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CLINICAL EVALUATION OF DENTAL RESTORATIVE MATERIALS

FINAL REPORT

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1. Closure of the Public Health Service Hospital

Effective November 1, 1981, the Department of Health and Human Services support for the Public Health Service Hospital in San Francisco was terminated. The closure of the PHS Hospital resulted in the loss of a dentist, dental assistant, laboratory technician, and secretary, which represented a 50 percent reduction in personnel involved in this project.

The two dentists, Drs. Hamilton and Ellison who were originally involved in our clinical research activities were PHS commissioned officers. When the Hospital was closed, both these individuals were transferred to other duties with the Indian Health Service. Similarly, the employment of the three federal civil service employees were also terminated. Fortunately, we were able to retain the services of a dental assistant and laboratory technician, who were University of California employees. Later, we were also able to rehire Dr. James Ellison as a U.C. employee when he resigned his PHS commission. Although the closure of the Hospital had a significant demoralizing effect upon our personnel, we were able to retain an effective core of individuals to continue, at a reduced level, our original program goals.

The Hospital closure also resulted in the interruption of certain critical services, such as janitorial, sanitary, electrical, mechanical maintenance, heating and phone service, which were necessary for our clinical and laboratory operations. Upon closure of the Hospital, the buildings and grounds were turned over to the U.S. Army. The main hospital building is currently being utilized by diverse Department of Defense agencies, such as the Defense Language Institute, clinical facilities of Letterman Army Medical Center, and certain Army Medical Reserve Units. Accordingly, we were requested to move our clinical operatories, supporting laboratory, office areas, and computer facilities to another building in which our materials testing laboratory was located. Fortunately this building is conveniently located for patient access and has ample space for clinical operatories, waiting room, offices and computer hardware. The consolidation of the clinical evaluation and materials testing facilities to the same building also lends itself to increased efficiency.

During the lengthy transition period between the closure of the Hospital and formal operation by the U.S. Army, our reduced staff was responsible for the actual relocation of clinical equipment, office items and computer hardware. In order to maintain the same lighting condition which is critical for the evaluation of the color stability of restorative materials, we also transferred the fluorescent fixtures to match those

which were present in our former clinical operatories. We moved the clinical computer system to a much larger room which is air conditioned and centrally located in reference to our clinical operatories and office areas. We also installed the necessary cables connecting the computers' central processing unit with the remote terminals located in the operatories and office areas.

In view of the closure of the PHS Hospital, we felt that to minimize the potential lose of patients it was vitally important to notify all the dental research patients that the dental research program was still active at a new location. Therefore, a significant effort was made to notify all 1,024 patients in our computer files of our continued operation, new location, telephone numbers, and we requested that they provide us with current demographic information. On the basis of these responses, our entire patient demographic data base has been updated. As might be anticipated, the closure of the hospital and the loss of civil service personnel, some of whom were patients, coupled with the reduction in restorative care necessitated by our smaller staff has had an impact upon our active patient population. To date, we have historical clinical data on a total of 5,505 restorations, placed in 1,024 patients. Of these patients, 569 are active, and they possess 3,881 restorations. The remaining 455 patients, representing 1,624 restorations, are inactive. Therefore, approximately 70 percent of the restorations originally placed are still available for subsequent yearly evaluations.

When the PHS Hospital closed, the principal investigator, Dr. Joseph P. Moffa, a U.S. Public Health Service commissioned officer, was detailed to the U.S. Army. Currently, logistical support for the project is performed with the cooperation of tne Letterman Army Institute of Research (LAIR) at the Presidio of San Francisco. This federal agency provides the research program with contractual assistance, ordering supplies, and providing electrical, janitorial, telephone and other auxiliary functions necessary for the continuation of the project. In addition to these services, we also have available statistical consultation, audiovisual, and the assistance of other research specialties.

One of the problems which occurred upon closure of the PHS Hospital was the need to establish an NIH recognized Institutional Review Board to approve research involving human subjects. Pending the establishment of this board, we were restricted from conducting human studies. Upon compliance, this restriction was removed in April, 1982. In view of significant budgetary restrictions, it was decided to transfer the contract for our three research personnel from the University of California to the University of the Pacific, School of Dentistry. This transfer resulted in a significant reduction in personnel costs and also provided us with additional review by their Scientific and Human Use Committees.

In summary, the closure of the PHS Hospital has had an impact upon the conduct of this project in that it necessitated a 50 percent reduction in staff, an interruption in clinical and laboratory operations necessitated

by the relocation, and it required the re-establishment of new organization affiliations. The transition has necessitated a curtailment of the scope of research activities. Major emphasis has been placed upon retaining the interest and vitality of our research patient population and restructuring the program for greater efficiency.

2. Evaluation of Base-Metal Alloys and Ceramic Materials

A. Incidence of Nickel Sensitivity:

It has been well documented that nickel is one of the most common causes of allergic contact dermatitis, and dermatologists maintain that it produces more allergic reactions than all other metals combined. In view of the expanded dental usage of nickel containing alloys, questions have been raised whether intra-oral exposure to a nickel containing alloy can result in an induced nickel sensitivity. Accordingly, a retrospective epidemiological study was conducted to determine whether there was a positive relationship between the incidence of nickel sensitivity and the presence of intra-oral nickel containing dental alloys.

Adult male and female patients requiring routine dental care at this clinical research facility were patch tested for their sensitivity to both nickel and chromium. The outer arm was selected as the test site. Nickel sulfate, 2.5% in petrolatum and potassium dichromate, 0.5% were the screening allergens used. According to standards established by the International and North American Contact Dermatitis Group, the allergens were applied and the test sites were examined independently by two examiners five days after initial placement. The reactions at the test sites were classified according to the following criteria:

1. Negative - no reaction
2. Weak Positive - papules of less than 75% of the test site
3. Strong Positive - confluent papules equal to or greater than 75% of the test site.

In addition, each patient was requested to complete a health history questionnaire which included questions relating to current medication, sensitivity to any metals or jewelry, presence of pierced ears and metallic implants. Patients with dermatologic conditions and those receiving corticosteroids or any other medication which might interfere with the interpretation of the planned sensitivity patch tests were excluded from the study.

All patients were given a dental examination and the following information was collected and entered into our clinical computer system:

1. Demographic information to include the patients' age, sex, race, and occupation.
2. Classification of both fixed and removable prostheses present in the patients' oral cavity, with particular emphasis upon whether these were gold alloy, nickel-chromium, cobalt-chromium alloys and their duration.

3. Results of the patch tests and the health history questionnaire.

The hypothesis to be tested was that there would be no significant difference in the presence of nickel sensitivity between those patients who possess intra-oral nickel dental appliances and control patients with no intra-oral exposure to nickel. The hypothesis was tested by constructing contingency tables and assessing statistical significance using the Chi-square statistic. A probability of less than five percent was selected to signify statistical significance.

The traditional method that dermatologists employ to determine whether a metal contains sufficient quantities of nickel to elicit a reaction in a sensitized individual is the dimethylglyoxime test. This test involves placing a drop of liquid 'A' which is a 1% solution of dimethylglyoxime and one drop of liquid 'B' which is a 10% solution of ammonium hydroxide or the suspected metal. Alternatively, the drops can be placed on a cotton swab and rubbed on the metal surface. A resulting pink discoloration is a positive indication for the presence of nickel. We found that this test is unreliable for dental alloys. This test will fail to produce a pink discoloration, in spite of the fact that a dental alloy contains nickel and will produce a dermal reaction in a nickel sensitive individual.

To date, we have examined and conducted patch tests for both nickel and chromium on 443 patients. Of this number 171 were females and 272 were males. As shown in Table 2-1, dental examinations revealed that approximately one-third of both sexes possessed fixed prostheses made with identified nickel-chromium dental base-metal alloys, VERABOND, ALPHA MS, and BIOBOND CB.

Table 2-1

PATIENT DISTRIBUTION

	Males	Females
Number of patients with Intra-oral Nickel	76	53
Total number of patients examined	272	171
Percent of Patients with Intra-oral Nickel	28%	31%

Examination of the incidences of nickel sensitivity in female patients in the 25-44 age group had a significantly higher incidence of nickel sensitivity than other age groups (significance level 2.7%). As showen in Table 2-2, 7 of the 72 patients or 9.7 percent of the females in the 25-44 age group were strongly sensitive to nickel. In contrast, the incidence

of nickel sensitivity in all other age groups was only 2 out of 100 individuals, or only 2.0 percent. Therefore, females within the ages of 24-44 had a sensitivity to nickel which was 4.9 times that of other age groups. In contrast, the incidence of nickel sensitivity in male patients revealed no significant difference between the various age groups. Within the 25-44 age group, approximately one percent of males were found sensitive to nickel as compared to ten percent for females.

As shown in Table 2-3, we found that of the 171 women tested, a total of 129 or 75 percent of them had their ears pierced, as compared to only 7 percent for men. Interestingly, none of the males with pierced ears, tested positively to nickel. In contrast, 90 percent of the total number of positive reactions to nickel were found in female patients with pierced ears. Those women who reported to have suffered from skin problems associated with the wearing of jewelry, such as itching, swelling and redness, also accounted for 90 percent of the total positive reactions to nickel. Approximately one-quarter of women who experienced these jewelry related skin problems were found to be sensitive to nickel, and within the 24-44 age group, the incidence of nickel sensitivity increased to one-third of this age group.

In view of the very significant correlation of pierced ears with the incidence of nickel sensitivity, it was decided to stratify the analysis of female sensitivity on this basis when examining the effects of intra-oral exposure to nickel. As shown in Tables 2-4 and 2-5, we found that four percent of female patients with a history of intra-oral exposure to nickel were also sensitive to this metal. We found that six percent of female patients with no evidence of intra-oral exposure to nickel were also sensitive to this metal. Statistical analysis revealed that there was no significant difference between the test group, who had experienced intra-oral exposure, and the control group with no oral exposure to nickel. Similar results were obtained with the male participants in the study. However, in view of the low incidence of nickel sensitivity in males, i.e., less than 1.0%, statistical analysis was not possible with the present limited sample size.

In summary, the study revealed a very significant difference between male and female sensitivity to nickel. Less than one percent of males were reactive, while the overall sensitivity of females was five percent. The relative risk of female sensitivity to nickel between the ages of 24-44 was 4.8 times that of other age groups. In this age group, 9.7 percent of females were sensitive to nickel as compared to 0.8 percent for males. For females there was a very positive correlation with pierced ears and jewelry related dermatologic symptoms. For all age groups, the sensitivity to chromium was 1.5 percent for males and 4.5 percent for females. There was no evidence of cross reactivity between nickel and chromium. We did not find any correlation between the increased incidence of nickel sensitivity and the dental use of nickel containing base-metal alloys.

