



DEPARTMENT OF RESTORATIVE DENTISTRY
707 Parnassus Ave.
San Francisco, CA 94143-0758
TEL: (415) 476-0860
FAX: (415) 476-0858

CLINICAL EVALUATION OF KERR HERCULITE
COMPOSITE RESINS VS DISPERSALLOY DENTAL AMALGAM
IN OCCLUSAL CLASS I AND CLASS II RESTORATIONS

5-YEAR FINAL REPORT

Incorporating:

I. 5-Years Clinical Trial Data
June, 1990

II. 5-Years Wear Assessment
by Indirect Evaluation of Dental Replicas
March 1992

James C. Setcos, D.D.S. (Indiana)
B.D.Sc. (Melb), L.D.S. (Vic), M.Sc. (London)
Associate Professor of Restorative Dentistry



INDIANA UNIVERSITY

DEPARTMENT OF DENTAL MATERIALS

1121 West Michigan Street

Indianapolis, Indiana 46202-5186

(317) 274-8408

SCHOOL OF DENTISTRY

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Clinical Trial

5-Year Data

June, 1990

Ralph W. Phillips, M.S., D.Sc.
Research Professor of Dental Materials

James C. Setcos, D.D.S. (Indiana)
B.D.Sc. (Melb), L.D.S. (Vic), M.Sc. (London)
Assistant Professor of Dental Materials

CLINICAL INVESTIGATION OF KERR HERCULITE
POSTERIOR DENTAL COMPOSITE RESINS

I. OBJECTIVE

The object was to evaluate the clinical performance of Kerr's light activated posterior composite resins, Herculite Condensable (28034) and Herculite Syringeable (28035), compared to Johnson and Johnson's Dispersalloy dental amalgam.

II. CLINICAL POPULATION

A. Restoration

1. Class I and Class II restorations were placed in human permanent teeth. The number and distribution of the materials is shown in Table 1.
2. Specific teeth to be used for each material were determined by randomized assignment.
3. Teeth needing Class I or Class II restorations and those with existing defective restorations were acceptable.
4. Teeth to be restored must have an occluding tooth.
5. Teeth needing the restoration of an entire cusp and most mandibular first premolars were not acceptable.

B. Patients

1. The patient must have been in need of the appropriate restoration. There were no exclusions based on age or sex. All patients were adults.
2. Patients were available for evaluation for at least five years after completion of the restorations.
3. All patients included in the study have been advised as to the nature and intent of this clinical study and have signed a written statement affirming their cognizance and consent.

4. If for any reason the tooth should be in need of further treatment due to the restorative procedure during the study, the restoration will be free of charge to the patient.

III. METHODOLOGY

- A. A standard cavity design was used for all materials due to the large number of restorations which were replacements for existing defective restorations. This was a modern type of preparation with rounded internal angles. No cavosurface marginal bevel was used.
- B. A calcium hydroxide (Kerr Life) was placed prior to the insertion of the restoration.
- C. Moisture contamination was avoided by the use of a rubberdam.
- D. Acid etch technique using 60 seconds etch, and Kerr Bonding Resin was used with the composite resins.
- E. The materials were mixed, manipulated, placed and finished according to the respective manufacturer's instructions.

IV. DATA COLLECTION

These restorations were evaluated over a period of five years. Evaluations were done at baseline, 6 and 12 months; then yearly up to 5 years, at which times the following data was collected:

1. The clinical evaluation of color-match, cavo-surface marginal discoloration, anatomic form, margin adaptation and caries was performed by two evaluators standardized in the use of the U.S.P.H.S. criteria (after Ryge). The appropriate clinical evaluation forms were completed.
2. Quadrant dental impressions were made of the restorations using an accurate silicone impression material. Models were poured from each impression using high quality epoxy resin. The models were used to examine the wear rate of the materials (see 4) and as a record of the anatomic form of the restoration at that time.
3. Color photographic transparencies (1.5 times magnification) were made of each restoration to document conditions of the materials.
4. The models of the restorations were evaluated by at least two evaluators trained in the use of the "Vivascale" standard casts. The evaluators each performed their independent estimations of wear, and after testing for homogeneity of estimations both within the evaluators and between the

evaluators, the data was analyzed in toto. The test for homogeneity was in order to show that there was no significant difference between successive evaluations for each evaluator nor a significant difference between evaluators.

V. RESULTS

Table 1 shows the distribution of Class I and Class II restorations in molars and premolars. While the ratio of Class I to Class II restorations is not 1:2 as suggested by the American Dental Association, at the five year recall, 30 Class II restorations were evaluated (as compared to the required minimum of 13).

Table 2 give the number and percentage of Herculite restorations as evaluated as "alpha" and "bravo" by the modified USPHS clinical criteria. There was one "charlie" rating at the four year recall for marginal adaptation. Table 3 show similar results for Dispersalloy amalgam.

