

Clinical Evaluation
of
HERCULITE (Injectable/Condensable)
A Light-Cured Posterior Composite Resin
Five Year Report

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PURPOSE:

The purpose of this study was to evaluate the clinical performance of HERCULITE as a restorative material in Class I and II cavity preparations. The study was originally intended to be conducted over a three year period, but was extended to a five year period. All phases of the project were carried out in the Department of Biomaterials Clinical Research at the University of Alabama at Birmingham.

METHODS:

A total of eighty (80) restorations of HERCULITE was placed into Class I and II cavity preparations of permanent teeth. The distribution of restorations with respect to molar and premolar as well as a class of cavity preparations is as follows:

<u>Type</u>	<u>%</u>	<u>Type</u>	<u>%</u>
Class I -	36	Premolar -	51
Class II -	44	Molar -	34

All cavity preparations and insertion of restorations were carried out under a rubber dam. In general amalgam type cavity preparations were employed for each restoration. The occlusal cavosurface margins, however, were modified with a 45 degree bevel. The gingival margins were also beveled 20 degrees with a gingival margin trimmer. This procedure was used to eliminate friable or loose enamel rods as well as to maximize the width of the enamel in this region. Both the pulpal and axial walls were coated with a thin layer of calcium hydroxide (Dycal, L.D. Caulk Company). Immediately, thereafter, all enamel walls were etched with a 37% solution of phosphoric acid, washed thoroughly and then dried with air. The etchant process was extended to about one (1.0) mm beyond the cavosurface margin onto the uncut enamel.

An enamel bonding agent was applied to all preparations. All Class II cavity preparations were matrixed with a properly contoured and wedged matrix band. Preoperative wedging was utilized in an effort to compensate for the thickness of the matrix band. Such a procedure was necessary to minimize the occurrence of open or loose proximal contacts. Approximately one half of the HERCULITE restorations was inserted into the preparation with a plastic placing instrument in small segments. Each segment was condensed or packed carefully by means of an amalgam condenser. The other half of the restorative material was injected into the cavity preparation with a Syntrex syringe. Gross material removal and surface finishing was carried out with finishing burs, hand cutting instruments and polishing devices. Interproximal margins were surfaced with thin finishing strips.

All procedures were carried out by a team of clinical investigators trained in the techniques of long term clinical studies. All were full time members of the Department of Restorative Dentistry.

EVALUATIONS:

Direct: Each restoration was evaluated directly by two clinicians trained in the technique as developed by the United States Public Health Service (RYGE). Evaluations were carried out at baseline, six months, one, two, three and five years. In each case the restorations were evaluated for the following characteristics:

1. Color Matching Ability
2. Interfacial Staining (cavosurface margin discoloration)
3. Secondary Caries
4. Wear or Loss of Anatomic Form
5. Marginal Integrity
6. Surface Texture

A description of the various characteristics evaluated in the study is included in the appendix. Only the surface texture criteria were not included in the original system as developed by Ryge.

Disagreement between evaluators resulted in a forced consensus. The percent of time disagreement occurred was recorded. Values in the appendix represent a consensus or agreed upon results. An inter-examiner agreement of 85% or higher was considered necessary for statistical significance.

Indirect: In addition to direct evaluations each restoration was also evaluated indirectly. Colored 2 x 2" transparencies at an original magnification of 1.5x were made of the restorations. These records were taken to coincide with the direct evaluation time schedule. These were obtained for the purpose of substantiating direct evaluations of color match and interfacial staining.

Finally, die stone casts (Velmix - Kerr Mfg. Co.) taken from polyvinyl siloxane (Express - 3M Co.) impressions were made of each restored tooth. Each cast was compared to a set of calibrated standard casts (M-L Scale) by two evaluators on two separate occasions for the purpose of determining quantitatively loss of material on the occlusal surface. The standard casts represented loss of anatomic contour in approximately 25 micrometer intervals from 0-500 micrometers. The system is designed to measure loss of material at a 25 micrometer level. However, it is possible by careful comparison to attain values to the nearest 12.5 micrometers. The die stone casts were also used for the purpose of determining approximate wear or flattening of the proximal contacts.