FEMALE'S SENSITIVITY TO NICKEL AND CHROME TABLE 2-2

AGE YRS	NO. IN GROUP N= 172	STRONGLY POSITIVE NICKEL	STRONGLY POSITIVE CHROMATE	WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE NICKEL & CHROMATE	STRONGLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE CHROMATE & WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE
		% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)
(=24	21	4 (1)	4 (1)	0 (0)	14 (3)	0 (0)	4 (1)	0 (0)	0 (0)
25-34	52	9 (5)	9 (5)	1 (1)	21 (11)	0 (0)	3 (2)	1 (1)	0 (0)
35-44	20	10 (2)	0 (0)	0 (0)	25 (5)	0 (0)	5 (1)	0 (0)	0 (0)
45-54	42	2 (1)	0 (0)	4 (2)	16 (7)	0 (0)	2 (1)	0 (0)	0 (0)
)=55	37	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TOTAL	172	5 (9)	4 (7)	1 (3)	15 (26)	0 (0)	2 (5)	0 (1)	0 (0)

FEMALE'S SENSITIVITY TO NICKEL AND CHROME TABLE 2-3

WHO HAVE PIERCED EARS

AGE YRS	NO. IN GROUP N= 130	STRONGLY POSITIVE NICKEL	STRONGLY POSITIVE CHROMATE	WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE NICKEL & CHROMATE	STRONGLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE CHROMATE & WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE
		% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)
(=24	20	5(1)	5(1)	0(0)	15(3)	0(0)	5(1)	0(0)	0(0)
25-34	45	11(5)	8(4)	2(1)	22(10)	0(0)	4(2)	2(1)	0(0)
35-44	19	10(2)	0(0)	0(0)	26(5)	0(0)	5(1)	0(0)	0(0)
45-54	27	0(0)	0(0)	7(2)	7(2)	0(0)	0(0)	0(0)	0(0)
)=55	19	0(0)	5(1)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
TOTAL	130	6(8)	4(6)	2(3)	15(20)	0(0)	3(4)	0(1)	0(0)

FEMALE'S SENSITIVITY TO NICKEL AND CHROME TABLE 2-4

AND ENVIRONMENTAL FACTORS

	NO. IN GROUP	STRONGLY POSITIVE NICKEL	STRONGLY POSITIVE CHROMATE	WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE NICKEL & CHROMATE	STRONGLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE CHROMATE & WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE
		% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)
FIXED GOLD ALLOY	50	4 (2)	4 (2)	4 (2)	6 (3)	0 (0)	0 (0)	2 (1)	0 (0)
FIXED NICKEL ALLOY	54	3 (2)	3 (2)	3 (2)	9 (5)	0 (0)	3 (2)	1 (1)	0 (0)
REMOVABLE CHROME COBALT	16	0 (0)	0 (0)	6 (1)	12 (2)	0 (0)	0 (0)	0 (0)	0 (0)
REMOVABLE NICKEL ALLOY	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PIERCED EARS & FIXED GOLD ALLOY	36	5 (2)	2 (1)	5 (2)	5 (2)	0 (0)	0 (0)	2 (1)	0 (0)
PIERCED EARS & FIXED NICKEL ALLOY	41	4 (2)	4 (2)	4 (2)	12 (5)	0 (0)	4 (2)	2 (1)	0 (0)
METAL IMPLANT & FIXED GOLD ALLOY	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
METAL IMPLANT & FIXED NICKEL ALLOY	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

MALE'S SENSITIVITY TO NICKEL AND CHROME TABLE 2-5

AND ENVIRONMENTAL FACTORS

	NO. IN GROUP	STRONGLY POSITIVE NICKEL	STRONGLY POSITIVE CHROMATE	WEAKLY POSITIVE NICKEL	WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE NICKEL & CHROMATE	STRONGLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE	STRONGLY POSITIVE CHROMATE & WEAKLY POSITIVE NICK.	WEAKLY POSITIVE NICKEL & WEAKLY POSITIVE CHROMATE
		% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)	% (NO.)
FIXED GOLD ALLOY	58	3 (2)	3 (2)	3 (2)	5 (3)	0 (0)	0 (0)	1 (1)	0 (0)
FIXED NICKEL ALLOY	62	3 (2)	3 (2)	3 (2)	8 (5)	0 (0)	3 (2)	1 (1)	0 (0)
REMOVABLE CHROME COBALT	19	0 (0)	0 (0)	5 (1)	10 (2)	0 (0)	0 (0)	0 (0)	0 (0)
REMOVABLE NICKEL ALLOY	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PIERCED EARS & FIXED GOLD ALLOY	42	4 (2)	2 (1)	4 (2)	4 (2)	0 (0)	0 (0)	2 (1)	0 (0)
PIERCED EARS & FIXED NICKEL ALLOY	49	4 (2)	4 (2)	4 (2)	10 (5)	0 (0)	4 (2)	2 (1)	0 (0)
METAL IMPLANT & FIXED GOLD ALLOY	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
METAL IMPLANT & FIXED NICKEL ALLOY	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

B. Laboratory Experiments of the Thermal Properties of Base-Metal and Ceramic Materials.

Despite some setbacks resulting from the USPHS closure and the subsequent loss of our trained technician, the achievements of this years experimental work have been quite satisfactory and significant.

During this phase of experimentation, different materials were tested: Borosilicate Glass NBS 717 (NBS Borosilicate Glass 717, Washington, D.C.); a high gold ceramo alloy, Jelenko O (Jelenko and Company, Armonk, New York); a palladium-silver alloy, Jelstar (Jelenko and Company, Armonk, New York); and a nickel-chromium alloy, Biobond CB (Dentsply, York, Pennsylvania). Specimen fabrication was fairly straight forward for the Borosilicate Glass NBS 717, Jelenko O and Biobond CB. With respect to specimen fabrication with Jelstar, a certain number of difficulties were encountered, and technique adjustments were necessary. The usual specimen preparation method consisting in joining all of the specimen to a common reservoir, as seen in Figure 2-1, showed to be deficient as it yielded a very small percentage of usable specimens. As a result, our method had to be reassessed and had to eliminate the commom reservoir and invest the specimen molds in a fan-like display which proved to be much more practical and successful only yielding few defective specimens (Figure 2-2). As much as possible, we attempted to closely follow manufacturers' recommendations. In the case of Jelstar, the manufacturer (Jelenko and Company, Armonk, New York) recommends the use of their "thermotrol" casting set up. Attempt to cast this alloy with this piece of equipment was not successful, as the thermotrol heating coil burned out having been pushed to its maximum. However, we were successful in casting suitable and usable specimens using the induction casting machine (Nobilium).

Another problem we had to solve involved preheating of specimen left in 'standby' in the muffle furnace prior to actual start of an experimental run. Due to scheduling times at early stages of experimentation, various heat soaking intervals of time were used yielding scattered results due to alloy annealing which occurred during the heat soak 'standby' stage. To remediate to this situation, experimental runs were scheduled to start early in the day and continue without interruption until completion, thus avoiding heat soaking dwells.

Borosilicate specimens were cut from a larger ingot received from the National Bureau of Standards to yield square cross section beams with the following dimensions: 2 X 2 mm X 45 mm. The ceramo alloy specimens were cast according to manufacturers' recommendations and yielded test rods with the following dimension: 1.2 mm in diameter by 45 mm in length. Metal specimens were subjected to four firing cycles ranging from 1200 to 1900 degrees Fahrenheit to duplicate a heat treatment history similar to that recommended for use in laboratory fabrication of procelain fused to metal prostheses. The experimental apparatus consisted of a muffle furnace and was capable of reaching temperatures of 1200 degrees centigrade. The furnace was controlled by a microcomputer capable of

raising, maintaining and decreasing temperature at given rate. In addition, the muffle temperature was monitored at various locations by thermocouples feeding their output to a variable speed strip chart recorder. Changes in specimen deformation were measured by means of a direct current displacement transducer with a built-in linearity of $\pm$ 3.2 cm. The linear displacement transducer signals were recorded on the strip chart recorder. In addition, both the thermocouple and the transducer outputs were transmitted and stored in a computer via a digital analogue interfacer. Data analysis and output was done automatically. The logic diagram describing this experimental set up is illustrated in Figure 2-3.

For an actual experiment, the specimen was placed at the extremity of a 2.5 cm diameter, 25 cm long vitreous silicate tube (Figure 2-4) and centrally loaded with 3.2 gm total load, via a vitreous silicate rod at the end of which was suspended the transducer core as well as the dead weight needed in establishing the desired stress for the experimental run.

Results of experiments performed with borosilicate glass NBS 717 specimens showed a good agreement with the NBS specification data sheet. The plot of specimen creep rate recorded against temperature varying from 800 to 1100 degrees centigrade show good reproducibility and linearity with correlation coefficient of 0.99. Annealing point measurements performed with the same material yielded values with a deviation of $\simeq$ 1% of the published NBS data 516, versus ours at 510 degrees centigrade (Figure 2-5).

Results obtained with ceramo alloy specimens showed good fit with linearity over a broad range of temperatures used in this project (Figure 2-6). Scatter of data at the onset as well as at the termination of the experiment is noticeable. The scatter at the onset of the experiment is thought to be due to the slow rate of specimen deflection as compared to the relatively faster rate of temperature increase, whereas, the offset of data from linearity at the highest limits of test temperatures, it is felt, were due to geometical factors, such as, constraint of the specimen extremities on the glass tube support. However, the intervening recorded creep point values showed good fit with a straight line with a reliability coefficient of 0.98. Comparison of log of the creep rate against temperature (C.) of the three ceramo alloys studied in this research project is shown in Figure 2-7. As can be observed, the high gold content and the palladium silver alloys showed greater creep rates as compared to the nickel-chromium based alloy. Moreover, the actual creep behavior of the two noble ceramo alloys took effect at a lower temperature, around 800 degrees centigrade, as compared to the Ni-Cr alloy which actually started to deform between 1000 and 1050 degrees centigrade.

Table 2-6 summarizes the overall experimental results obtained by testing of the alloys. Activation energies were computed using the equation describing viscous flow $\dot{\varepsilon} = ke^{-\Delta H/RT}$ where R is the gas constant and ΔH the activation energy.

TABLE 2-6

DATA COMPARING ACTIVATION ENERGIES TO CREEP RATES OF ALLOYS STUDIED

Alloy	Activation Energy*	Creep rate at 600 C**	Creep rate at 1000 C**
Jelstar	60.342	4.16E-8	3.10E-4
Jelenko 'O'	59.389	2.51E-8	5.01E-4
Biobond CB	160.996	1.63E-13	2.26E-5

* K cal/mole
** mm/sec

One of the observations which was drawn at the earlier stages of this research project was that apparatus design, heating and cooling rates, as well as load and specimen preparation, had a marked effect on the results obtained. However, through trials and proper control, it is felt that with the experimental design offered here it is possible to generate and duplicate data based on a well established NBS standard and this with simple and reliable equipment apparatus.

From the standpoint of predictability and reliability, it is our opinion that the described experimental apparatus has offered the means of generating data which agrees with accepted and established reference materials, such as Borosilicate Glass NBS 717. It will be noted that special care was taken to isolate and shield the experimental apparatus and the surrounding working environment by use of a stable DC power supply, and that constant and uniform temperature chamber around the transducer reduced drift and fluctuations which otherwise would have affected the general accuracy and reproducibility of data obtained.

The use of a real time on line computer provided us with recordings, storage and retrival of data which would have been lost if the manual mode of data recording had been used. In addition, the fully automated data analysis system gave the opportunity to treat the results without human bias or error. Lastly, it provided for fast, easy, concise and readable illustration of data, the treatments of which would have been lengthy and taxing.

With respect to the overall data obtained, two points appear to stand out. Noble ceramo alloys do display higher creep rates as compared to base metal Ni-Cr alloy. Among the reasons for this, composition and structural imperfections can account for a portion of such differences. But it is felt that, in addition, factors related to surface make-up as influenced by oxide formation could have a definite influence on the general high temperature behavior of the alloys. Pre and post experiment observations showed that scale-like covering of oxide occurred around the specimens during testing episodes. Further observations also showed that

the creep values of Ni-Cr base alloys not only were of low magnitude, but that their onset occurred at the maximum temperature which might be encountered during firing of porcelain, i.e., between 1000 and 1050 degrees centigrade. This observation is especially important when studying data displayed in Table 2-6. Creep rate of all alloys, especially Biobond CB, was small at low starting temperatures used in this experimental project. At those temperatures, mechanical as well as thermal fluctuations were of such magnitude that they partially overshadowed the actual specimen deformation. However, between 900 and 1000 degrees centigrade, creep rate of noble alloy specimens were large enough that extraneous perturbations produced by the experimental apparatus were negligible as compared to the overall deformation recorded (Figure 2-8). This observation is furthermore reinforced by the fact that during procelain firing, actual thermo-mechanical changes in the metal-porcelain composite occurred while the material is at that temperature range. This temperature range, 900 to 1000 degrees centigrade, should be the critical temperature to study. Higher as well as lower temperatures, although of importance in studying the overall behavior of the material, are not as essential in computing data, such as given in Table 2-6, and may be detracting from the analysis by fluctuations which are random and difficult to control. With respect to the Biobond CB alloy, it is felt that its deformation under the conditions of this study was small and at 1050 degrees centigrade, well beyond current laboratory handling temperatures, was somewhat minimal and very much the same as the standard NBS 717 values used in calibration in the study.