Table 4 shows all restorations known to be lost from the study as failures, possibly due to material related causes or other reasons such as tooth cusp fracture.

Tables 5 through 10 detail the alpha and bravo clinical evaluations for all clinical criteria.

Color Match

Tables 2, 5, and 7 show alpha ratings consistently over 90% which indicates an excellent color matching ability for the Herculite restorations.

Marginal Adaptation

Tables 5 and 7 show that over 84% of the restorations were rated as alpha for all time periods. The bravo category, which indicates a catch to the explorer in two directions, accounted for all of the remainder except for one "charlie" rating at the 4 year recall. This restoration is listed as a failure, and was replaced (Code #2,15 Occ:designated "Large marginal crevice"). The bravo ratings were essentially for minor chipping at some point on the restoration margin.

Marginal Discoloration

All ratings were alpha or bravo. A rating of bravo indicates that there is some discoloration evident, but which is not perceived to have penetrated in a pulpal direction. In some cases dentin stained prior to restoration may not be scored "bravo" in the earlier recalls, but may be scored as "bravo" later. There was no perception of marginal leakage occurring with the restorations.

Secondary Caries

No cases of secondary caries were detected for any of the restorations.

Temperature Sensitivity

At five years there were no patients who felt that their tooth was sensitive to temperature changes. Earlier there were some restorations which showed some temperature sensitivity but examination did not find any open margin, leakage or other problem.

Anatomic Form

The clinical evaluation of anatomic form was carried out and is shown in Tables 2, and 5 through 10. In addition, replicas of the restorations were evaluated. The results of indirect evaluation of the models according to the Vivascale standard casts method (similar to that reported in Dental Materials, 2:198-201, 1986) showed a wear rate for the Herculite restorations of $66 \pm 40 \mu\text{m}$ which is well within the American Dental Association limit of $150 \mu\text{m}$ after three years. After five years the mean value for the indirect wear evaluation was $81 \pm 40 \mu\text{m}$ total (Figure 1). This is a mean value of $16 \mu\text{m}$ per year, which is a very low rate of wear.

Summary

The clinical evaluation of Herculite posterior composite resin was conducted for Class I and Class II restorations in molars and premolars and is reported after five years. The results up to this time indicate that Herculite is performing satisfactorily under clinical conditions and satisfies the American Dental Association's guidelines for "Full Acceptance".



March 27, 1992

James C. Setcos, DDS (Indiana)
B.D.Sc. (Melb), L.D.S. (Vic), M.Sc. (London)
Associate Professor of Restorative Dentistry
University of California, San Francisco

TABLE 1

HERCULITE AND DISPERSALLOY
CLASS I & CLASS II
MOLAR & PREMOLAR DISTRIBUTION

MATERIAL		CLASS I			CLASS II		
		PREMOLAR	MOLAR	TOTAL	PREMOLAR	MOLAR	TOTAL
HERCULITE TOTALS	BASELINE	29	26	55	21	19	40
	3-YEARS	24	24	48	18	12	30
	5-YEARS	24	23	47	18	12	30
DISPERSALLOY TOTALS	BASELINE	0	11	11	5	11	16
	3-YEARS	0	7	7	5	9	14
	5-YEARS	0	7	7	4	9	13

TABLE 2

HERCULITE TOTALS

NUMBER AND PERCENTAGE OF RESTORATIONS IN CATEGORY

	ALPHA RATINGS				BRAVO RATINGS				
	BASELINE	3-YEARS	5-YEARS	BASELINE	3-YEARS	5-YEARS	BASELINE	3-YEARS	5-YEARS
TOTAL EVALUATED	95	78	77	95	78	77	95	78	77
COLOR MATCH	94(99%)	73(94%)	71(92%)	1(1%)	5(6%)	6(8%)			
MARGINAL ADAPTATION									
(OCCLUSAL)	95(100%)	71(91%)	66(86%)	0(0%)	7(9%)	11(14%)			
(PROXIMAL)	40(100%)	27(90%)	26(84%)	0(0%)	3(10%)	5(16%)			
MARGINAL DISCOLORATION	93(98%)	68(87%)	70(91%)	2(2%)	10(13%)	7(9%)			
ANATOMIC FORM									
(OCCLUSAL)	95(100%)	74(95%)	64(83%)	0(0%)	4(5%)	13(17%)			
(PROXIMAL)	40(100%)	30(100%)	29(94%)	0(0%)	0(0%)	2(6%)			
TEMPERATURE SENSITIVITY	92(97%)	78(100%)	77(100%)	3(3%)	0(0%)	0(0%)			