RESULTS:

Direct Evaluation: The results of the direct clinical evaluations for each patient are given in the appendix. Included are the patients identification, tooth number and surface, insertion date and the result of the direct evaluations. The numbers under

each column represent the various characteristics evaluated for each of the restorations. These were as follows:

1. Color Matching Ability
2. Interfacial Staining or Microleakage
3. Secondary Caries
4. Wear or Loss of Anatomic Form
5. Marginal Integrity
6. Surface Texture

In general, the A or Alfa notation indicates a condition of ideal. B or Bravo indicates a condition of clinically acceptable, whereas, C or Charlie indicates a condition of clinically unacceptable for that particular characteristics.

The results of the indirect clinical evaluation are given in Tables I and II. Again the numbers over each column represent the various characteristics evaluated for each restoration. A description of each category is given above.

TABLE I
Direct Clinical Evaluations
(Number of Alfas)
Category

Time	1	2	3	4	5	6	(No.)
Baseline	86	87	87	87	87	87	87
6 months	85	87	87	87	86	86	87
1 year	75	76	78	76	75	78	78
2 years	69	72	76	58	57	68	77
3 years	63	74	76	63	61	76	76
5 years	53	53	52	37	45	52	54

TABLE II
Direct Clinical Evaluations
(% Alfa)
Category

Time	1	2	3	4	5	6	Recall (%)
Baseline	99	100	100	100	100	100	100
6 months	98	100	100	100	99	100	100
1 year	96	97	100	97	96	100	100
2 years	90	94	99	88	94	87	89
3 years	83	97	100	83	80	100	87
5 years	98	98	96	69	83	96	68

Indirect Evaluation: Results of the indirect evaluation or values obtained from the calibrated standard (M-L Scale) are given in Table III.

TABLE III
Indirect Clinical Evaluations
(M-L Scale)

	Wear in Micrometers		
	<u>Actual</u>	<u>Adjusted*</u>	(σ)
	\bar{x}	\bar{x}	
Baseline	6	0	12
6 months	16	10	15
1 year	24	18	20
2 years	39	33	25
3 years	54	49	32
5 years	72	66	29

*Adjusted value obtained by subtracting baseline value from value obtained at each recall.

DISCUSSION:

Color - As can be seen from Table I and II, the color matching ability of HERCULITE was excellent. Specifically, over the course of five years the percent of restorations exhibiting an ideal color match ranged from 83 to 99%. At the end of five years only one restoration (2%) did not exhibit an ideal color matching characteristic. As compared to nearly all posterior composite resins, HERCULITE is exceptional. The color matching ability was so excellent that defining the margins was sometimes a

significant problem. The ideal color match can probably be attributed to inherent color stability as well as the high surface luster throughout the five years of observation. The relative translucency of the material tends to make it take on the natural color characteristics of the adjacent tooth structure.

Several examples of the color matching ability of HERCULITE are presented in Figs. 1 - 9. Given are the patients name, tooth number and site, age as well as cements.

<u>Fig. No.</u>	<u>Patient</u>	<u>Tooth #/Site</u>	<u>Age</u>	<u>Comments</u>
1	J. Kassaw	15-O	5 yr	Ideal color match, Excellent surface texture
2	J. Kassaw	14-O	5 yr	Excellent color
3	L. Thompson	20-DO	5 yr	Excellent opacity/ translucency ratio Superficial marginal staining
4	J. Kassaw	30-O	5 yr	Good color match; Localized pit
5	A. Hendricks	5-DO	5 yr	Excellent shading and translucency. Apparent centric contact near ridge
6	L. McKinney	14-MO	5 yr	Excellent color and surface texture
7	A. Bryant	19-O	5 yr	Excellent color match. Slight marginal defect.
8	J. Kassaw	03-O/OL	5 yr	Slight opacity and marginal ditching.
9	M. Fondren	03-OL	5 yr	Good color: superficial surface defects.

As can be seen from these illustrations, the general surface color matching ability of HERCULITE at the end of five years was excellent, particularly the ratio of opacity to translucency. No inherent color changes were detected.

Interfacial Staining - Interfacial staining was held at a minimum throughout the course of the three years. During this period of time the alfa ratings ranged from 100 to 94% (second year). At the end of the fifth year the value for this increased to 98%. This phenomenon probably is not associated with microleakage but rather superficial "ditching" which occurred along the margins. Note figures 8 and 9.

Caries - Three (3) of the restorations over a three year period exhibited secondary caries. At the end of five years the caries rate increased to five. This problem was associated with defective margins generated at the time of insertion. At least one of them, however, may have been caused by a chipped or fractured margin at several year of service. An example of this situation is illustrated in Fig. 10.