It is to be noted that although the current set of experiments tend to point out some of the high temperature behavior of ceramo alloy, it is restricted by the parameters used in this study and cannot be all encompassing when considering actual clinical cases.

In summary, we have developed a computer augmented test apparatus, programs, and real-time storage capabilities to study the creep behavior of ceramo alloys and the viscosity of porcelains. The calibration and testing of the apparatus fall within the accepted error of experimental variations based on established NBS standards. Of the three types of ceramo alloys studied, the two noble compositions showed higher creep rates than the Ni-Cr alloy tested. Within the thermal range utilized in the firing of dental porcelain, the degree of distortion of noble composition alloys was very significantly greater than the Ni-Cr alloy which was indistinguishable from the experimental error of the test apparatus.

REFERENCED MATERIAL

1. Moffa, J.P.; Lugassy, A.A.; Gucks, A.D.; and Gettleman, L.: An Evaluation of Nonprecious Alloys for Use with Porcelain Veneers. Part One, Physical Properties, J. Prosth Dent, 30: 424-431, 1973.

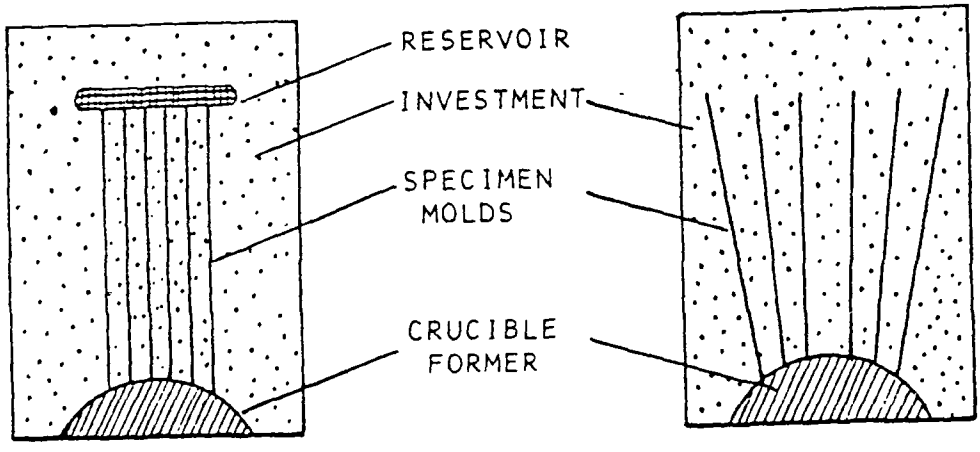
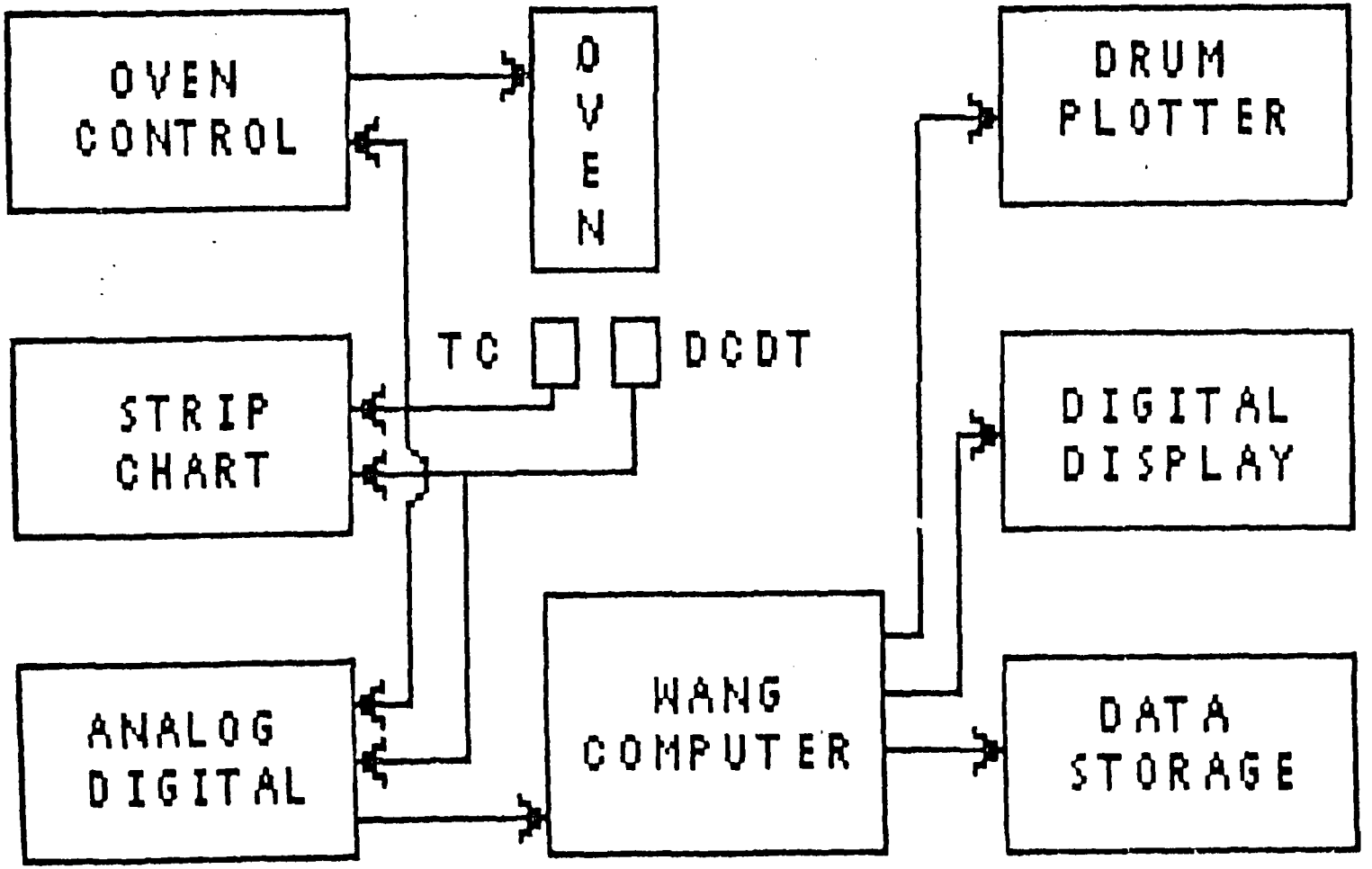


