



NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY

SUBMARINE BASE, GROTON, CONN.

REPORT NUMBER 792

CLINICAL EVALUATION OF AN ADHESIVE SEALANT
FOR CONTROLLING DENTAL CARIES IN NAVAL PERSONNEL:

ONE-YEAR RESULTS

by

George T. Eden, CDR, DC, USN

and

M.A. Mazzarella, CAPT, DC, USN

Bureau of Medicine and Surgery, Navy Department
Research Work Unit MF51.524.012-0020.01

Released by:

R.L. Sphar, CDR, MC, USN

Officer-in-Charge

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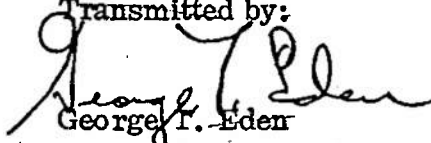
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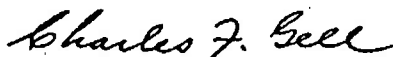
Bureau of Medicine and Surgery, Navy Department
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Transmitted by:



George T. Eden
Commander, DC, U.S. Navy
Head, Dental Research Branch

Reviewed and Approved by:



Charles F. Gell, M.D., D.Sc. (Med)
SCIENTIFIC DIRECTOR
NavSubMedRschLab

Approved and Released by:



R. L. Sphar, CDR, MC, USN
OFFICER IN CHARGE
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SUMMARY PAGE

THE PROBLEM

To ascertain the effectiveness of an adhesive type sealant material in reducing the incidence of dental caries in Naval personnel, with a view to including treatment with this type of material, should it prove effective, in the Navy's Preventive Dentistry Program. Such polymeric pit and fissure sealants have been reported as highly effective in reducing occlusal caries in children.

FINDINGS

a. Results tabulated after one year of using this sealant material on 111 subjects showed no reduction in the occlusal caries attack rate.

b. The very low occlusal caries attack rate of 1.67% for one year in 660 control teeth indicates that sealant application would not be cost effective in the young adult population which makes up the U.S. Navy, regardless of the caries prevention potential of the sealant.

APPLICATION

Analysis of the data at the end of the first year of this study strongly suggests that sealant application is ineffective in preventing new occlusal caries in young male adults and provides sufficient evidence to discourage the use of such a sealant on active duty personnel.

ADMINISTRATIVE INFORMATION

This investigation was conducted as part of Bureau of Medicine and Surgery Research Work Unit MF51.524-012-0020 - Evaluation of Polymeric Pit and Fissure Sealants as a Dental Decay Preventive in Submarine Personnel. The present report is Number One on this Work Unit. It was submitted for review on 8 August 1974, approved for publication on 20 August 1974, and designated as NavSubMedRsSchLab Report No. 792.

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ABSTRACT

A polymeric pit and fissure sealant reported effective in preventing occlusal dental decay in children was evaluated in 111 young men who were candidates for entrance into the Naval Submarine School.

The sealant application had not shown any measurable treatment effect in the study population at the end of the first year of this two-year study.

The very low occlusal attack rate for untreated control teeth (1.67% for one year) strongly suggests that sealant application, regardless of treatment effect, would not be a cost effective measure in active duty Navy personnel.

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CLINICAL EVALUATION OF AN ADHESIVE SEALANT
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ONE-YEAR RESULTS

INTRODUCTION

A significant reduction in the rate of new caries formation followed implementation of the Navy's three-agent stannous fluoride program¹. The caries inhibiting effect of both dietary and topical fluoride is concentrated on smooth enamel surfaces, however,^{2,3,4} and provides relatively less protection to the fissured chewing surfaces of the posterior teeth. The identification of a complementary measure which would result in material reductions in new occlusal caries would extend the value of the Navy's Preventive Dentistry Program.

Buonocore⁵ in 1955 reported an acid modification of dental enamel which promoted adhesion of polymethylmethacrylate (PMMA) filling resin to the tooth surface. A modification of this acid-etch technique, used in conjunction with the dimethacrylate monomer (Bis-GMA), developed by Bowen⁶, has found wide use in the sealing of occlusal pits and fissures as a decay preventive measure in youthful patients.

