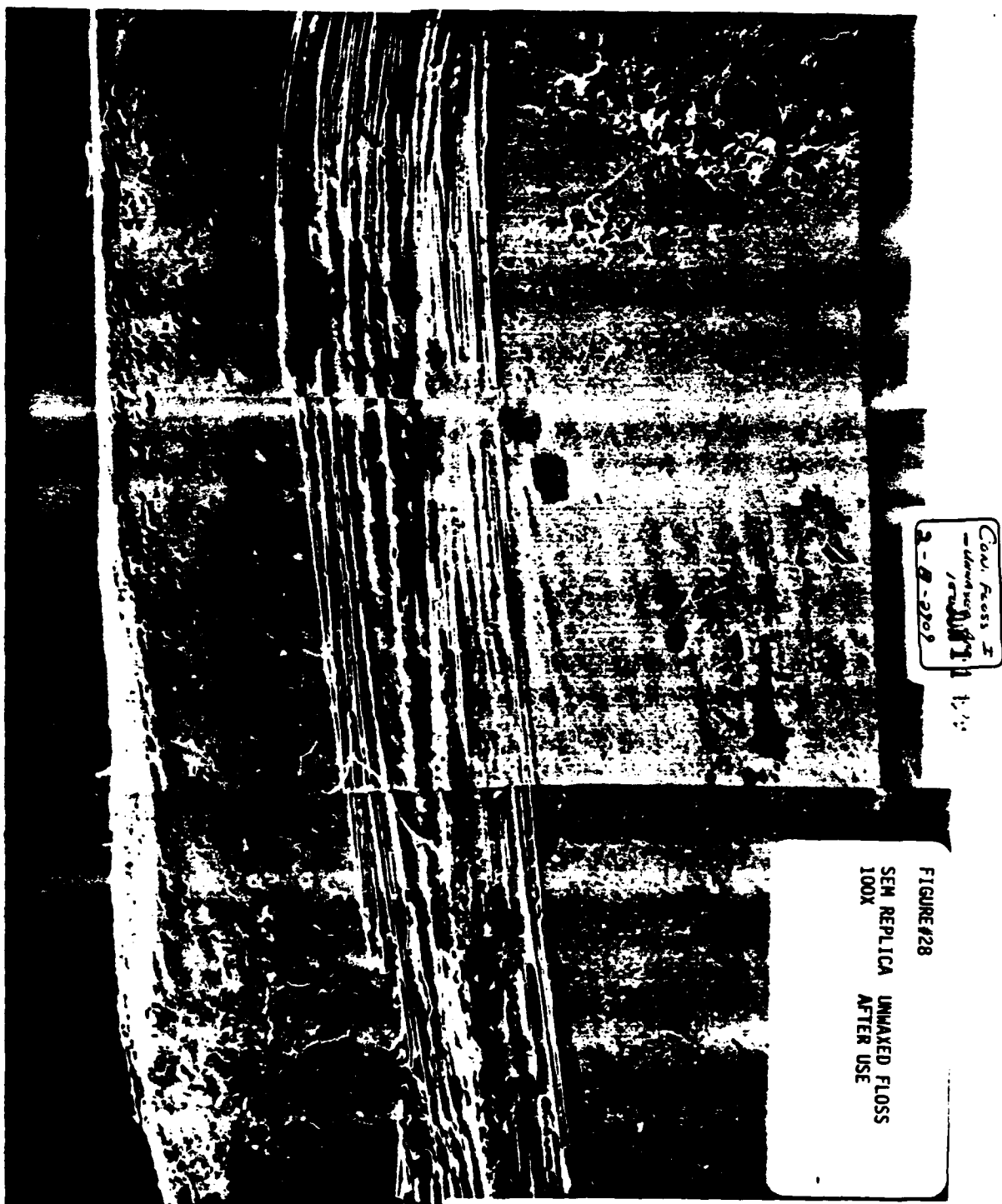


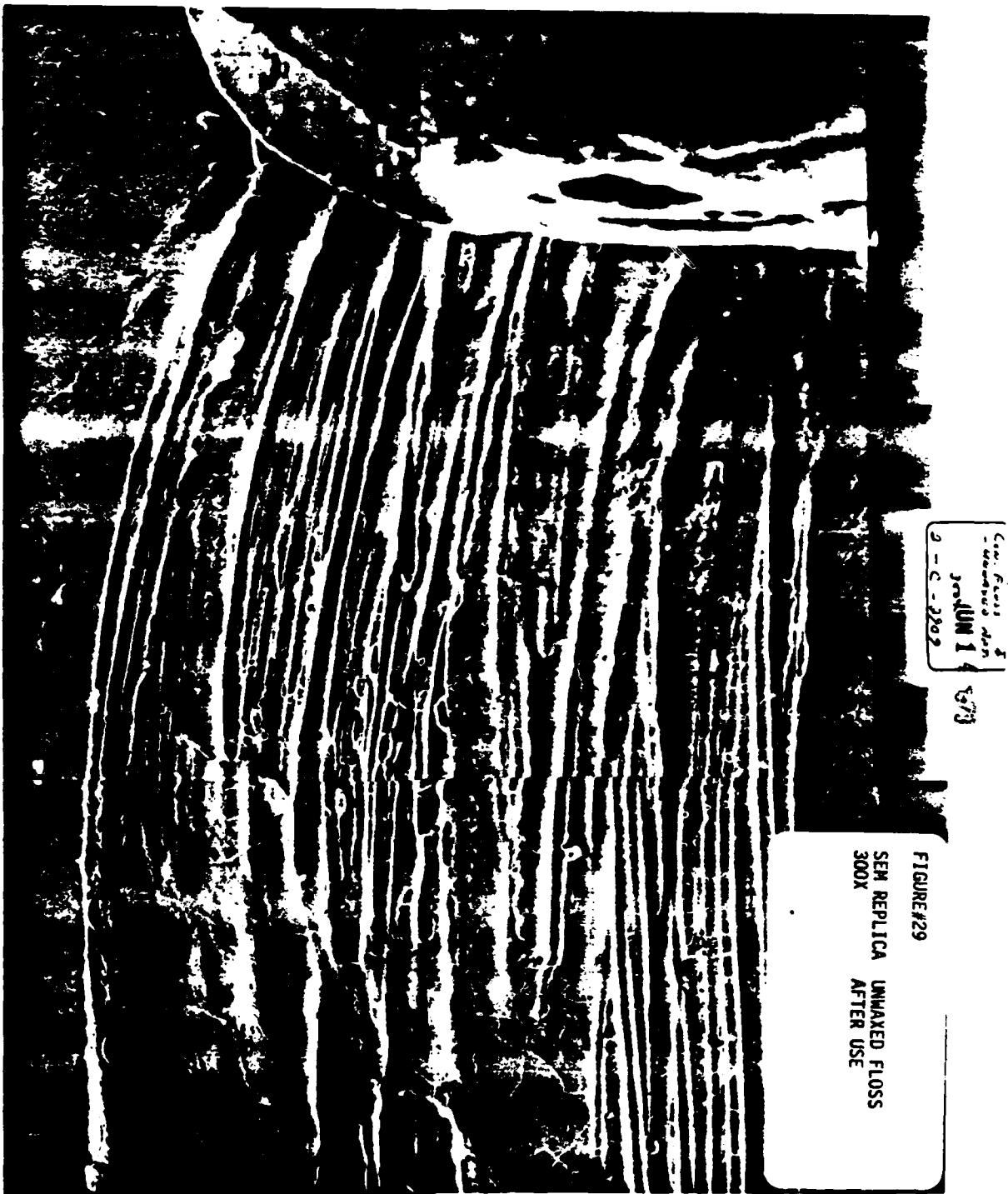
Don. Floss 1
- 100x 100
1 - 8-8-79

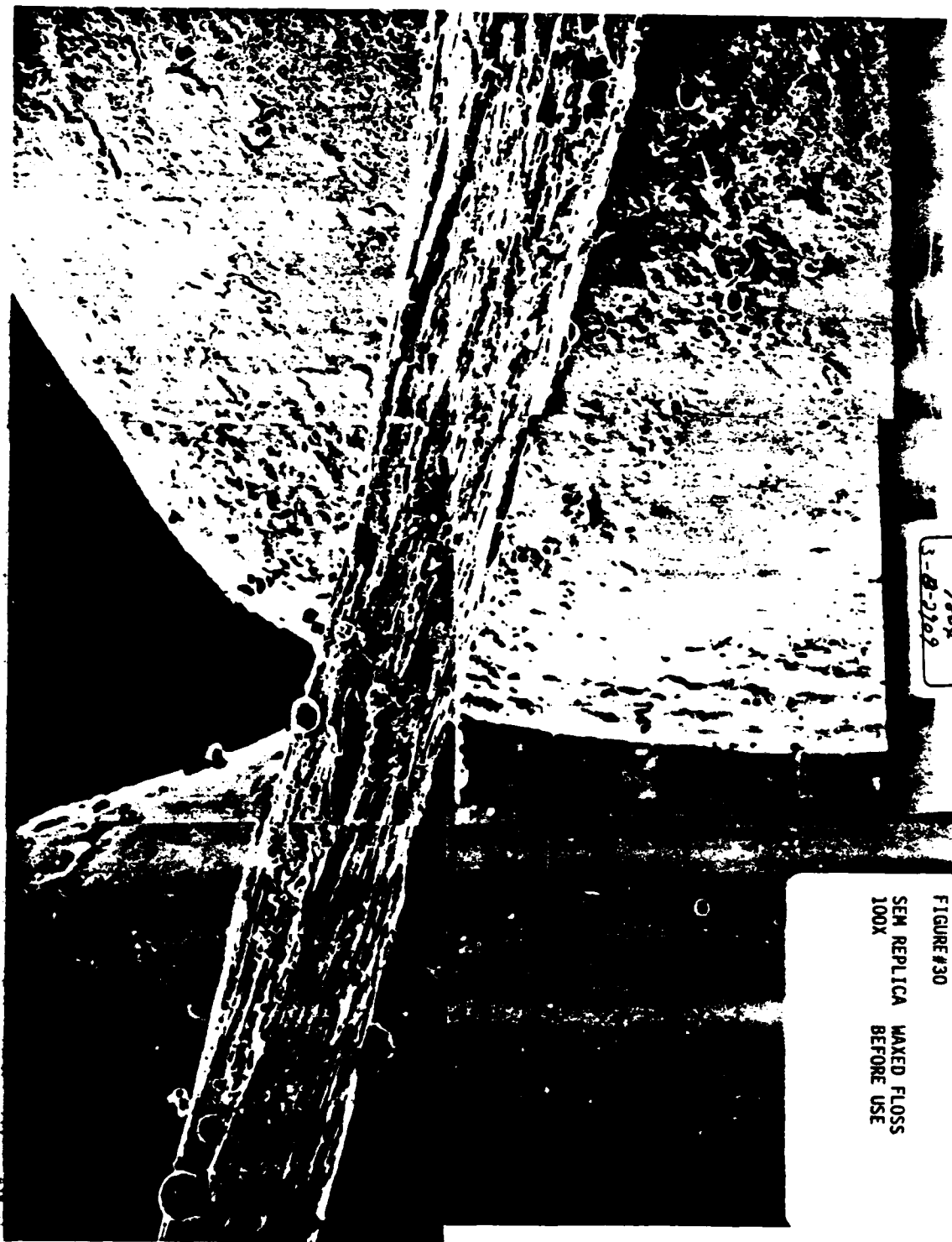
8 879

FIGURE 26