FIGURE 2-1

FIGURE 2-2



LOGIC DIAGRAM

FIGURE 2-3

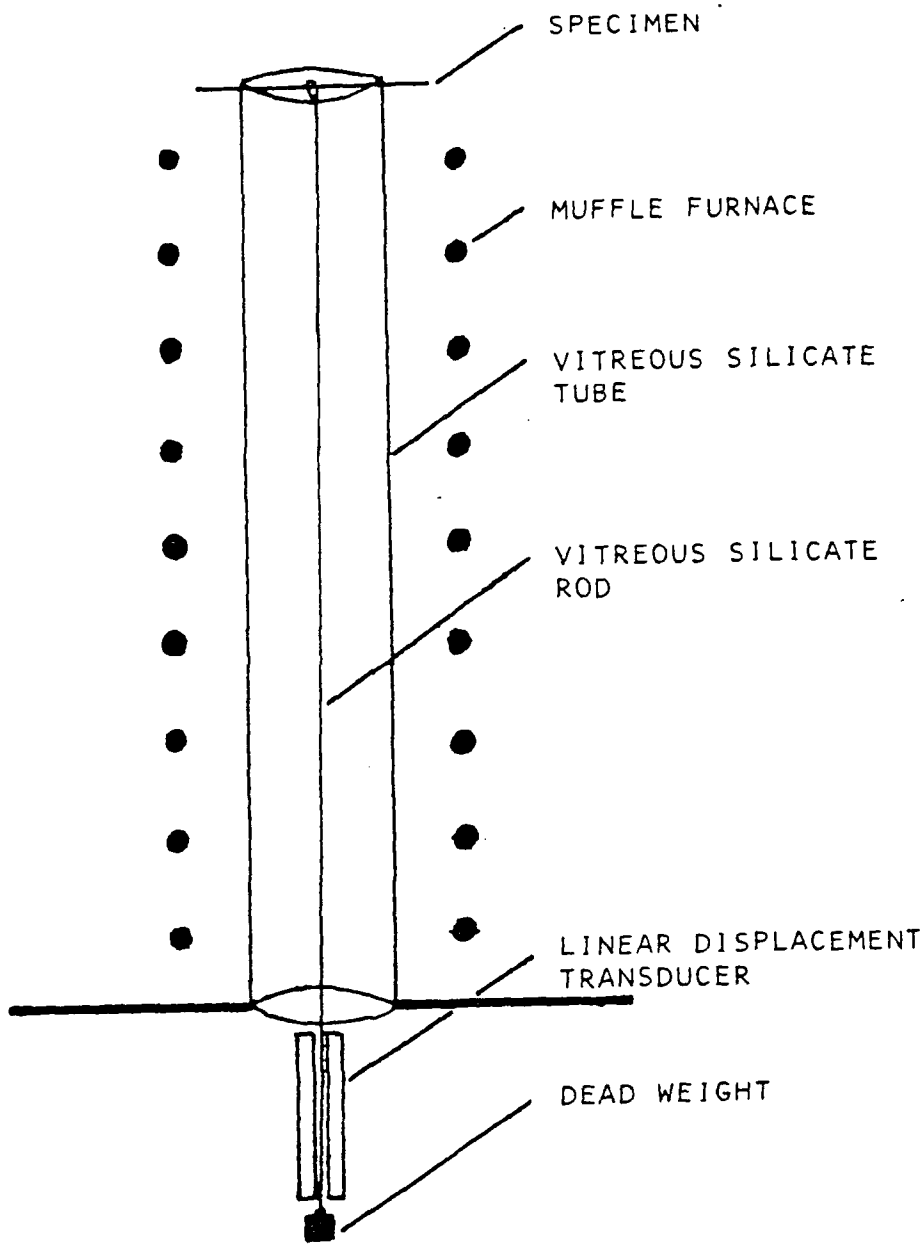

SPECIMEN
MUFFLE FURNACE
VITREOUS SILICATE TUBE
VITREOUS SILICATE ROD
LINEAR DISPLACEMENT TRANSDUCER
DEAD WEIGHT

FIGURE 2-4

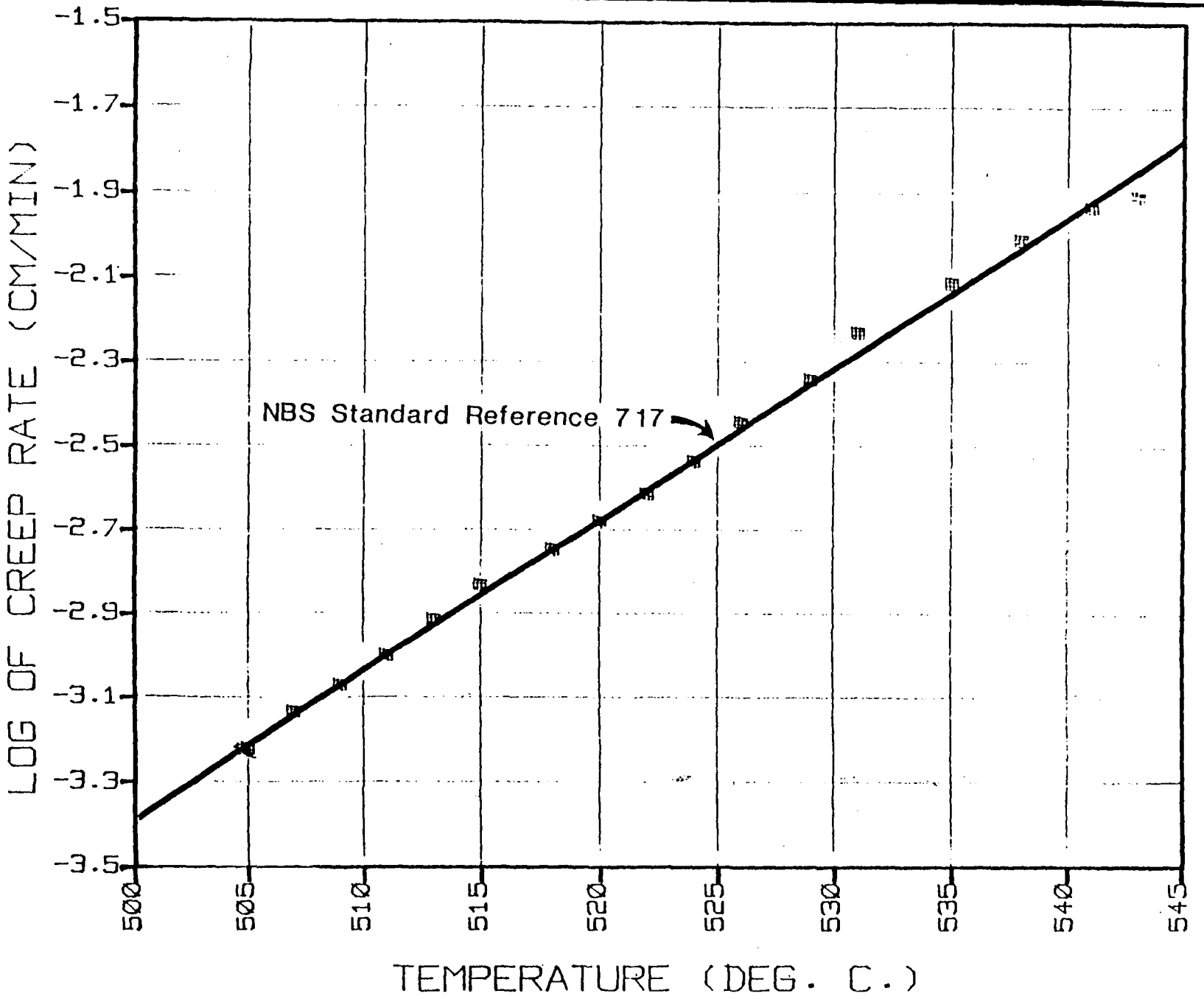

LOG OF CREEP RATE (CM/MIN)
-1.5
-1.7
-1.9
-2.1
-2.3
-2.5
-2.7
-2.9
-3.1
-3.3
-3.5
NBS Standard Reference 717
500
505
510
515
520
525
530
535
540
545
TEMPERATURE (DEG. C.)

FIGURE 2-5

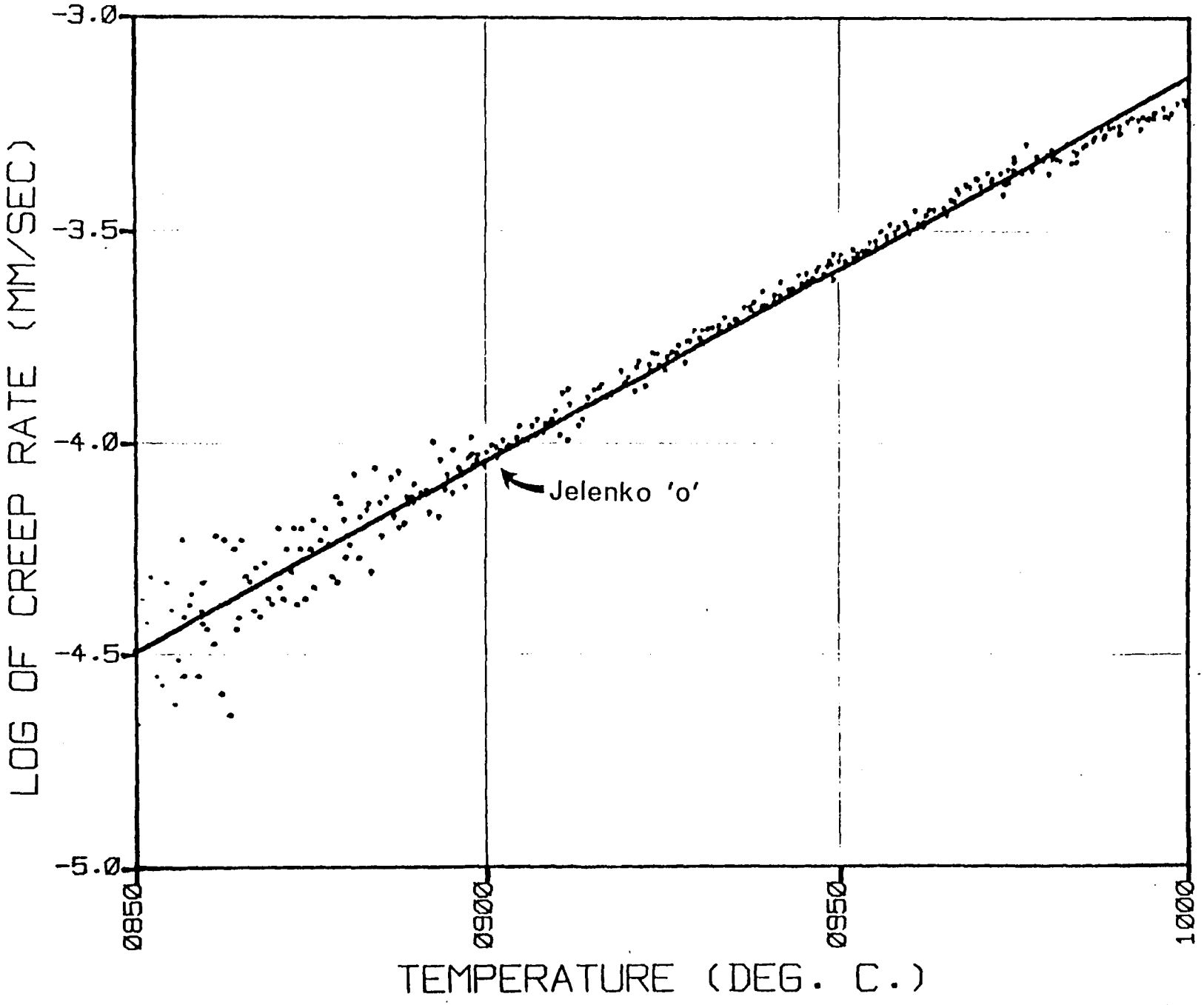

-3.0
-3.5
-4.0
-4.5
-5.0
LOG OF CREEP RATE (MM/SEC)
Jelenko 'o'
0850
0900
0950
1000
TEMPERATURE (DEG. C.)

FIGURE 2-6

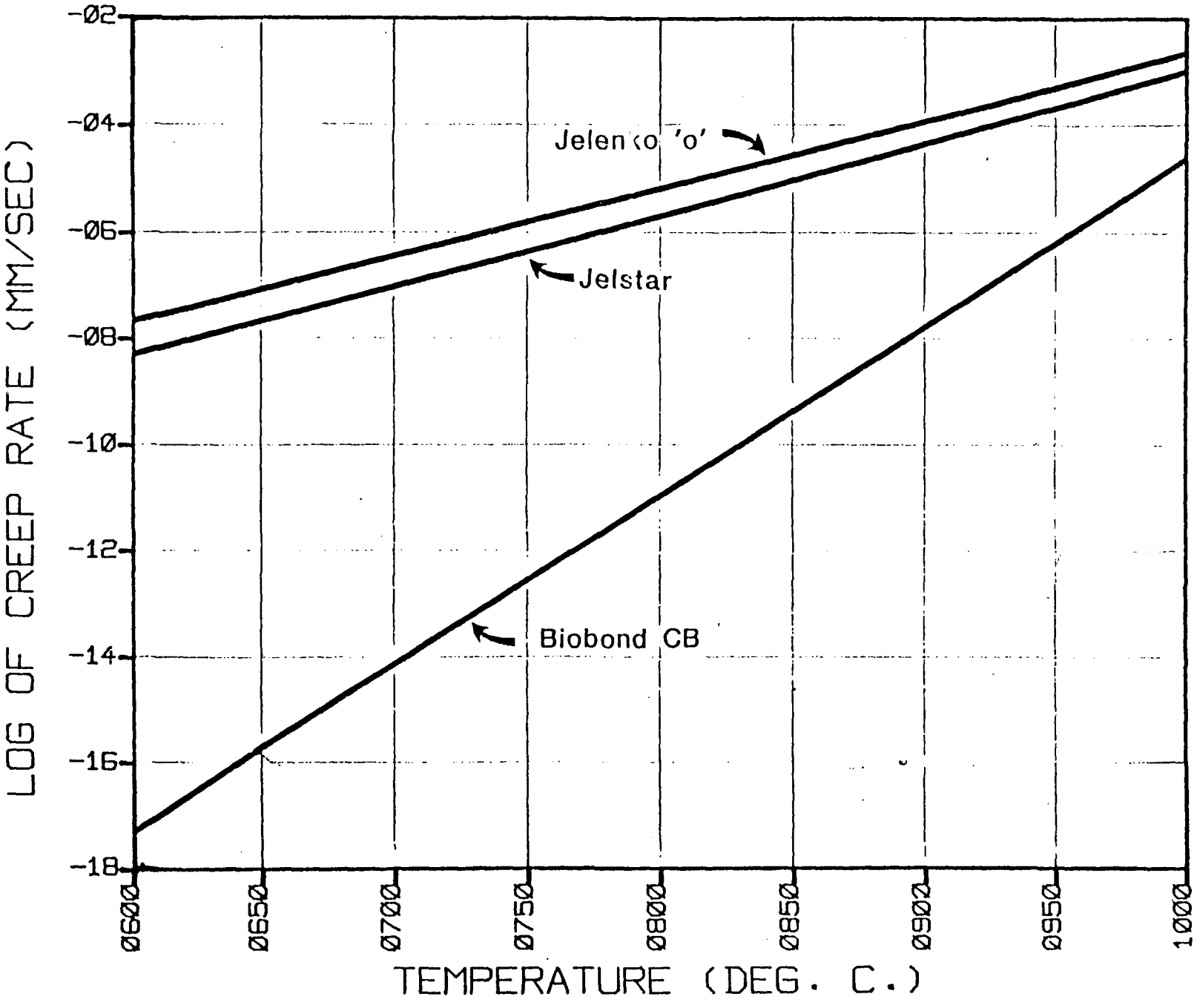

LOG OF CREEP RATE (MM/SEC)
-02
-04
-06
-08
-10
-12
-14
-16
-18
Jelenko 'o'
Jelstar
Biobond CB
0600
0650
0700
0750
0800
0850
0900
0950
1000
TEMPERATURE (DEG. C.)