The dramatic reduction in occlusal decay for children reported by Buonocore⁷ (up to 99% reduction in occlusal decay for two years) and others^{8,9,10} following one application of sealant is of obvious interest to the U.S. Navy which is composed primarily of young adults whose dental care needs are presumably related to those of adolescents.

To establish the desirability of conducting a sealant trial in Naval personnel 18-22 years of age, two young Navy populations were surveyed to determine whether the need for occlusal surface protection did indeed exist, and also to assist the investigator in preparing the protocol for a sealant evaluation.

In September-October 1971, 263 consecutive Submarine School candidates at the Naval Submarine Base New London, Groton, Connecticut, were examined and the number of occlusal surfaces at risk (occlusal surface caries free, no occlusal fillings, no proximal decay) was determined. Considering 1st, 2nd, 3rd molars and 1st, 2nd bicuspid (20 teeth/man) the 263 examinees had a total possible 5260 occlusal surfaces. Of these 5260 occlusal surfaces, 2014 were caries-free with no occlusal fillings and in teeth with no proximal decay so that 38.3% of all possible posterior teeth were at risk to occlusal caries and would conceivably benefit from sealant application. The average number of occlusal surfaces at risk per man was 7.6 and the modal number at risk per man was 6.0. The actual proportion of posterior teeth at risk in fact would be somewhat higher because of the above figures were not corrected for extracted teeth or unerupted 3rd molars.

A larger survey was conducted in October 1971 on 1000 consecutive

recruits by Commander James Klima at the Naval Training Center, Great Lakes, Illinois, to confirm the results of the New London survey and to provide a more reliable estimate of the number of occlusal surfaces at risk per man among a broad cross-section of newly enlisted personnel. The results shown in Table I mirror the New London survey in that 39.3% of all possible occlusal surfaces were at risk with an average number of 7.9 occlusal surfaces at risk per man. Factoring out 1280 unerupted 3rd molars from the 20,000 possible occlusal surfaces increases the best estimate of occlusal surfaces at risk to 42.0%. As in the New London survey, this figure (42%) still underestimates the real proportion of surfaces at risk because the total of possible occlusal surfaces was not further reduced by the number of extracted posterior teeth.

MATERIALS AND METHODS

Two hundred ninety-nine (299) Submarine School candidates (ages 17-23) with 1794 pairs of noncarious posterior teeth were chosen as subjects for the sealant evaluation. Participation in the study was voluntary and each subject was informed orally and in writing of sealant development, its possible benefits, and the pertinent elements of his participation in the current study.

Since the use of homologous, contralateral pairs ensures that variation due to oral environment, mechanical stress, and other undefined sources of experimental error will be minimized, the distribution of suitable caries-free

occlusal pairs was determined for the New London group. The experimental design involving matched pairs has been employed by Buonocore¹¹, Richardson⁸, and Horowitz¹⁰ in sealant studies and is based primarily on the symmetry of carious involvement within individual mouths¹². For this particular study, it was decided that each participant should have at least one pair of caries free 1st or 2nd molars. Twenty-six per cent of the examinees (69 of 263) met this minimum criterion.

Only noncarious teeth were chosen for the study. Teeth patently decayed were excluded. Teeth with deep grooves, discolorations, or explorer catches were not excluded, but teeth with occlusal pits and fissures which felt soft at their base, elicited pain from the subject when probed, resisted withdrawal of the explorer tine, or with enamel whose light-refractive qualities were significantly altered through decalcification were excluded. Starlite 23 explorers, examined under a 30 power binocular microscope for consistency of point taper and wear, bite-wing x-rays, and the investigator's extensive experience in operative dentistry were the final elements in determining tooth eligibility.

No attempt was made to further subclassify noncarious occlusal surfaces as to probable susceptibility, although the subjects' prior decay experience was noted by recording Decayed, Missing, Filled, Teeth (DMFT) and Decayed, Missing, Filled Surfaces (DMFS) at the time of sealant placement.