SEM REPLICA UNMAXED FLOSS
100X BEFORE USE









Con. Floss
-Waxed
100x
3-B-2209

10/15

FIGURE#30
SEM REPLICA WAXED FLOSS
100X BEFORE USE



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DATE 10-10-2003 BY 3042

FIGURE#31

SEM REPLICAS WAXED FLOSS
300X BEFORE USE



Co. F. 1000 F. 2
-waxed floss
100x
4-B-3909

FIGURE #32
SEM REPLICA WAXED FLOSS
100X AFTER USE



SEM 14 679
Y-C-2209

FIGURE#33
SEM REPLICA WAXED FLOSS
300X AFTER USE





Revised
- Revised
JUN 1 4 1975
6-C-2702

FIGURE#35
SEM REPLICA JAFFE DENTAL RIBBON
300X
AFTER USE

1-A-2209
 ~25x
 Com. Res. Inst.
 -4/10/50
 5

FIGURE 36
SEM REPLICA
25X

UNAXED FLOSS
BEFORE USE

CONVENTIONAL FLOSS

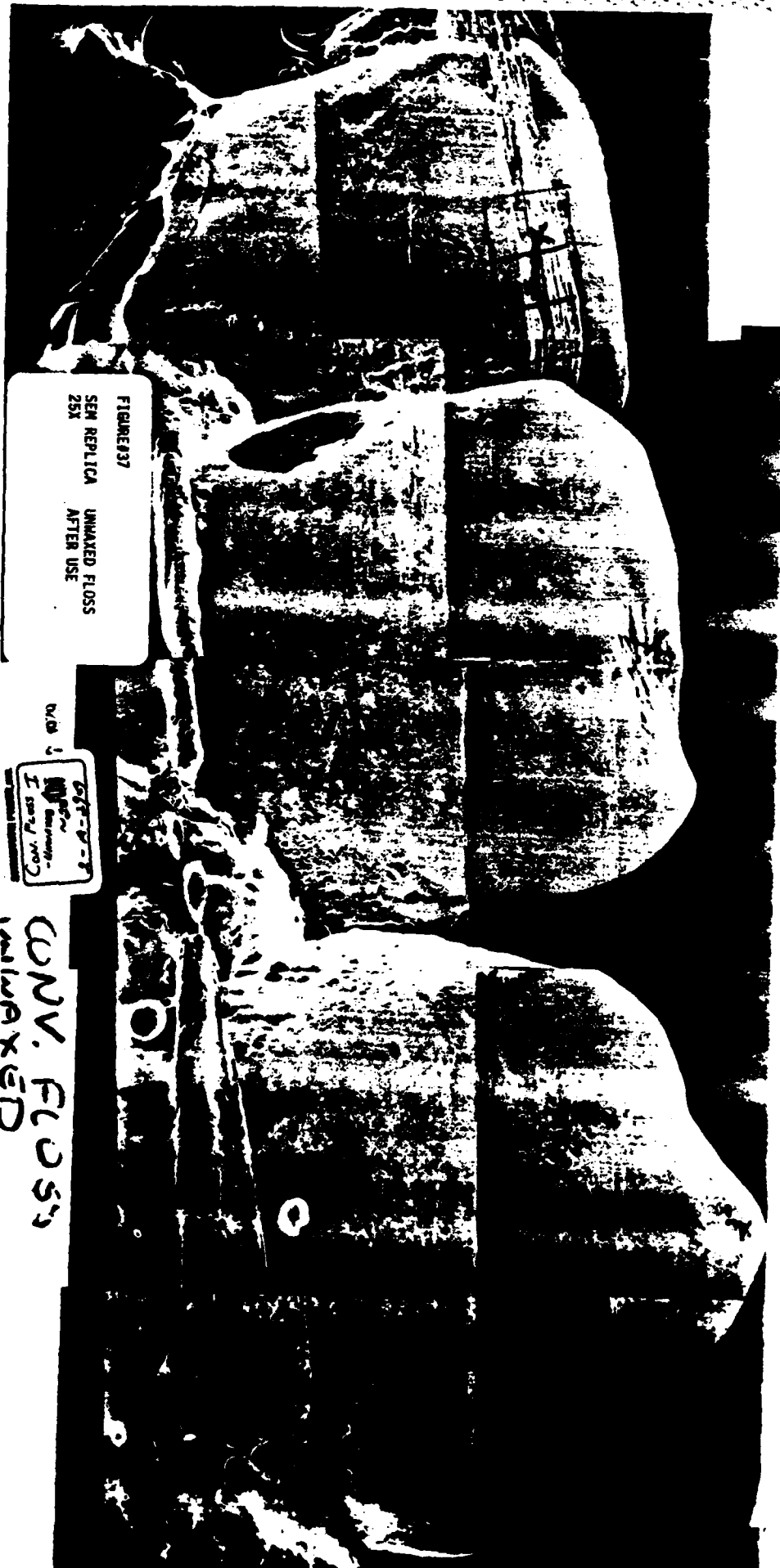
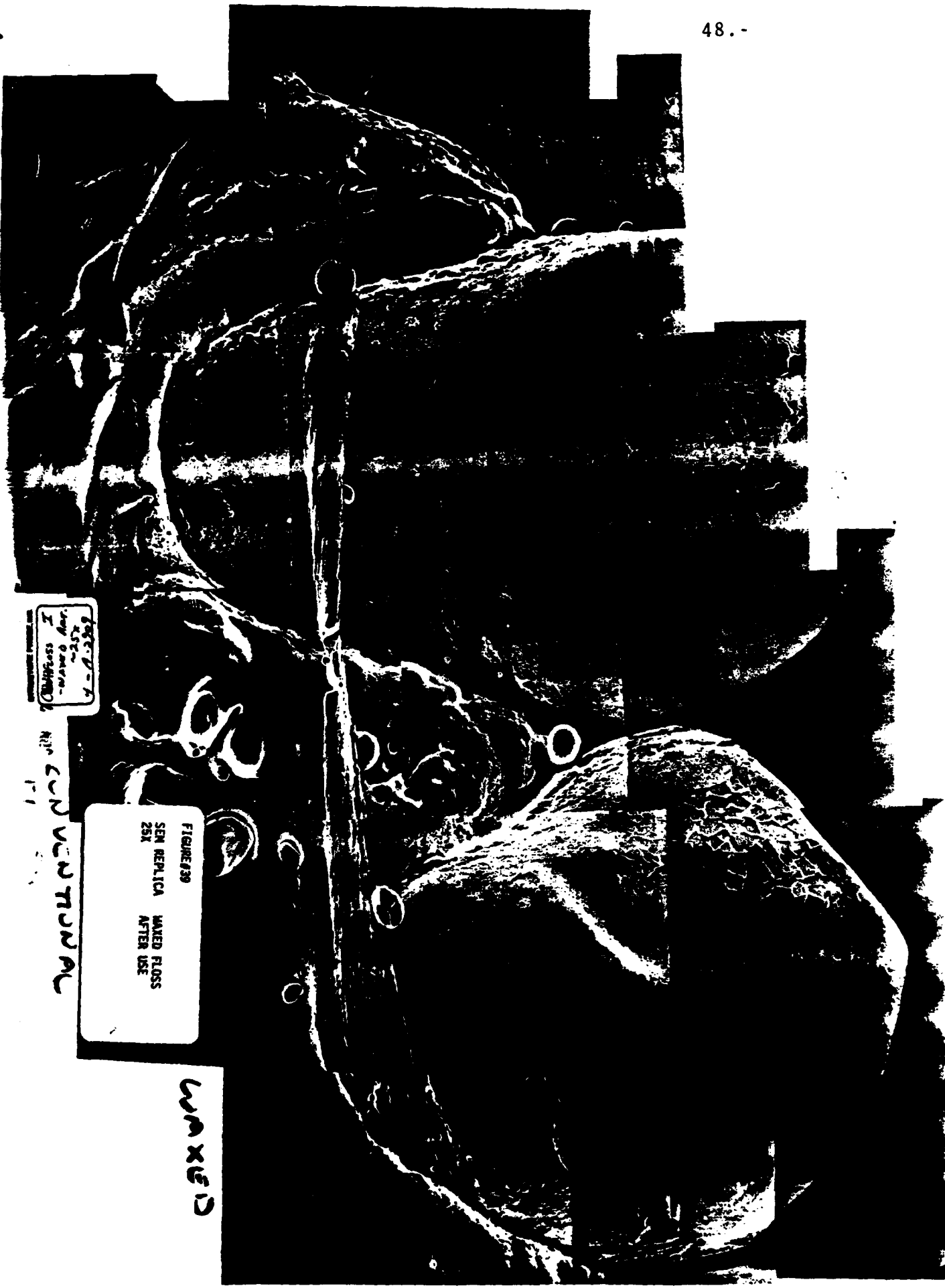