FIGURE 2-7

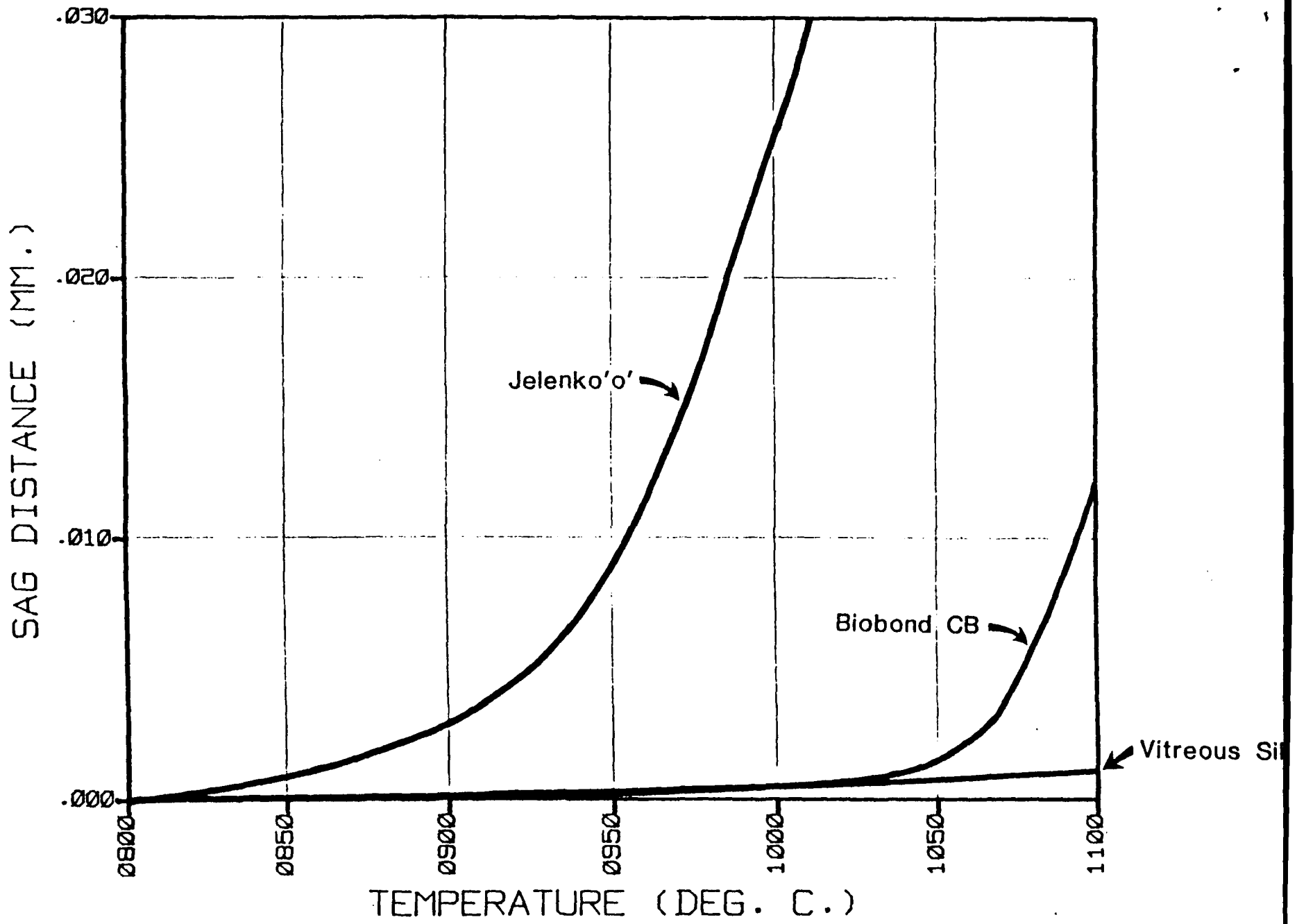

.030
.020
.010
.000
SAG DISTANCE (MM.)
Jelenko'o'
Biobond CB
Vitreous Si
0800
0850
0900
0950
1000
1050
1100
TEMPERATURE (DEG. C.)

FIGURE 2-8

2. Lugassy, A.A. and Kumamoto, Y.: Creep of Alloys Used in Porcelain Fused to Metal Restorations, IADR Progr and Abst 53: No. 740,. 1974.

3. Bertolotti, R.L. and Moffa, J.P.: Alloys as a Function of Temperature, J Dent Res 59: 2062-2065, 1980.

4. Napolitano, A. and Hawkins, E.G.: Standard Reference Material 717 (leaflet). NBS, Washington D.C., 1969.

5. Nielsen, J.P. and Tuccillo, J.J.: Calculations of Interfacial Stress in Dental Porcelain Bonded to Gold Alloy Substrate. J Dent Res 51: 1043-1047, 1972.

3. Clinical Evaluation of Composite Resins and Amalgam Alloys.

Upon the approval of the human use aspects of this project in April 1982, we continued our long-term annual recall of research patients. Our current computer records indicate that since the clinical research program was started, we have twelve years of clinical data on 1024 patients involving a total of 5,505 identified amalgam, composite, and crown and bridge restorations. Over the twelve years in which this data was collected, certain patients were unavailable for re-examination due to assorted reasons, such as mortality, moving out of the immediate area, unwillingness to continue to participate, etc. While the former PHS Hospital was fully operational, a significant proportion of our patient population were employees and their families. Upon closure of the PHS Hospital certain of these patients were lost to the study.

As mentioned previously in this report, we sent out a mailing to all known patients to determine their correct addresses, telephone numbers and to inform them of our continued operation, new location and telephone numbers. The results of this rather extensive undertaking revealed that we received replies from 569 patients, which was 56 percent of the total number of patients in our computer files. These patients were found to possess 3,881 restorations, or 70 percent of the number originally placed by our research staff.

At the recent recall period, Dr. James Ellison and I examined 1,640 anterior and posterior restorations, of which 582 were composite resins and 1058 were amalgam restorations. These clinical examinations were performed on a blind basis, without knowledge of the identity of the materials or knowledge of each other's ratings. Computer programs have been written which permit the analysis of the level of agreement between examiners for each criteria and the extent to which each examiner agrees with the consensus rating, when indeed a disagreement did occur. The levels of agreement between evaluators ranged from 84.1 percent for the assessment of cavo-surface marginal discoloration to 98.6 percent for detection of caries. The overall mean level of agreement for all criteria was 89.6 percent. Analysis of the agreement of each examiner with the consensus revealed that both examiners were equally distributed, i.e.

neither examiner appeared to predominate over the other's where disagreements existed.

A. Evaluation of Composite Resins

In a previous clincial evaluation of an experimental composite resin for the restoration of posterior teeth, we utilized a proprietary composite resin as the control. Since dental amalgam is the current material of choice for posterior operative procedures, subsequent clinical evaluations of the use of composites for posterior restorations have utilized dental amalgam as a control.

The same formulation, of an experimental strontium glass filled composite resin provided to us by the S.S. White Company, was compared to the performance of a proprietary dental amalgam, EASE (L.D.Caulk Company).

Tables 3-1 and 3-2 represent the distribution of ratings for the criteria of Anatomic Form and Marginal Adaptation. At the fifth year recall period, 19 of the remaining 43 composite restorations (44%) showed evidence of occlusal wear. In contrast only 2 of the remaining 62 (3%) EASE amalgam restorations showed any evidence of wear. These differences were highly significant.

In contrast, only 5 of the remaining 43 composite restorations (2%) showed evidence of marginal deterioration. The EASE amalgam, 22 of the remaining 62 restorations (35%), showed evidence of marginal deterioration. Once again, these differences were highly significant.

Over the course of the five year study, in addition to the ratings previously described, we also maintained a tabulation of the reasons why restorations were <u>not</u> evaluated. These reasons for non-evaluation were divided into three categories, i.e., those reasons <u>related</u> to failure of the restorative material, reasons <u>unrelated</u> to failure of the restorative material, and reasons attributable to patient complications. We feel it is important to assess these reasons, as they are indicative of the major modes of failure and reflect the percent of restorations which remain functional at each recall period. At any recall period, the number of restorations lost due to patient complication, since they represent restorations for which no data is available, is subtracted from the total number of restorations of which longevity data is available. Figure 3-1 is a graph which compares the percentage of strontium composite and EASE amalgam restoration which remained functional at each yearly recall period.

As can be seen in this graph, there appears to be systematic decrease in the percentage of composite restorations which remain functional at each yearly recall period. At the end of five years, only 58.1 percent of composite restorations remained functional as compared to 86.1% for the EASE amalgam restoration. An examination of the reasons for replacement reveals that approximately one-half of the related reasons for failure

DISTRIBUTION OF RATINGS: TABLE 3-1

ANATOMIC FORM

RATINGS	STRON COMPOSITE		EASE	
	PERIOD # 0	PERIOD # 5	PERIOD # 0	PERIOD # 5
ALPHA	101	24	108	60
BRAVO	0	19	0	2
CHARLIE	0	0	0	0
DELTA	0	0	0	0
HOTEL	0	0	0	0
NON EVALUATION REASONS				
(RELATED)				
RELATED-CARIES (J)	0	8	0	3
RELATED FRACTURE (K)	0	3	0	2
OPEN MARGIN (L)	0	1	0	0
LEAKAGE (M)	0	2	0	0
WEAR (N)	0	1	0	0
COLOR (P)	0	0	0	0
HYPEREMIA (Q)	0	1	0	0
CONTACT/CONTOUR (R)	0	0	0	0
OTHER-RELATED (S)	0	1	0	0
(UNRELATED)				
CARIES-UNRELATED (T)	0	4	0	1
FRACTURE-UNRELATED (U)	0	4	0	3
ENDODONTIC TREATMENT (V)	0	4	0	1
CROWN & BRIDGE (W)	0	0	0	0
TOOTH MISSING (X)	0	0	0	0
OTHER UNRELATED (Y)	0	2	0	0
(PATIENT COMPLICATIONS)				
DROPPED FROM STUDY (1)	0	15	0	23
HEALTH REASON (2)	0	0	0	0
SCHEDULING COMPLIC (3)	0	3	0	3
FEDERAL SERVICE (4)	0	0	0	2
UNABLE TO CONTACT (5)	0	9	0	8
BROKEN APPOINTMENT (6)	0	0	0	0
NO EVALUATION RECORD	0	0	0	0
IMPROVED	0	0	0	0
NO CHANGE	0	24	0	60
DETERIORATED	0	19	0	2
STUDY TOTAL	0	43	0	62
NON-EVALUATION RELATED	0	17	0	5
NON-EVALUATION UNRELATED	0	14	0	5
	0	27	0	36

DISTRIBUTION OF RATINGS: TABLE 3-2

MARGINAL ADAPTATION

RATINGS	STRON COMPOSITE		EASE	
	PERIOD # 0	PERIOD # 5	PERIOD # 0	PERIOD # 5
ALPHA	101	38	108	40
BRAVO	0	5	0	21
CHARLIE	0	0	0	1
DELTA	0	0	0	0
HOTEL	0	0	0	0
NON-EVALUATION REASONS (RELATED)				
RELATED-CARIES (J)	0	8	0	3
RELATED FRACTURE (K)	0	3	0	2
OPEN MARGIN (L)	0	1	0	0
LEAKAGE (M)	0	2	0	0
WEAR (N)	0	1	0	0
COLOR (P)	0	0	0	0
HYPEREMIA (Q)	0	1	0	0
CONTACT/CONTOUR (R)	0	0	0	0
OTHER-RELATED (S)	0	1	0	0
(UNRELATED)				
CARIES-UNRELATED (T)	0	4	0	1
FRACTURE-UNRELATED (U)	0	4	0	3
ENDODONTIC TREATMENT (V)	0	4	0	1
CROWN & BRIDGE (W)	0	0	0	0
TOOTH MISSING (X)	0	0	0	0
OTHER UNRELATED (Y)	0	2	0	0
(PATIENT COMPLICATIONS)				
DROPPED FROM STUDY (1)	0	15	0	23
HEALTH REASON (2)	0	0	0	0
SCHEDULING COMPLIC (3)	0	3	0	3
FEDERAL SERVICE (4)	0	0	0	2
UNABLE TO CONTACT (5)	0	9	0	8
BROKEN APPOINTMENT (6)	0	0	0	0
NO EVALUATION RECORD	0	0	0	0
IMPROVED	0	0	0	0
NO CHANGE	0	38	0	40
DETERIORATED	0	5	0	22
STUDY TOTAL	0	43	0	62
NON-EVALUATION RELATED	0	17	0	5
NON-EVALUATION UNRELATED	0	14	0	5
NON-EVAL PTNT COMPLIC	0	27	0	36
TOTAL COUNT	0	101	0	108