The sealant chosen for evaluation was Caulk Nuva-Seal*. Nationally advertised

**L.D. Caulk Corp., Milford, Delaware*

TABLE I - CARIES DATA FOR 1,000 CONSECUTIVE NAVY RECRUITS AT
GREAT LAKES RECRUIT TRAINING CENTER - OCTOBER 1971

MOLARS

	Sound occlusal No proximal caries	Cariou occlusal No proximal caries	Cariou proximal or proximal occlusal	Unerupted Partially or total
Upper	1493	640	822	422
Lower	1287	549	836	858
All molar	2780	1189	1658	1280

BICUSPIDS

Upper	2278	69	856	-
Lower	2801	93	474	-
All Bicuspid	5079	162	1330	

MOLARS AND BICUSPIDS COMBINED

Upper	3771	709	1678	422
Lower	4088	642	1310	858
TOTAL	7859	1351	2988	1280

Total possible occlusal surfaces/man (U/L 1st, 2nd bicuspid; 1st, 2nd, 3rd molar) = 20.

Total possible occlusal surfaces in 1000 recruits. 20 x 1000 = 20,000.

Total observed occlusal surfaces at risk 7,859; 7.86/man.
(No occlusal fillings, no occlusal or proximal caries)

% occlusal surfaces at risk $\frac{7859}{20,000} = 39.3\%$

(a) % occlusal surfaces at risk adjusted for unerupted 3rd molars $\frac{7859}{18,720} = 42.0\%$

material purchased through commercial sources was used initially and then replaced by the commercial formulation with .007% by weight FD+C #17 Red Dye added to assist in visualizing the transparent sealant. This dyed formulation which has been used in studies by Going¹³, Swartz¹⁴, and Harris¹⁵ was furnished by the L. D. Caulk Corporation. The sealant was placed in accordance with the manufacturer's directions. Additional safeguards were employed in that a voltage monitoring strip chart recorder was employed during sealant placement to ensure continuous delivery of adequate voltage to the ultraviolet light source (Nuva-Lite)* used for sealant polymerization. Also, a new air compressor** with suitable characteristics was installed to permit confidence in meeting the requirements for moisture- and oil-free air necessary to dry the tooth surfaces for maximum wetting by the polymer with penetration of surface irregularities and effective bonding.

Prior to sealant placement, each subject was supplied with a soft multi-tufted nylon toothbrush and one ounce of unflavored flour of pumice with water added to produce a thick slurry. Subjects were instructed to scrub their occlusal surface using one minute and one quarter of the pumice for each quadrant.

Starting in the upper arch, one tooth of the most posterior eligible tooth pair was sealed using cotton rolls for isolation. (Right or left quadrant for the first sealed tooth was decided

*L. D. Caulk Corp., Milford, Delaware

**Air Techniques, Oil-less Compresso-Dri, Model A8T - Air Techniques, Inc. 2020 Jericho Turnpike, New Hyde Park, New York.

for the first patient each day by a coin toss). The arch was crossed for each successive sealed tooth to aid in confounding intrasubject masticatory bias. Each successive patient for the day was begun with the first sealed tooth on the side opposite the beginning side for the previous patient. Following placement of the sealant, occlusion was adjusted to achieve group function with only a slight opening of the bite that the patient felt he could tolerate while milling in. Contacts were then checked with dental floss, any sealant in the interproximal area was removed, and the subject was released.

Re-examinations were conducted as subjects became available in New London or in the home ports to which subjects were transferred in other Naval Districts following their graduation from the Naval Submarine School. All re-examinations were conducted by the principal investigator. The nominal interval for re-examinations was six months, with the last examination intended at two years. Appropriate class indicators were used to group examination data at the 6 month, 12 month, and 18 month points.