FIGURE 37
SEM REPLICA UNAXED FLOSS
25X AFTER USE

681-A-8
NO. 1
CONV. FLOSS
UNAXED

CONV. FLOSS
UNAXED



685-7-238
-wax & Am.
-25%
I
Chaffress

CONVENTIONAL

FIGURE 39
SEN REPLICA
25X
WAXED FLOSS
AFTER USE

WAXED



FIGURE 40
SEN REPLICA
25X
JAFPE DENTAL
REFUGE USE

2047-P-2
JAFPE
DENTAL
REFUGE USE

ADHESIVE TAPE
BEFORE

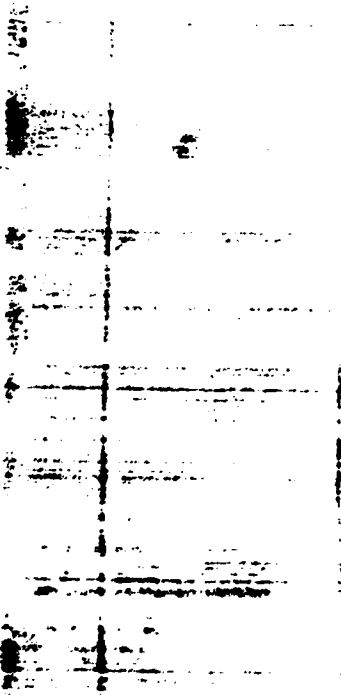




FIGURE A1
SEM REPLICA
25X
JAFFE DENTAL RIBBON
AFTER USE

100x-7-9
Jaffe - 64
J. Jaffe

ADHESIVE TAPE
AFTER

DISCUSSION

A. SEM Results of Actual Floss Samples Before and After Use

Photographs were taken on three types of floss, prepared for SEM examination employing two sample preparation procedures (air-dried versus gluteraldehyde fixation). A total of six samples were examined at 100, 300, 1000, and 3000X magnification. Overall, the air-dried, unfixed samples best contrasted the differences between the floss samples during usage. The gluteraldehyde-fixed samples generally showed little change in appearance after use in the oral cavity. This was due to either chemical degradation or experimental sample heterogeneities.

The unwaxed floss samples were made up of numerous free-floating fibers. This unbonded configuration appears to provide a greater amount of inter-fiber space than the waxed floss for particle entrapment. After cleaning an interproximal space, the unfixed, unwaxed floss was covered with a fairly homogeneous paste (see figs. 1 and 2). No bacterial structures were observed at 1000 or 3000X magnification. This plaque material filled and bridged between the individual filaments (see figs. 3 and 4). The fixed, unwaxed floss samples were as clean before their use as after (see figs. 5-8).

The waxed floss samples were covered with a smooth wax layer extending two to three fibers deep. This wax coating appeared still intact after usage (see figs. 9-12). Only fixed samples had exposed inter-fiber spaces (see fig. 13). This may be due to chemical dehydration. The waxy layer did give a rougher appearance (see figs. 14-16). Generally, the debris particles were difficult to identify from the waxy layer. The paste-like material filled the valleys of coated fibers.