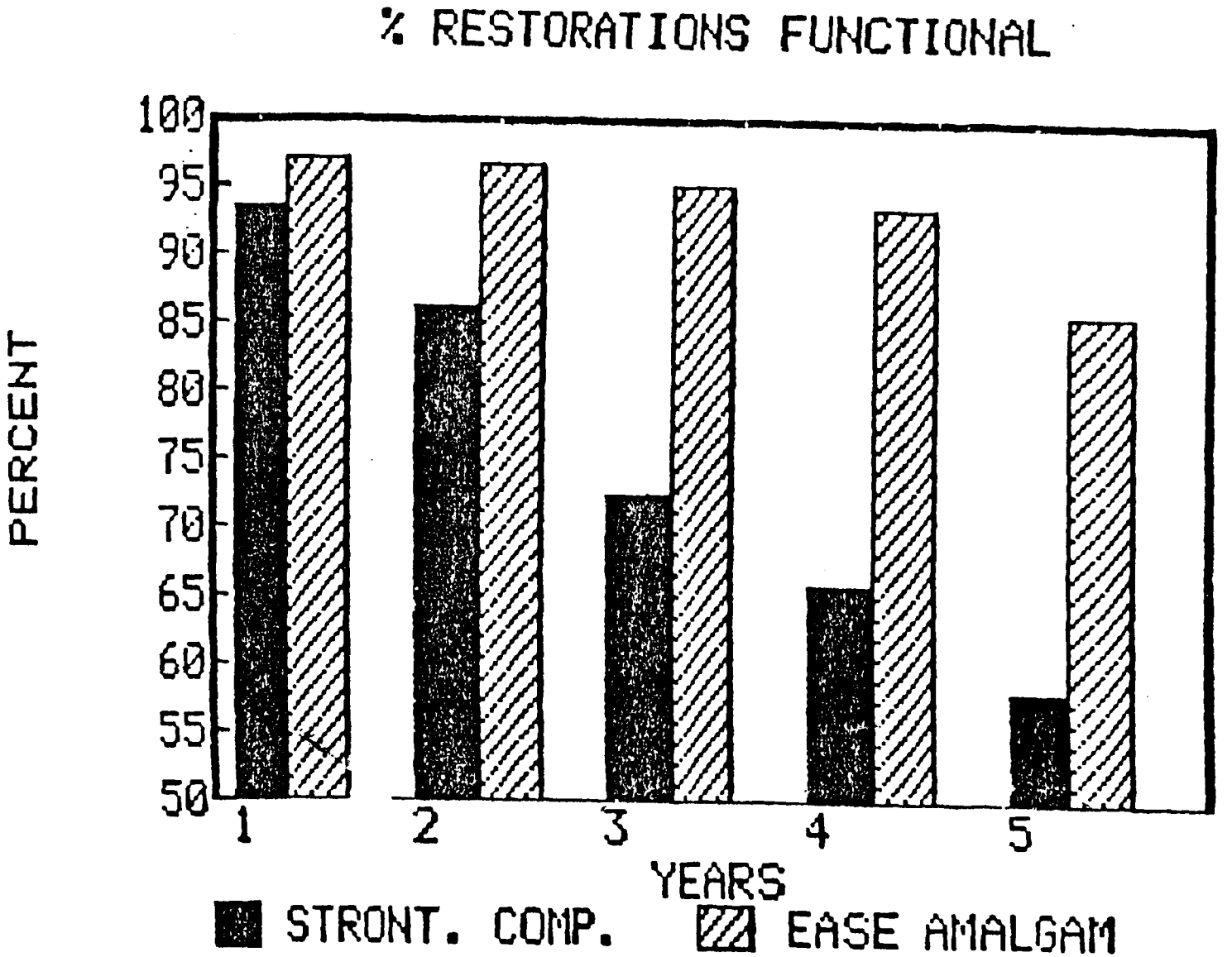

% RESTORATIONS FUNCTIONAL
PERCENT
100
95
90
85
80
75
70
65
60
55
50
1
2
3
4
5
YEARS
STRONT. COMP.
EASE AMALGAM

FIGURE 3-1

were due to caries and the remainder due to fractures, open margins, excessive marginal leakage and hyperemia. Interestingly, only one restoration was replaced because of excessive wear. For both the composite and the amalgam restorative materials, approximately the same number of restorations were replaced for 'unrelated' reasons. It should be noted that there was a suspicously higher number of composite restorations which were replaced because of the need for endodontic treatment. It is conceivable that marginal leakage, the pulpal irritational properties of composites, and the acid-etch procedure may be indirectly responsible for the need for endodontic treatment.

Some pertinent observations should also be made concerning the use of composite resins as a posterior restorative. As will be discussed later, we made replicas of certain restorations and took clinical photographs at yearly intervals. Examination of these replicas and photographs reveal certain characteristics of the wear of posterior composites. Firstly, loss of material appears not to be a localized phenomenon attributable to the opposing tooth's functional cuspal movements. If that were the case, we would expect to see excessive wear in the areas of centric hold and along cuspal inclines which are functional during working and balancing mandibular excursions. This is not the case in that we observe a generalized loss of material, especially in occlusal locations which are completely inaccessable to the opposing cusp tip. Therefore, there is little evidence that loss of composite substance is the sole result of a two body wear mechanism. There is increasing evidence that the action of the food bolus is a major contributing factor of the disintegration and loss of occlusal composite substance.

We have observed an accelerated loss of composite material, especially in the facial and lingual extensions of multi-surfaced occlusal restorations. It can be assumed that these extensions serve as exits for the food bolus when it is sujected to compressive stresses by the opposing occlusion. We have also observed a gradual, but progressive deterioration in the contact relationship between composite restored teeth, especially when both contacting proximal surfaces were restored with composite resin. We theorize that the gradual loss of occlusal substance weakens the contact relationship until the food bolus can achieve an exit between the teeth at which time the process becomes further aggravated.

The comparatively high incidence of recurrent caries with posterior composites is a matter of serious concern. It should be stressed that the teeth were acid-etched and restoration carefully placed under rubber dam. In spite of these measures, we are seeing caries. The proximal gingival area of a Class II restoration is an area of high suspicion. Although the composites were injected into place, it is conceivable that the inability to pack the material, as we do amalgam, may be responsible for inadvertent voids in difficult access areas. It is also possible that the very small amount of gingival enamel available for bonding may also be a contributing factor. In spite of the fact that diligence and care went into the placement of this material, the incorporation of small bubbles during the spatulation is an inescapable occurrence. When these inadvertent voids occur on the margins, it can cause leakage and caries. It has not been

uncommon for us to examine the margins of a composite restoration with a sharp explorer and find only one area of penetration in an otherwise marginally perfect restoration. Our experience with composites has led us to be highly suspicious of what might appear (in the case of an amalgam restoration) to be a trivial defect. Excavation of the composite resin, in these instances, usually reveals an underlying carious lesion. Unlike dental amalgam, whose corrosion products act to seal small marginal discrepancies, composite resins lack this ability. Therefore, we have learned that voids and other marginal defects in composite resin restorations must be considered highly suspect.

A proprietary composite resin, PROFILE, which is allegedly based on the same formulation as the strontium composite used in the aforementioned study, has been introduced on the dental market. Accordingly, we have conducted two clinical studies to compare its performance to two different amalgam alloys, SYBRALOY and DISPERSALLOY. In cooperation with the dental clinic at the NIDR Clinical Center, we have also conducted a clinical study to determine its clinical performance in deciduous teeth.

The data presented in Table 3-3 represents the distribution of ratings for Anatomic Form for the PROFILE and the two amalgam alloys, SYBRALOY and DISPERSALLOY in permanent teeth. The data revealed that 22 of the remaining 48 composite restored teeth (46%) showed evidence of wear at the third year recall period. This relatively high wear rate was very significantly different from the two comparative amalgam alloys. An analysis of the percent of restorations which remained functional at the third year recall period was very similar to that previously described with the experimental strontium composite. We found that 76.7% of the PROFILE restorations remained functional as compared to 85.3% and 95.1%, respectively for SYBRALOY and DISPERSALLOY. Once again, caries, fractures, and open margins were the major reasons for replacement.

The data presented in Table 3-4 represents the data for the study in primary teeth comparing PROFILE and EASE dental amalgam. It must be recognized that since these materials were placed in deciduous teeth a high percentage of these were missing (unrelated reason code 'X') after the first year. In a deciduous dentition, it would appear that for a period of two years, there was no difference in the performance of the composite resin and the comparison amalgam alloy.

As mentioned previously, a proprietary composite resin, PROFILE, which is allegedly based on the same formulation as the strontium composite used in the aforementioned study, has been introduced on the dental market. When the experimental strontium composite resin restorations were originally inserted, we placed a stainless steel pin on the occlusal surface which was ground flush with the surface to serve as fiducial reference point to assess later occlusal wear. A polyether impression was taken at the base-line appointment and at each later annual recall examination. From these impressions, epoxy replicas were produced of the occlusal surface of the restored and adjacent teeth. We also produced similar models of PROFILE restorations, and it was decided to compare the wear of the proprietary and experimental materials after two years of function.

DISTRIBUTION OF RATINGS: TABLE 3-3

ANATOMIC FORM

RATINGS	PROFILE		SYBRALOY		DISPERSALLOY	
	PERIOD # 0	PERIOD # 3	PERIOD # 0	PERIOD # 3	PERIOD # 0	PERIOD # 3
ALPHA	99	26	94	59	98	68
BRAVO	3	21	7	5	9	8
CHARLIE	0	1	0	0	0	2
DELTA	0	0	0	0	0	0
HOTEL	0	0	0	0	0	0
NON-EVALUATION REASONS						
(RELATED)						
RELATED-CARIES (J)	0	4	0	0	0	1
RELATED FRACTURE (K)	0	2	0	5	0	1
OPEN MARGIN (L)	0	1	0	0	0	0
LEAKAGE (M)	0	0	0	0	0	0
WEAR (N)	0	0	0	0	0	0
COLOR (P)	0	0	0	0	0	0
HYPEREMIA (Q)	0	0	0	0	0	0
CONTACT/CONTOUR (R)	0	0	0	0	0	0
OTHER-RELATED (S)	0	0	0	0	0	1
(UNRELATED)						
CARIES-UNRELATED (T)	0	2	0	1	0	0
FRACTURE-UNRELATED (U)	0	0	0	3	0	1
ENDODONTIC TREATMENT (V)	0	0	0	0	0	0
CROWN & BRIDGE (W)	0	0	0	1	0	0
TOOTH MISSING (X)	0	3	0	0	0	0
OTHER UNRELATED (Y)	0	0	0	1	0	0
(PATIENT COMPLICATIONS)						
DROPPED FROM STUDY (1)	0	23	0	10	0	13
HEALTH REASON (2)	0	4	0	1	0	0
SCHEDULING COMPLIC (3)	0	2	0	5	0	2
FEDERAL SERVICE (4)	0	0	0	1	0	0
UNABLE TO CONTACT (5)	0	13	0	9	0	10
BROKEN APPOINTMENT (6)	0	0	0	0	0	0
NO EVALUATION RECORD	0	0	0	0	0	0
IMPROVED	0	0	0	4	0	1
NO CHANGE	0	26	0	55	0	73
DETERIORATED	0	22	0	5	0	4
STUDY TOTAL	0	48	0	64	0	78
NON-EVALUATION RELATED	0	7	0	5	0	3
NON-EVALUATION UNRELATED	0	5	0	6	0	1
NON-EVAL PTNT COMPLIC	0	42	0	26	0	25
TOTAL COUNT	0	102	0	101	0	107