<u>Fig. No.</u>	<u>Patient</u>	<u>Tooth #/Site</u>	<u>Age</u>	<u>Comments</u>
10	J. Kassaw	2-O	5 yr.	Fracture & caries

Wear - The percent of restorations exhibiting no clinical evidence of wear (Alfa) was from 100% at baseline and at one year. At the end of three years this value decreased to 83%. Finally at the end of five years the percent of restorations exhibiting no evidence of clinical wear was 69%. No Charlie values were recorded for wear over the sixty months of clinical evaluation.

MARGINAL INTEGRITY: (Marginal Adaptation)

The HERCULITE restorations tended to exhibit a "microditching" characteristic. This particular feature is similar to that observed in traditional microfilled composite

resins. Specifically, after approximately one year, the margins of some of the restorations on the occlusal surfaces began to develop a minor crevice. This particular defect is self limiting in size and plays no apparent role in the degradation of the restoration. At no time did it appear to cause bulk fracture or secondary caries. Conceivably, the greatest disadvantage to this clinical characteristic is its potential for attracting stain along the margins. Incidentally, this type of marginal degradation may be attributed to a reduced flexural fatigue strength which is commonly characteristic of all submicron sized filler particles. An examination by SEM revealed that the marginal fracturing or "ditching" is cohesive in nature. In other words the defect was entirely within the composite but within several microns of the interface between restorations and tooth structure.

WEAR: (Loss of Anatomic Form)

The wear resistance of HERCULITE was shown to be unusually high. The generalized loss of material as determined by the use of calibrated dies (M-L scale, optical standards) was determined to be considerably less than most other materials evaluated in our facility. Specifically, at the end of five years the total loss of material from the occlusal surface averaged only 76 micrometers. As shown in Figs. 11 and 12, the wear rate was linear. The average annual rate of wear, regardless of the time period was approximately 15 micrometers. This value is far below the maximum level defined by the ADA/CDMIE.

The distribution of restorations with respect to wear on the occlusal surface at the end of five (5) years is presented in Fig. 13. As can be seen from this normal distribution curve, all the wear values fall into a normal pattern. Almost ninety (90) percent of samples exhibited 25 to 100 micrometers of wear. None of the restorations exhibited wear values exceeding 150 micrometers over the five year period. A number of examples of the amount of wear as well as wear patterns and marginal

"ditching" are presented in 12-26. Identified are patient's name, tooth number and site, age of the restoration and general comments as they relate to the individual restoration.

<u>Fig. No.</u>	<u>Patient</u>	<u>Tooth #/Site</u>	<u>Age</u>	<u>Comments</u>
14A	M. Isenberg	21-DO	5yr	Base of cast
14B	M. Isenberg	21-DO	5yr	Excellent wear resistance and surface texture; most wear along buccal margin
15A	A. Bryant	30-O	5yr	Base of cast
15B	A. Bryant	30-O	5yr	Excellent wear; note minor "ditching" along lingual margin
16A	A. Bryant	19-O	5yr	Base of cast
16B	A. Bryant	19-O	5yr	Excellent wear resistance; little evidence of ditching.
17A	L. McKinney	14-MO	5yr	Base of cast
17B	L. McKinney	14-MO	5yr	Minor wear; not apparent center contact area
18A	J. Kassaw	14-O	5yr	Base of cast
18B	J. Kassaw	14-O	5yr	Moderate wear some "ditching"
19A	P. Bryant	12-O	5yr	Base of cast

19B	P. Bryant	12-O	5yr	Slight generalized wear; note excellent proximal contour
20A	J. Martin	19-O	5yr	Base of cast
20B	J. Martin	19-O	5yr	Above average wear
21A	M. Fondren	31-MO	5yr	Base of cast
21B	M. Fondren	31-MO	5yr	Excellent wear resistance
22A	L. Thompson	29-DO	5yr	Base of cast
22B	L. Thompson	29-DO	5yr	Excellent wear resistance; slight "ditching"
23A	A. Hendricks	5-DO	5yr	Base of cast
23B	A. Hendricks	5-DO	5yr	Example of minimal marginal "ditching"
24A	S. Haigh	13-MO	5yr	Base of cast
24B	S. Haigh	13-MO	5yr	Average wear
25A	M. Moore	5-MOD	5yr	Base of cast
25B	M. Moore	5-MOD	5yr	Example of maximum marginal "ditching"
26A	W. Hodge	4-MOD	5yr	Base of cast
26B	W. Hodge	4-MOD	5yr	Upper limit of wear
27A	M. Fondren	14-OL	5yr	Base of cast

27B	M. Fondren	14-OL	5yr	Example of "ditching"
28A	D. Boudaway	13-MOD	5yr	Base of cast
29B	D. Boudaway	13-MOD	5yr	Good wear resistance

As can be seen, HERCULITE is a very wear resistant posterior composite resin over a five year period. Note the presence of limited marginal ditching as well as small areas of localized wear.