Criteria for caries assessment on re-examination were those used in selecting subjects, except that a sealed tooth with sealant intact was assumed noncarious and those study teeth (sealant or control) found to have restorations upon re-examination were assumed to have been carious. Sealant retention was judged subjectively as (a) Intact (no significant wear); (b) Intact but worn (significant wear has occurred, but all pits and fissures were still coated); (c) Partially intact (at least a

portion of the pits, fissures, and grooves were still coated while some of these vulnerable areas were now exposed through sealant loss); and (d) Sealant lost (all sealant lost or only isolated tags remained on inclined planes or other "clean" areas of the occlusal surface).

RESULTS

A total of 20 teeth (9 sealant treated, 11 controls) of 1320 study teeth in 111 subjects were found to be carious (Table II). The average time of service to date, calculated by combining the 6 month, 12 month, and 18 month groups was one year, and the overall occlusal caries attack rate for this period was 1.52% (1.67% control; 1.36% sealant).

Table III shows that the mean DMFT score of all subjects was 5.6 and their mean age was 21.6 years at the time of sealant placement. Mean DMFS score was 7.2 and 51 unrestored carious lesions were present.

Retention data for the clear and the tinted material differed greatly (Table IV). "Complete retention" was as-

TABLE II - NEW CARIES IN STUDY TEETH

	(n)	Sealant	Control
6 Months	Clear (0)	-	-
	Tinted (156)	0	0
12 Months	Clear (98)	0	1 (1)
	Tinted (238)	5 (4 + 1 ^F)*	3 (2 + 1 ^F)
18 Months	Clear (105)	3 (1 + 2 ^F)	5 (3 + 2 ^F)
	Tinted (63)	1 (1)	2 (2)

*Refers to Filling, i.e., 5 (4 + 1^F) states that 5 surfaces are scored as carious; 4 actual caries assessed by the examiner and 1 constructive caries assigned for an occlusal filling.

signed to those coatings judged (a) Intact and (b) Intact but worn. "At least partial retention" was defined as a combination of (a) and (b) above with (c) partially intact. "Sealant lost" (d) has been described above.

"Complete retention" was noted for the tinted sealant in 57.6% of 238 teeth at 12 months and 41.3% of 63 teeth at 18 months. "Complete retention" for the clear sealant was 91.8% of 98 teeth at 12 months and 92.4% of 105 teeth at 18 months. "At least partial retention" was noted for the tinted sealant in 76.4% of 238 teeth at 12 months and 68.3% of 63 teeth at 18 months. "At least partial retention" for the clear sealant was 99% of 98 teeth at 12 months and 95.2% of 105 teeth at 18 months.

The hypothesis that the tinted and clear sealants did not differ in duration of retention was tested by Chi square analysis for both the 12 month and 18 month data (Table V). Extremely significant differences (.005 level) were found in each case. Retention of the clear sealant was markedly superior.

The accelerated loss rate of tinted sealant relative to clear sealant can be seen in the proportion of teeth with "sealant lost" at 6, 12, and 18 month evaluations. Tinted sealant loss was 17% at 6 months, 24% at 12 months, and 32% at 18 months while clear sealant loss was only 1.0% at 12 months and 5% at 18 months. No data is available for clear sealant at 6 months.

Table VI itemizes the new occlusal caries by location. The bicuspid which constituted 57.06% of the 1320 study

TABLE III - SUBJECT DATA AT TIME OF SEALANT PLACEMENT

	Subjects	Pairs	Unrestored Carious Surfaces	DMF Surfaces	Mean DMFS	Mean DMFT	Mean Age
6 months tinted	25	156	7	125	5.0	2.7	20.85
12 months tinted	41	238	38	300	7.3	8.6	21.83
18 months tinted	11	63	0	71	6.5	4.4	22.07
All tinted	77	457	45	496	6.4	6.1	21.58
12 month clear	16	98	5	164	10.3	4.8	22.09
18 months clear	18	105	1	144	8.0	4.6	21.41
All clear	34	203	6	308	9.1	4.7	21.73
All subjects	111	660	51	804	7.2	5.6	21.63

Mean Age 21.63 years (n = 103); ages of 8 subjects not recorded).