DISTRIBUTION OF RATINGS: TABLE 3-4

ANATOMIC FORM

RATINGS	PROFILE PERIOD # 0	PROFILE PERIOD # 2	EASE PERIOD # 0	EASE PERIOD # 2
ALPHA	60	31	49	26
BRAVO	1	6	1	3
CHARLIE	0	0	0	1
DELTA	0	0	0	0
HOTEL	0	0	0	0
NON-EVALUATION REASONS (RELATED)				
RELATED-CARIES (J)	0	0	0	0
RELATED FRACTURE (K)	0	1	0	0
OPEN MARGIN (L)	0	0	0	0
LEAKAGE (M)	0	0	0	0
WEAR (N)	0	0	0	0
COLOR (P)	0	0	0	0
HYPEREMIA (Q)	0	0	0	0
CONTACT/CONTOUR (R)	0	0	0	0
OTHER-RELATED (S)	0	0	0	0
(UNRELATED)				
CARIES-UNRELATED (T)	0	0	0	0
FRACTURE-UNRELATED (U)	0	0	0	0
ENDODONTIC TREATMENT (V)	0	0	0	0
CROWN & BRIDGE (W)	0	0	0	0
TOOTH MISSING (X)	0	13	0	12
OTHER UNRELATED (Y)	0	0	0	0
(PATIENT COMPLICATIONS)				
DROPPED FROM STUDY (1)	0	0	0	0
HEALTH REASON (2)	0	0	0	0
SCHEDULING COMPLIC (3)	0	0	0	0
FEDERAL SERVICE (4)	0	0	0	0
UNABLE TO CONTACT (5)	0	0	0	0
BROKEN APPOINTMENT (6)	0	0	0	0
NO EVALUATION RECORD	0	10	0	8
IMPROVED	0	0	0	1
NO CHANGE	0	31	0	25
DETERIORATED	0	6	0	4
STUDY TOTAL	0	37	0	30
NON-EVALUATION RELATED	0	1	0	0
NON-EVALUATION UNRELATED	0	13	0	12
NON-EVAL PTNT COMPLIC	0	10	0	8
TOTAL COUNT	0	61	0	50

The two year replicas of the experimental and proprietary composite restored posterior teeth were coded, and four different dentists were instructed to rank the replicas in increasing order of severity of observable occlusal wear. If the proprietary material was the same as the experimental material, it would be expected that the rankings of each would be randomly distributed. If on the other hand, a difference existed between materials, stratification could be expected. Analysis of the data by appropriate non-parametric statistical tests revealed that the proprietary material specimens, PROFILE, were concentrated at the end of the spectrum which showed evidence of severe wear. These differences were statistically significant, indicating that there was a difference in occlusal wear between the experimental material we evaluated and PROFILE which is currently on the market.

The replica ranking technique also revealed another valuable area of information. A comparison was made of the clinical ratings attributed to these teeth by the Ryge criteria of Anatomic Form and a similar assessment of the replicated models. It was strikingly apparent that the clinical ratings tended to underestimate the extent of occlusal loss of material and was not as sensitive as the replica technique. It is conceivable that the similarity in color between the composite and natural tooth structure makes discrimination of clinical loss more difficult than the same examination of epoxy replicas. In addition, the lighting, the ability to view the tooth/restorative material interface at different angles and possibly at increased magnification, further increases the sensitivity of the replica technique.

In any event, there is a very high probability that the Ryge criteria of Anatomic Form tend to produce 'false negative' findings and underestimate the actual extent of occlusal wear. Therefore, in two studies previously mentioned, a negative finding of occlusal wear is subject to question. On the other hand, where the Ryge criteria shows a statistically significant difference in wear rate, this wear is real and in all probability greater than actually reported.

The previous composite resin studies have all delt with the use of these materials as restorative agents for posterior teeth. We now have five year data comparing the performance of microfilled composites to a conventional composite for the restoration of anterior teeth. ADAPTIC RADIOPAQUE was the conventional composite and two versions of ISOPAST and FINESSE were the microfilled materials.

Table 3-5 represents a summary of the distribution of ratings for Color for the four materials over the five year course of the study. There appears to be a progressive deterioration in the color stability of all 3 microfilled composite resins, as compared to the conventional composite ADAPTIC RADIOPAQUE. The differences were statistically significant.

As shown in the data in Table 3-6 on Marginal Discoloration, all four materials show a progressive increase in marginal discoloration. In fact, only approximately 36 percent of the originally placed restorations did not show any evidence of marginal discoloration at the end of five years. There was a statistically significant higher rate of marginal discoloration of the ISOPAST-USA than the other three materials.

DISTRIBUTION OF RATINGS
CRITERIA - COLOR MATCH

TABLE 3-5

	A	B	C	D	H	NOT EVALUATED RELATED	NOT EVALUATED UNRELATED	PATIENT COMPLICATIONS	TOTAL
PERIOD NO. 0									
ADAPTIC - RADIO.	99	2	0	0	0	0	0	0	101
ISOPAST - EUROPE	99	1	0	0	0	0	0	0	100
ISOPAST - USA	96	2	0	0	0	0	0	0	98
FINESSE	102	0	0	0	0	0	0	0	102
PERIOD NO. 1									
ADAPTIC - RADIO.	80	8	0	0	0	0	1	12	101
ISOPAST - EUROPE	82	11	0	0	0	1	0	6	100
ISOPAST - USA	83	13	0	0	0	0	0	2	98
FINESSE	102	0	0	0	0	0	0	0	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 2									
ADAPTIC - RADIO.	77	5	0	0	0	3	1	15	101
ISOPAST - EUROPE	74	7	0	0	0	1	1	17	100
ISOPAST - USA	90	2	0	0	0	3	1	2	98
FINESSE	78	8	1	0	0	3	2	10	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 3									
ADAPTIC - RADIO.	70	3	0	0	0	6	2	20	101
ISOPAST - EUROPE	57	7	0	0	0	9	3	24	100
ISOPAST - USA	74	6	0	0	0	6	4	8	98
FINESSE	66	7	1	0	0	5	5	18	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 4									
ADAPTIC - RADIO.	54	5	0	0	0	7	2	33	101
ISOPAST - EUROPE	37	12	0	0	0	17	3	31	100
ISOPAST - USA	59	12	0	0	0	9	5	13	98
FINESSE	48	15	0	0	0	7	6	26	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 5									
ADAPTIC - RADIO.	37	7	3	0	0	8	2	44	101
ISOPAST - EUROPE	22	17	2	0	0	18	3	38	100
ISOPAST - USA	38	26	1	0	0	11	6	16	98
FINESSE	27	21	1	0	0	7	6	40	102
	0	0	0	0	0	0	0	0	0

DISTRIBUTION OF RATINGS
CRITERIA - MARGINAL DISCOLORATION

TABLE 3-6

	A	B	C	D	H	NOT EVALUATED RELATED	NOT EVALUATED UNRELATED	PATIENT COMPLICATIONS	TOTAL
PERIOD NO. 0									
ADAPTIC - RADIO.	91	9	1	0	0	0	0	0	101
ISOPAST - EUROPE	92	5	3	0	0	0	0	0	100
ISOPAST - USA	88	9	1	0	0	0	0	0	98
FINESSE	92	9	1	0	0	0	0	0	102
PERIOD NO. 1									
ADAPTIC - RADIO.	67	13	8	0	0	0	1	12	101
ISOPAST - EUROPE	67	14	12	0	0	1	0	6	100
ISOPAST - USA	79	14	3	0	0	0	0	2	98
FINESSE	92	9	1	0	0	0	0	0	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 2									
ADAPTIC - RADIO.	59	13	10	0	0	3	1	15	101
ISOPAST - EUROPE	59	14	8	0	0	1	1	17	100
ISOPAST - USA	61	28	3	0	0	3	1	2	98
FINESSE	74	10	3	0	0	3	2	10	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 3									
ADAPTIC - RADIO.	51	15	7	0	0	6	2	20	101
ISOPAST - EUROPE	38	19	7	0	0	9	3	24	100
ISOPAST - USA	43	32	5	0	0	6	4	8	98
FINESSE	53	17	4	0	0	5	5	18	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 4									
ADAPTIC - RADIO.	24	28	7	0	0	7	2	33	101
ISOPAST - EUROPE	27	19	3	0	0	17	3	31	100
ISOPAST - USA	26	40	5	0	0	9	5	13	98
FINESSE	34	26	3	0	0	7	6	26	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 5									
ADAPTIC - RADIO.	14	25	8	0	0	8	2	44	101
ISOPAST - EUROPE	17	18	6	0	0	18	3	38	100
ISOPAST - USA	18	42	5	0	0	11	6	16	98
FINESSE	29	26	0	0	0	7	6	40	102
	0	0	0	0	0	0	0	0	0

DISTRIBUTION OF RATINGS
CRITERIA - SURFACE CHARACTER

TABLE 3-7

	A	B	C	D	H	NOT EVALUATED RELATED	NOT EVALUATED UNRELATED	PATIENT COMPLICATIONS	TOTAL
PERIOD NO. 0									
ADAPTIC - RADIO.	16	56	29	0	0	0	0	0	101
ISOPAST - EUROPE	99	0	1	0	0	0	0	0	100
ISOPAST - USA	97	1	0	0	0	0	0	0	98
FINESSE	101	1	0	0	0	0	0	0	102
PERIOD NO. 1									
ADAPTIC - RADIO.	8	41	39	0	0	0	1	12	101
ISOPAST - EUROPE	75	11	7	0	0	1	0	6	100
ISOPAST - USA	86	6	4	0	0	0	0	2	98
FINESSE	101	1	0	0	0	0	0	0	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 2									
ADAPTIC - RADIO.	5	31	46	0	0	3	1	15	101
ISOPAST - EUROPE	71	5	5	0	0	1	1	17	100
ISOPAST - USA	82	8	2	0	0	3	1	2	98
FINESSE	84	1	2	0	0	3	2	10	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 3									
ADAPTIC - RADIO.	3	26	44	0	0	6	2	20	101
ISOPAST - EUROPE	45	14	5	0	0	9	3	24	100
ISOPAST - USA	72	7	1	0	0	6	4	8	98
FINESSE	73	1	0	0	0	5	5	18	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 4									
ADAPTIC - RADIO.	1	11	47	0	0	7	2	33	101
ISOPAST - EUROPE	37	8	4	0	0	17	3	31	100
ISOPAST - USA	62	7	1	0	0	9	5	13	98
FINESSE	69	0	0	0	0	7	6	26	102
	0	0	0	0	0	0	0	0	0
PERIOD NO. 5									
ADAPTIC - RADIO.	1	3	43	0	0	8	2	44	101
ISOPAST - EUROPE	29	8	4	0	0	18	3	38	100
ISOPAST - USA	57	6	2	0	0	11	6	16	98
FINESSE	47	2	0	0	0	7	6	40	102
	0	0	0	0	0	0	0	0	0

One of the alleged advantages of the mircofilled resins is their ability to be surface finished and achieve a surface character similar to that of natural tooth structure. The data in Table 3-7 appears to indicate that this is indeed a property of these microfilled materials. There was a significant difference between ADAPTIC and the 3 microfilled resins in regard to surface character. We also examined the percent of restorations which remained functional at the end of five years. ADAPTIC RADIOPAQUE restorations had the highest number of restorations still functional at the end of five years, which was 82.4%, as compared to 78.7%, 76.8% and 66.1% for FINESSE, ISOPAST-USA and ISOPAST-EUROPE, respectively.

In summary, microfilled composite resins for the restoration of anterior teeth show problems of color stability, and like conventional composites, there is also progressive evidence of marginal discoloration. Their major advantage appears to be their ability to achieve a surface finish similar to natural tooth structure. However, this advantage is suppressed by the poor color stability and marginal discoloration tendancy of these materials. Composite resins, for the restoration of posterior teeth, appear inferior to dental amalgam in regard to progressive wear of the material and offer obvious advantages in regard to esthetics and marginal adaptation. However, due to reasons of caries, fractures, open margins, and marginal leakage, only 58 percent of posterior composite resins have remained functional at the end of five years, as compared to 86 percent for a dental amalgam.

B. Evaluation of Dental Amalgams

During the course of the study period, we recalled patients with amalgam restorations which were placed over a twelve year period and represented a wide range of formulations and manufacturers. It is widely held that "an amalgam is not finished until it is polished". Dental schools require that dental students polish all amalgam restorations for it is assumed that a more homogeneous surface will deter tarnish and corrosion and make the restoration less susceptible to marginal deterioration. It is apparent that polishing requires additional professional time which contributes to the overall fee which the patient must pay. In view of the additional cost which polishing a restoration demands, it is important to determine what effect this procedure has upon the resistance to marginal deterioration and the ultimate longevity of the restorative procedure.