SURFACE TEXTURE:

Another interesting feature of HERCULITE is its excellent surface smoothness. The surface generally appeared (by means of an explorer and colored photographs) to be as smooth as the surrounding enamel. This property remained constant throughout the five years of observation.

BULK FRACTURE:

A limited number of restorations underwent bulk fracture. This condition, which is not uncommon to microfilled and submicron posterior composite resins occurred almost without exception on premolars. All of the fractures except one developed in Class II restorations. These fractures perhaps may be associated with unusual stress concentrations such as strongly accentuated cusps coming in contact with the proximal marginal ridge. They may be related to a reduced elastic modulus, yield strength and flexural modulus which are more characteristic of the fine particle or submicron (≤ 1.0 micrometers) posterior composite resins.

CONCLUSION:

HERCULITE is a highly wear resistant material which performs exceptionally well in posterior teeth. The average annual wear rate at the end of three years, for example, was shown to be 16.3 micrometers. At the end of five (5) years this value decreased only slightly 13.2 micrometers. In other words the wear rate remained constant over the five year period. The color matching ability and surface texture of HERCULITE strongly resembled that of the surrounding tooth structure. For example, at the end of five years the percent of restorations exhibiting a perfect color match was 98%. Also at the end of five years the alfa values for surface smoothness was 96%.

Considering the clinical results obtained over a the five year period, HERCULITE fully qualifies as a candidate for full compliance by the Council on Dental Materials, Instruments and Equipment of the American Dental Association. In this regard a summary table presenting the ADA/CDMIE acceptance levels at the time this study was initiated and the results of the five year clinical study is included.

7/6/90



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HERCULITE

Patient	Tooth #	Insertion Surface Date	0 Months Evaluation					Six Months Evaluation					One Year Evaluation					Two Year Evaluation					Three Year Evaluation					Five Year Evaluation																	
			1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6							
76. Fondren, M	2-O	10/01/84	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	B	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	A
77. Perry, A	28-O	10/01/84	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
78. Perry, A	29-O	10/01/84	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
79. Perry, A	13-DO	10/03/84	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	B	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	A	A
80. Bahr, M	12-DO	10/25/84	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	A	A	A

HERCULITE

Summary of 5 Year Clinical Data

Condition (5 Years)	ADA Guidelines	1 Year			2 Years			3 Years			5 years		
		98% Alfa 2% Bravo 0% Charlie	90% Alfa 10% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	94% Alfa 6% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	83% Alfa 17% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	83% Alfa 17% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie
Color Match (USPHS)	10% Charlie	98% Alfa 2% Bravo 0% Charlie	90% Alfa 10% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	94% Alfa 6% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	83% Alfa 17% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	83% Alfa 17% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	
Interfacial Staining (USPHS)	10% Charlie	97% Alfa 3% Bravo 0% Charlie	94% Alfa 6% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	94% Alfa 6% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	97% Alfa 3% Bravo 0% Charlie	98% Alfa 2% Bravo 0% Charlie	
Anatomic Form (Standard Casts)	250 µm	18µm	33µm	18µm	33µm	18µm	49µm	49µm	66µm	49µm	49µm	66µm	
Interproximal Contact	95% Alfa	98% Alfa	100% Alfa	98% Alfa	100% Alfa	98% Alfa	100% Alfa	100% Alfa	100% Alfa	100% Alfa	100% Alfa	100% Alfa	
No. Restorations Evaluated	≥ 20	73	73	73	73	73	70	70	57	70	70	57	
Molars (At Recall)	N/A	45%	41%	45%	41%	45%	52%	52%	36%	52%	52%	36%	
Class II (At Recall)	N/A	60%	60%	60%	60%	60%	57%	57%	56%	57%	57%	56%	

**UNITED STATES PUBLIC HEALTH SERVICE
(RYGE) CRITERIA FOR DIRECT CLINICAL EVALUATIONS**

Restorations

Category	Characteristic	Method
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Color Match