TABLE 3
DISPERSALLOY TOTALS
NUMBER AND PERCENTAGE OF RESTORATIONS IN CATEGORY

	ALPHA RATINGS				BRAVO RATINGS			
	BASELINE	3-YEARS	5-YEARS	BASELINE	3-YEARS	5-YEARS	BASELINE	5-YEARS
TOTAL EVALUATED:	27	21	20	27	21	20	27	20
COLOR MATCH*								
MARGINAL ADAPTATION								
(OCCLUSAL)	27(100%)	15(71%)	14(70%)	0(0%)	6(29%)	6(30%)	0(0%)	6(30%)
(PROXIMAL)	16(100%)	11(79%)	8(58%)	0(0%)	3(21%)	5(42%)	0(0%)	5(42%)
MARGINAL DISCOLORATION*	27(100%)	21(100%)	20(100%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
ANATOMIC FORM								
(OCCLUSAL)	27(100%)	20(95%)	18(90%)	0(0%)	1(5%)	1(5%)	0(0%)	1(5%)
(PROXIMAL)	16(100%)	14(100%)	13(100%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
TEMPERATURE SENSITIVITY	25(93%)	21(100%)	20(100%)	2(7%)	0(0%)	0(0%)	0(0%)	0(0%)

*"HOTEL"

TABLE 4

FAILED RESTORATIONS

HERCULITE TOTAL PLACED 95

REASON FOR FAILURE	CODE #	TOOTH #	# OF MONTHS AT FAILURE
MATERIAL RELATED			
RESTORATION FRACTURED	9	18 MO	25
LG MARGIN CREVICE	2	15 OCC	48
RESTORATION FRACTURED	24	31 MO	60
EXCESSIVE WEAR FROM OPPOSING CUSP	24	14 MODL	33
OTHER REASONS			
REQUIRED ENDODONTICS	16	5 MO	13
CUSP FRACTURE	27	31 OCC	18
TOOTH FRACTURE BELOW GINGIVA	29	19 MOD	24
DISPERSALLOY: TOTAL PLACED, 27			
REASON FOR FAILURE	CODE #	TOOTH #	# OF MONTHS AT FAILURE
MATERIAL RELATED			
RESTORATION FRACTURED	28	14 MO	24
OTHER REASONS			
CUSP FRACTURED	4	15 OCC	22
CUSP FRACTURED	5	15 OB	24

"CODE #" is patient trial identification number.

TABLE 5

HERCULITE S
NUMBER AND PERCENTAGE OF RESTORATIONS IN CATEGORY

ALPHA RATINGS							
TOTALS:	BASELINE 52	6 MONTHS 52	1 YEAR 52	2 YEAR 49	3 YEAR 46	4 YEAR 46	5 YEAR 45
COLOR MATCH	51(98%)	52(100%)	52(100%)	44(90%)	44(96%)	38(83%)	43(96%)
MARGINAL ADAPTATION (occlusal) (proximal)	52(100%) 19(100%)	51(98%) 19(100%)	47(90%) 17(89%)	44(90%) 11(69%)	43(93%) 14(93%)	41(89%) 12(71%)	38(84%) 14(82%)
MARGINAL DISCOLORATION	51(98%)	51(100%)	48(92%)	47(96%)	42(91%)	41(89%)	39(87%)
ANATOMIC FORM (occlusal) (proximal)	51(100%) 19(100%)	52(100%) 19(100%)	52(100%) 18(95%)	47(96%) 15(94%)	42(91%) 15(100%)	38(83%) 16(94%)	37(82%) 16(94%)
TEMPERATURE SENSITIVITY	51(98%)	52(100%)	52(100%)	48(98%)	46(100%)	46(100%)	45(100%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

TABLE 6

HERCULITE S
NUMBER AND PERCENTAGE OF RESTORATIONS IN CATEGORY

BRAVO RATINGS							
Totals:	Baseline 52	6 Months 52	1 Year 52	2 Year 49	3 year 46	4 year 46	5 years 45
COLOR MATCH	1(2%)	0(0%)	0(0%)	5(10%)	2(4%)	8(17%)	2(4%)
MARGINAL ADAPTATION							
(occlusal)	0(0%)	1(2%)	5(10%)	5(10%)	3(7%)	4(9%)*	7(16%)
(proximal)	0(0%)	0(0%)	2(11%)	5(31%)	1(7%)	5(29%)	3(18%)
MARGINAL DISCOLORATION	1(2%)	0(0%)	4(8%)	2(4%)	4(9%)	5(11%)	6(13%)
ANATOMIC FORM							
(occlusal)	0(0%)	0(0%)	0(0%)	2(4%)	4(9%)	8(17%)	8(18%)
(proximal)	0(0%)	0(0%)	1(5%)	1(6%)	0(0%)	1(6%)	1(6%)
TEMPERATURE SENSITIVITY	1(2%)	0(0%)	0(0%)	1(2%)	0(0%)	1(6%)	1(6%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

*There was one "Charlie" rating in marginal adaptation at the four year recall period.