In regard to clinical amalgam research, previous investigators have focused their attention upon marginal deterioration. The assumption which has been made is that there is a positive correlation between an improvement in an amalgams' resistance to marginal deterioration and the increased longevity of a restoration made with this amalgam alloy. During the course of this study, we have continued to gather long-term clinical data to assess the validity of some of these and other current concepts in restorative dentistry.

In order to determine whether polishing decreases tarnish and corrosion or whether it enhances the resistance to marginal deterioration, a study was started five years ago. Identical batches of the same alloy were placed by the one operator under standardized conditions. The only difference was that one randomly selected restoration was polished after 24-48 hours, and the other restoration remained in the carved and unpolished condition. The restorations were evaluated on an annual basis independently by two examiners, and the data presented in Tables 3-8 and 3-9 summarize the changes in marginal adaptation and tarnish and corrosion which have occurred over the five-year observation period.

The data was statistically analyzed utilizing the Chi Square statistic with Yates Correction. A probability of less than 0.05 was selected to indicate statistical significance. This analysis revealed that at the fifth year evaluation period, with regard to marginal adaptation, EASE amalgam alloy both in the polished and unpolished condition, was found to be significantly different than the other three alloys. Similarly, EASE amalgam alloy, in the polished condition, was found to have a higher incidence of tarnish and corrosion than the other three alloys. When each alloy was compared to itself in the polished and unpolished conditions, TYTIN showed a significantly higher incidence of tarnish and corrosion in the unpolished condition, and EASE amalgam alloy showed a higher rate of marginal deterioration in the unpolished condition. It would appear that each alloy behaves differently when polished or unpolished, and it is impossible to make generalized statements concerning the long term effects of surface treatment upon marginal deterioration and tarnish and corrosion.

Since the effects of these procedures upon the life of the restoration is the ultimate objective, it was decided to examine the survival rate of the various amalgam alloys. For purposes of this report, survival rate is defined as the number of restorations which are considered functional at any recall period, divided by the number of restorations originally placed, minus those restorations which could not be evaluated because of patient complications, times 100. The survival rates for Dispersalloy, Tytin, Ease and Velvalloy in the polished condition were 78.3%, 71.6%, 86.1% and 82.4%. Comparable survival rates in the unpolished condition were 78.6%, 80.0%, 80.9%, and 90.0%, respectively. It is apparent that although polishing may produce a statistically observable effect upon certain of the alloys in regard to marginal deterioration, tarnish and corrosion, there does not appear to be any effect upon the longevity of the restoration at the five year recall period.

The results of this study are very similar to another long-term study which we are still collecting data. Over the past ten years we have been able to follow the clinical performance of two amlagam restorative materials, Dispersalloy and Spheraloy. Between September 1969 and January 1971, 112 Spheraloy and 97 Dispersalloy restorations were placed by a single operator. These restorations were polished in 24-48 hours and were evaluated on a blind basis annually for the first five years and then again at the tenth year by two independent examiners. Not only were the restorations evaluated, but the number of restorations which were replaced

DISTRIBUTION OF CHANGES TABLE 3-8

CRITERIA - MARGINAL ADAPTATION

MATERIAL NO.1 = EASE - UNPOLISHED
MATERIAL NO.2 = TYTIN - UNPOLISHED
MATERIAL NO.3 = VELVALLOY - UNPOL.
MATERIAL NO.4 = DISPERSALLOY - UNPOL.
MATERIAL NO.5 =

CHANGE FROM PERIOD 0 TO PERIOD 1	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	1	0	0	0	2	0	0
DETERIORATED	3	2	0	4	3	2	2	6
NO CHANGE	92	51	53	98	97	80	83	70

CHANGE FROM PERIOD 0 TO PERIOD 2	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	2	0	0
DETERIORATED	11	4	2	5	12	9	5	9
NO CHANGE	60	50	32	84	80	65	71	62

CHANGE FROM PERIOD 0 TO PERIOD 3	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	1	0	0
DETERIORATED	12	10	4	8	12	5	2	6
NO CHANGE	51	36	30	68	66	60	69	56

CHANGE FROM PERIOD 0 TO PERIOD 4	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	1	0	0
DETERIORATED	18	9	9	10	16	4	5	10
NO CHANGE	28	29	22	60	57	60	62	40

CHANGE FROM PERIOD 0 TO PERIOD 5	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	1	0	0
DETERIORATED	23	9	5	12	22	7	5	19
NO CHANGE	15	27	13	44	40	40	49	37

DISTRIBUTION OF CHANGES TABLE 3-9

CRITERIA - SURFACE CHARACTER

MATERIAL NO.1 = EASE - UNPOLISHED
MATERIAL NO.2 = TYTIN - UNPOLISHED
MATERIAL NO.3 = VELVALLOY - UNPOL.
MATERIAL NO.4 = DISPERSALLOY - UNPOL.
MATERIAL NO.5 =

CHANGE FROM PERIOD 0 TO PERIOD 1	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	0	0	0
DETERIORATED	2	6	0	5	1	0	0	8
NO CHANGE	93	48	53	97	99	84	85	66

CHANGE FROM PERIOD 0 TO PERIOD 2	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	0	0	0
DETERIORATED	9	15	2	19	7	7	3	17
NO CHANGE	62	39	32	70	85	69	73	54

CHANGE FROM PERIOD 0 TO PERIOD 3	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	0	0	0
DETERIORATED	19	15	6	13	18	10	19	12
NO CHANGE	44	31	28	63	60	56	52	52

CHANGE FROM PERIOD 0 TO PERIOD 4	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	0	0	0
DETERIORATED	20	15	8	21	29	12	19	6
NO CHANGE	26	23	23	49	43	53	48	44

CHANGE FROM PERIOD 0 TO PERIOD 5	UNPOLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4	POLISHED RESTORATIVE MATERIALS NO.1	NO.2	NO.3	NO.4
IMPROVED	0	0	0	0	0	0	0	0
DETERIORATED	21	16	3	25	25	11	14	14
NO CHANGE	17	20	15	31	36	37	40	42

and the reasons why they were replaced was also noted over this ten year interval. Over the observation period certain restorations could not be evaluated because of patient complications. The number of restorations lost each year due to patient complications increased each year and appeared to be similar for each of the two materials. As shown in the following data, the two materials were very similar in the percentage of molars and premolars remaining at ten years:

PERCENT OF TOOTH TYPE REMAINING - ALL TEETH AT TEN YEARS

	MOLARS	PREMOLARS
Dispersalloy	18%	24%
Spheraloy	17%	27%

There were a total of 90 restorations, 40 Dispersalloy and 50 Spheraloy restorations for which clinical performance and longevity data was available and the following is a summary of these restorations:

TEETH WITH KNOWN OUTCOME

Marginal Deterioration

Year	1	2	3	4	5	10
SPHERALOY						
No change	29	30	27	24	23	8
Deteriorated	18	15	12	11	9	17
DISPERSALLOY						
No change	33	30	27	24	23	16
Deteriorated	6	8	1	3	1	3
Chi Square =	4.48*	1.00	6.07+	2.53	3.85*	9.86#

* $p < 0.05$ + $p < 0.025$ # $p < 0.01$

Failed Due to Related Reasons

Year	1	2	3	4	5	10
SPHERALOY	1	1	10	12	13	17
DISPERSALLOY	1	3	4	7	9	11
Chi Square =	0.31	0.08	0.59	0.24	0.02	0.19

In this known group of 90 restorations, we found a significant difference between the two materials' resistance to marginal deterioration for years 1,3,5, and 10. However, in spite of these differences in the rate of marginal deterioration, there was no significant difference in the survival rate of Dispersalloy and Spheraloy restorations at the end of ten years. During the continuation of this study, we intend to increase the longevity data on these and other amalgam alloys currently in our computer data base.

4. Improve Computer Technology in Clinical Research.

In light of the severe reductions in personnel, progress in the area of clinical computer technology has been restricted to the development of software which will facilitate the analysis of clinical and laboratory data. In this connection, as mentioned previously in this report, computer programs have been written which allow us to store and analyze the thermal experimental data. Since there is only Dr. Ellison and I available as clinical examiners, it becomes vitally important that we maintain our calibration and level of agreement. Consequently, programs have been written which monitor our individual clinical assessments and serve as a basis for retraining, where warranted. In the area of the nickel sensitivity, programs have been written which analyze the multitude of factors which relate to this project.

We recognize that the ranking of replicas and possibly photographs are powerful tools for the assessment of clinical change in restorative materials. However, in a large clinical study, where the number of replicas can be in the hundreds, the problem of reliable discrimination and the ability to sort into an orderly sequence is at best questionable, extremely time-consuming, and mentally and physically fatiguing.

To solve this problem, a program was written for our Wang computer which is used to augment the conduct of our clinical research activities. In order to rank coded replicas or photographs into their correct order of increasing severity, the dental evaluators are directed by the computer throughout the entire procedure. The program has been

written so that the dental evaluator need only make a binary decision, i.e. compare only two replicas at any one time. The only decision required is to determine whether one replica is better, worse, or equal to the indicated replica. On the basis of the human decision rendered, the computer retains the comparative results in its memory, places them into their correct relative ranking to others previously evaluated, and instructs the human evaluator as to the next most expeditious comparison which may be required. The program was written to optimize the number of decisions required to an absolute minimum. For example, if there were 1,000 replicas previously ranked by the computer, in order to place the next replica into its appropriate ranking order, would require only 10 comparisons by the human evaluator.

The use of the computer for this novel application is a classic example of human/machine interaction in which each makes optimal utilization of the others unique capabilities. The human evaluator performs best at making simple yes or no visual comparisons and the computer utilizes its memory and logic to order the decisions into an assending array of target parameters. This program has been used to analyze the wear rate of several composites which were indistinguishable by conventional traditional clinical examination.

Programs have been developed for storing the data collected from the nickel sensitivity study. Computer analysis will facilitate the assessment of factors such as age, sex, occupation, previous history, and intra-oral contact with the target metals. In the area of <u>in-vitro</u> testing, programs have been written to facilitate the analysis and plotting of viscosity and thermal expansion data.

We have received numerous inquiries from the professional community concerning their confusion regarding the many so-called "precious" alloys which are available to them. In order to make it easier for clinicians and laboratory owners to make a rational selection of the host of casting alloys which are on the market, we have utilized our computer to store relevant data associated with these alloys. We have contacted the major dental alloy manufacturers in this country and we currently have data on approximatley 400 so-called "precious" dental casting alloys. The stored data includes the following:

1. Alloy Name
2. Manufacturer
3. Alloy Type
4. Alloy Color
5. Percent of the following metals:
   - Gold
   - Platinum
   - Palladium
   - Silver
6. Hardness
7. Elongation
8. Density
9. Price per ounce
10. Price per cubic centimeter

At the time the requested information was provided by the respective manufacturers, the computer was also provided with the cost of precious metals on the world market. Therefore, with knowledge of the price that each specific alloy was being sold for on that date, and knowledge of the percentages of precious metal content, the computer was programmed to calculate the ratio of the value of intrinsic metal content to the current sale price. This intrinsic value/sales price ratio was calculated for each alloy. It is thus possible for us to enter any days current world market price of precious metals, and allow the computer to normalize and compare the price per ounce and the price per cubic centimeter for all alloys in our data bank. The data can then be sorted and printed on the basis of any combination of the aforementioned ten parameters. As a case in point, it is currently possible to purchase a gold colored porcelain-fused-to-metal precious alloy for approximately $518 per ounce ($310 per cc) which contains 87 percent gold and 7 percent platinum... or purchase at the other end of the spectrum a 'white' ceramo-metal alloy which contains no gold, 60 percent palladium and 30 percent silver for $58 per ounce ($20 per cc). The dental practioner is keenly interested in acquiring information which will allow him to make a prudent selection of casting alloy based upon intended application, composition, mechanical properties, and lastly economic considerations.