Std. dev. 1.79 years.

teeth contributed only one carious occlusal surface for a caries attack rate of 0.13%. First molars which constituted 17.83% of the study teeth had an occlusal caries attack rate of 1.69%. Second molars which constituted 20.03% of the study teeth had an occlusal caries attack rate of 3.03%. The much more recently erupted 3rd molars which constituted only 5% of the study teeth had an attack rate of 10.46%.

DISCUSSION

Two important inferences can be drawn from the data gathered to date:

1. The occlusal caries attack rate of 1.67% for control teeth in this study is far less than the one year caries attack rates of 9.5% to 47% reported by Pollard⁹, Going¹³, and Buonocore⁷ in younger patients.

2. This occlusal sealant in this population offered no discernible treatment effect.

The high caries attack rate, soon after eruption, for occlusal surfaces of posterior teeth has been documented by Dirks^{16,17}, Reid¹⁸ and Carlos¹⁹. The very early involvement of posterior occlusal surfaces in the carious process

TABLE IV - SEALANT RETENTION WITH TIME (FOR CLEAR AND TINTED)

SUBJECTS	TINTED SEALANT			
25	<u>6 months</u>			
	Total pairs - 156			
	Intact	80	Complete retention 68%	At least partial retention 83%
	Intact but worn	27		
	Partially intact	23		
Lost	26	→ 17%		
41	<u>12 months</u>			
	Total pairs - 238			
	Intact	70	58%	76%
	Intact but worn	67		
	Partially intact	45		
Lost	56	→ 24%		
11	<u>18 months</u>			
	Total pairs - 63			
	Intact	10	41%	68%
	Intact but worn	16		
	Partially intact	17		
Lost	20	→ 32%		
CLEAR SEALANT ^a				
16	<u>12 months</u>			
	Total pairs - 98			
	Intact	79	92%	99%
	Intact but worn	11		
	Partially intact	7		
Lost	1	→ 1%		
18	<u>18 months</u>			
	Total pairs - 105			
	Intact	78	92%	95%
	Intact but worn	19		
	Partially intact	3		
Lost	5	→ 5%		

111
(TOTAL)

^aNo data available for six months.

TABLE V - SEALANT COVERAGE

12 months	Complete		Partial		Sealant Lost		Total		
	f	%	f	%	f	%	f	%	
Tinted	(Obs)	137	40.8	45	13.4	56	16.7	238	70.8
	(Exp)	160.8	47.9	36.8	11.0	40.4	12.0		
Clear		90	26.8	7	2.1	1	0.3	98	29.2
		66.2	19.7	15.7	4.7	16.6	4.9		
Total		227	67.6	52	15.5	57	17.0	336	100.0
<hr/>									
18 months									
Tinted		26	15.5	17	10.1	20	11.9	63	37.5
		46.1	27.5	7.5	4.5	9.4	5.6		
Clear		97	57.7	3	1.8	5	3.0	105	62.5
		76.9	45.8	12.5	7.4	15.6	9.3		
Total		123	73.2	20	11.9	25	14.9	168	100.0

H₀: Materials do not differ in duration of retention.

12 months $X^2 = 39.01$; with 2 df, p of $X^2 < 0.005$.

18 months $X^2 = 52.56$; with 2 df, p of $X^2 < 0.005$.

was undoubtedly the controlling factor in recent work by Graves²⁰ which indicated that sealants must be applied soon after eruption to afford optimum protection against caries.

Early protection is obviously not possible in a service population. The low occlusal caries attack rate reported here supports the reasoning that the most vulnerable pits and fissures which would

contribute to higher attack rates are no longer available in a study population from this age group. Reed¹⁸ in fact reported that the proportion of surfaces free of decay on the occlusal surface of the mandibular first molar decreases rapidly from 85% at age 5.5 to 21% at age 9.5 and remains relatively constant thereafter.