The Jaffe Dental Ribbon, unlike thread floss, is an extruded film that is coated with a mixture of adhesive and polishing particles. The protocol of use goes as follows: "Remove the paper covering the strip's adhesive. Elongate the three inch strip to about two feet and use like conventional floss." Upon SEM examination, the ribbon appeared uniformly coated with adhesive and cleansing particles. These abrasive agents were completely embedded and well-distributed in the adhesive (see figs. 17-19). After use in the oral cavity, the plaque deposits were again impossible to distinguish from the adhesive mixture. The surface of the unfixed sample had a slightly rougher appearance with some particles projecting from the film coating (see figs. 18-20). The fixed specimens gave no impression of change before and after use. It can only be speculated the plaque deposits were either washed away or covered by a chemically-altered adhesive (see figs. 21-25).

B. SEM REPLICA RESULTS

A total of six replicas were made of three types of floss, before and during use in the oral cavity. Each positive was examined under SEM and a series of photographs were assembled into montages. Magnifications of 25X, 100X, and 300X were done for each replica at the identical areas. Due to the inherent setting properties of the negative and positive replica material a number of air bubbles were present.

Two 25X montages illustrated the unwaxed thread floss cleaning the distal surface and gingival sulcus of the right mandibular canine (see figs. 36 and 37). Enamel tooth surface, plaque deposits and gingival tissue are easily distinguished. Some thread and interproximal detail were lost due to the replica material bridging and filling the gaps between the teeth. For this reason, sections of floss were studied as they left from behind the tooth surfaces. One can visualize how the thread flattened from its tight cable configuration as it positioned interproximally. This positioning of the thread can cause fray as illustrated in the 'before use' montage (see fig. 26). A number of fibers were broken off the replica confirming this phenomena. The interproximal area appeared clean suggesting the material had been picked up and was coating the thread. The unwaxed floss had entrapped material between its free-floating fibers. Some plaque material appeared to be squeezed out of these spaces as the cable moved and tightened (see figs. 28 and 29).

In the 25X montages of the replicas of waxed floss, the thread was shifted from the distal surface to deep inside the gingival sulcus of a second subject's right mandibular canine (see figs. 38 and 39). The 'before use' replica lacked the enamel and gingival surface of the 'after use' replica. With the replica system, it was still impossible to distinguish between the wax coating and interproximal debris. The waxy surface was visually smoother and intact after its usage. The rougher appearance of the thread before use may have been due to specimen preparation because a number of air bubbles and loose flakes were present (see figs. 30-33). The distal surface of this particular tooth visually had more plaque remaining after flossing than the two other flossing materials studies (see fig. 39). This may have been due to experimental error during the flossing exercise by the hygienist, or a waxy build-up from using this type of floss.

A 'before use' 25X magnification montage shows that the Jaffe dental ribbon did not replicate. Although a number of positives were made from a negative replica, no trace of the tape was seen (see fig. 40). The 'after use' montage showed the dental ribbon cleansing the mesial surfaces of the right lateral incisor appears clear of plaque build-up (see fig. 41). At higher magnifications, it was difficult to distinguish the adhesive-polishing particles matrix and the plaque that had been removed. The abrasive particles were protruding from the adhesive layer and were covered more with more film as the tape extended into the gingival pocket (see figs. 34 and 35). Unlike thread floss the elastic ribbon gave no appearance of fraying or breakage during use.

C. TEM THIN SECTION RESULTS

For the TEM work, before and after samples of the three floss types were embedded in Epon-812 epoxy, stained and diamond knife thin section. In spite of numerous attempts, suitable sections could not be obtained. It was suspected that areas containing debris materials were not sufficiently stable in the electron beam. For the TEM work, only dry samples were used. The wet (gluteraldehyde-fixed) samples would have required an alcohol dehydration treatment. The alcohol was shown to dissolve the ribbon adhesive.

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