Table 7

Herculite C
Number and Percentage of Restorations in Category

ALPHA RATINGS							
TOTALS:	Baseline 43	6 Months 43	1 Year 43	2 Year 38	3 Year 32	4 Year 33	5 Year 32
COLOR MATCH	43(100%)	43(100%)	41(95%)	32(84%)	29(91%)	29(98%)	28(87.5%)
MARGINAL ADAPTATION							
(occlusal)	43(100%)	40(93%)	40(93%)	27(71%)	28(88%)	31(94%)	28(87.5%)
(proximal)	21(100%)	21(100%)	19(90%)	11(61%)	13(87%)	14(100%)	12(86%)
MARGINAL DISCOLORATION	42(98%)	43(100%)	40(93%)	32(84%)	26(81%)	30(91%)	31(97%)
ANATOMIC FORM							
(occlusal)	43(100%)	43(100%)	43(100%)	34(89%)	32(100%)	25(76%)	27(84%)
(proximal)	21(100%)	21(100%)	21(95%)	18(100%)	15(100%)	14(100%)	13(93%)
TEMPERATURE SENSITIVITY	41(95%)	41(95%)	42(98%)	37(97%)	32(100%)	33(100%)	32(100%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

Table 8

Herculite C
Number and Percentage of Restorations in Category

BRAVO RATINGS							
TOTALS:	Baseline 43	6 Months 43	1 Year 43	2 Year 38	3 Year 32	4 Year 33	5 Year 32
COLOR MATCH	0 (0%)	0 (0%)	2 (5%)	6 (16%)	3 (9%)	4 (12%)	4 (12.5%)
MARGINAL ADAPTATION							
(occlusal)	0 (0%)	3 (7%)	3 (7%)	11 (29%)	4 (12%)	2 (6%)	4 (12.5%)
(proximal)	0 (0%)	0 (0%)	2 (10%)	7 (39%)	2 (13%)	0 (0%)	2 (14%)
MARGINAL DISCOLORATION	1 (2%)	0 (0%)	3 (7%)	6 (16%)	6 (19%)	3 (9%)	1 (3%)
ANATOMIC FORM							
(occlusal)	0 (0%)	0 (0%)	0 (0%)	4 (11%)	0 (0%)	8 (24%)	5 (16%)
(proximal)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)
TEMPERATURE SENSITIVITY	2 (5%)	2 (5%)	1 (2%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

Table 9

DISPERSALLOY
Number and Percentage of Restorations in Category

ALPHA RATINGS							
TOTALS:	Baseline 27	6 Months 27	1 Year 27	2 Year 25	3 Year 21	4 Year 19	5 Year 20
COLOR MATCH	-----	-----	-----	-----	-----	-----	-----
MARGINAL ADAPTATION							
(occlusal)	27(100%)	23(85%)	21(78%)	17(68%)	15(71%)	14(74%)	14(70%)
(proximal)	16(100%)	16(100%)	14(87.5%)	11(73%)	11(79%)	11(92%)	8(58%)
MARGINAL DISCOLORATION	27(100%)	27(100%)	27(100%)	25(100%)	21(100%)	18(95%)	17(85%)
ANATOMIC FORM							
(occlusal)	27(100%)	27(100%)	27(100%)	23(92%)	20(95%)	18(95%)	18(90%)
(proximal)	16(100%)	16(100%)	16(100%)	16(100%)	15(100%)	12(100%)	13(100%)
TEMPERATURE SENSITIVITY	25(93%)	26(96%)	27(100%)	25(100%)	21(100%)	19(100%)	20(100%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

Table 10

DISPERSALLOY
Number and Percentage of Restorations in Category

BRAVO RATINGS							
TOTALS:	Baseline 27	6 Months 27	1 Year 27	2 Year 25	3 Year 21	4 Year 19	5 Year 20
COLOR MATCH	-----	-----	-----	-----	-----	-----	-----
MARGINAL ADAPTATION							
(occlusal)	0 (0%)	4 (15%)	6 (22%)	8 (32%)	6 (29%)	5 (26%)	6 (30%)
(proximal)	0 (0%)	0 (0%)	2 (12.5%)	4 (27%)	3 (21%)	1 (8%)	5 (42%)
MARGINAL DISCOLORATION	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	3 (15%)
ANATOMIC FORM							
(occlusal)	0 (0%)	0 (0%)	0 (0%)	2 (8%)	1 (5%)	2 (10%)	1 (5%)
(proximal)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TEMPERATURE SENSITIVITY	2 (7%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

"Alpha" ratings indicate "no" temperature sensitivity, "Bravo" indicates some temperature sensitivity.

**FIGURE 1: KERR HERCULITE
WEAR RATE**