The 42% of all occlusal surfaces at risk in recruits from the Naval Training

TABLE VI - NEW CARIES BY LOCATION

	Tooth	Proportion of study teeth	# Carious	Caries attack rate
Upper	1st molar	10.42	3	
	2nd molar	10.56	3	
	3rd molar	2.33	4	
	1st bicuspids	14.95	-	
	2nd bicuspids	13.44	1	
		51.70	11	
Lower	1st molar	7.41	1	
	2nd molar	9.47	5	
	3rd molar	2.74	3	
	1st bicuspids	15.09	-	
	2nd bicuspids	13.58	-	
		48.29	9	
All	1st molar	17.83	4	1.69%
	2nd molar	20.03	8	3.03
	3rd molar	5.07	7	10.46
	1st bicuspids	30.04	-	
	2nd bicuspids	27.02	1	
		99.99	20	

Center, Great Lakes, were in those teeth (except for third molars) which survived the same environments which allowed decay in the remaining 58% sealant ineligible teeth.

Although the total number of new caries (20) was too small for more significant analysis, it should be noted that just one of 753 bicuspids (sealant and control) became carious. Among the remaining teeth, only the recently erupted third molars were attacked to a significant degree:

1st molar attack rate 1.69%

2nd molar attack rate 3.03% \cong 1.69²

3rd molar attack rate 10.46% \cong 3.03²

The caries attack rates, though derived from small numbers, suggest

that a second order relationship exists between molar occlusal attack rates and duration of oral exposure. Consistent with the findings of Graves²⁰, these attack rates strongly suggest that if sealants are to be applied to molar teeth as a preventive measure, the treatment should be accomplished immediately after eruption.

The marked superiority in duration of retention of the commercially obtained sealant over the tinted sealant points out the importance of employing the exact test formulation whose characteristics are of interest. The tinted sealant specially supplied by the manufacturer for investigational use after comprehensive laboratory testing did not accurately reflect the retention characteristics of the clear commercial product provisionally approved by the American Dental Association for distribution to the dental profession.

The dye in the tinted sealant apparently interfered with ultraviolet penetration into the resin mass inhibiting polymerization. This effect would logically be greatest in the portion of sealant most removed from the light source at the critical tooth resin interface and would account for inferior retention performance of the tinted sealant.

Subjects were primarily recruit training camp graduates from the Naval Training Center, Great Lakes; Naval Training Center, San Diego; and Naval Training Center, Orlando. For the period 1970-1972 a mean DMFT of 11.2 was reported for recruits at the Naval Training Center, Great Lakes²¹. Mean DMFT for recruits from the

Naval Training Center, San Diego, was reported to be 15-20% lower²², while no information was available for Naval Training Center, Orlando.

The mean DMFT for the study population was lower than that for newly enlisted Naval personnel at large. Undoubtedly, this was because of the minimum study criterion for one caries-free pair of 1st or 2nd molars which produced a study population with a mean DMFS (Decayed, Missing, Filled Surfaces) of 7.21 and a mean DMFT (Decayed, Missing, Filled Teeth) of 5.6. Evidently these young adults (26%, ca., one in four of all examinees) who have a sufficient number of occlusal surfaces to justify treatment in an efficient and economical fashion, do not benefit from its application.

Because the effect of this new treatment is still poorly defined and because of the low occlusal caries attack rates observed to date, the possibility that a measurable *treatment* therapeutic effect will appear during the second year of the study is not entirely discounted. It seems certain at this point, however, that sealant application to the posterior teeth of young Naval personnel cannot be justified.

CONCLUSIONS

1. Application of an ultraviolet-light-polymerized sealant (Nuva-Seal) did not provide a measurable treatment effect in young Naval personnel.

2. The very low occlusal attack rate for untreated control teeth

(1.67% for one year) indicates that sealant application, regardless of treatment effect, would not be a cost-effective measure in active duty Navy personnel.

3. The seemingly trivial addition of a dye to the clear commercial sealant formulation to improve visualization degraded intra-oral retention of the sealant significantly.

ACKNOWLEDGEMENT

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