Alfa (A)	The restoration appears to match the shade and translucency of adjacent tooth tissues.	Visual inspection
Bravo (B)	The restoration does not match the shade and translucency of adjacent tooth tissues, but the mismatch is within the normal range of tooth shades. (Within normal range:—similar to silicate cement restorations for which the dentist did not quite succeed in matching tooth color by his choice among available silicate cement shades).	Visual inspection
Charlie (C)	The restoration does not match the shade and translucency of the adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.	Visual inspection
Oscar (O)	The restoration cannot be examined without using a mouth mirror.	Visual inspection

Cavosurface Marginal Discoloration

Alfa (A)	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure.	Visual inspection
Bravo (B)	There is a visual evidence of marginal	Visual inspection

discoloration at the junction of the tooth structure and the restoration, but the discoloration has not penetrated along the restoration in pulpal direction.

Charlie (C) There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has penetrated along the restoration in a pulpal direction. Visual inspection

Recurrent Carries

Alfa (A)	The restoration is a continuation of existing anatomic adjacent to the restoration.	Visual inspection
Bravo (B)	There is visual evidence of dark deep discoloration adjacent to the restoration (but not directly associated with cavosurface margins).	Visual inspection

Contour or Loss of Substance (Wear)

Alfa (A)	The restoration is a continuation of existing anatomic form or is slightly flattened. It may be overcontoured. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time.	Visual inspection and explorer
Bravo (B)	A surface concavity is evident. When the side of the explorer is placed tangentially across the restoration, it does not touch two opposing cavosurface line angles at the same time, but the dentin or vase is not exposed.	Visual inspection and explorer
Charlie (C)	There is a loss of restorative substance such	Visual inspection

that a surface concavity is evident and the base and/or dentin is exposed.

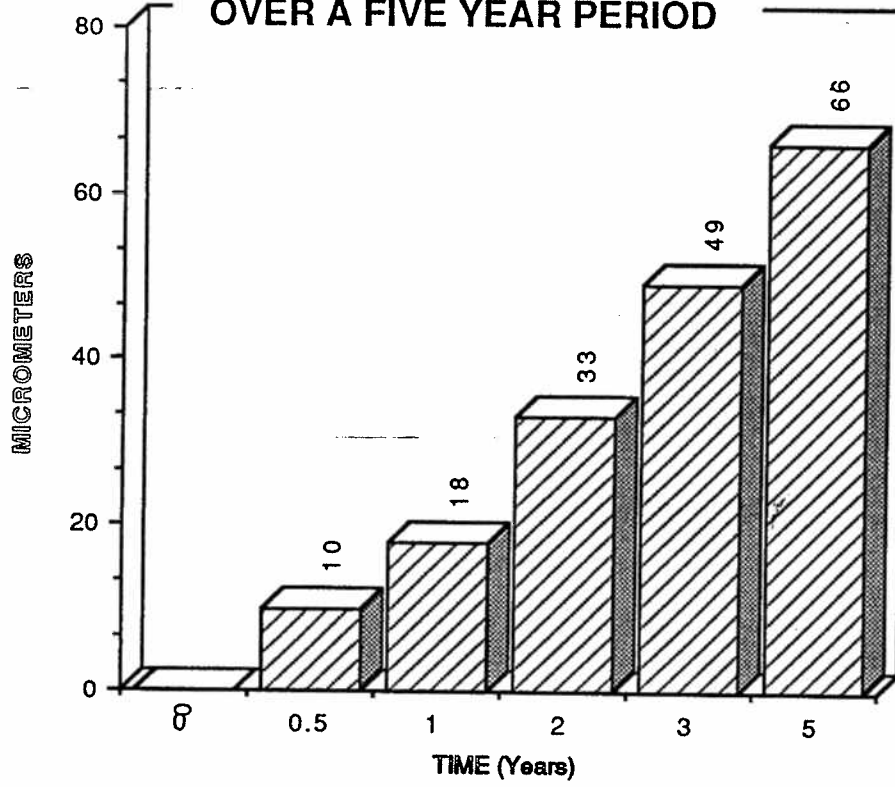
Marginal Integrity

Alfa (A)	The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does catch, there is no visible crevice along the periphery of the restoration.	Visual inspection and explorer
Bravo (B)	The explorer catches and there is visible evidence of a crevice, into which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The denting and/or the base is not exposed, and the restoration is not mobile.	Visual inspection
Charlie (C)	The explorer penetrates crevice defect extended to dentinoenamel junction.	Visual inspection

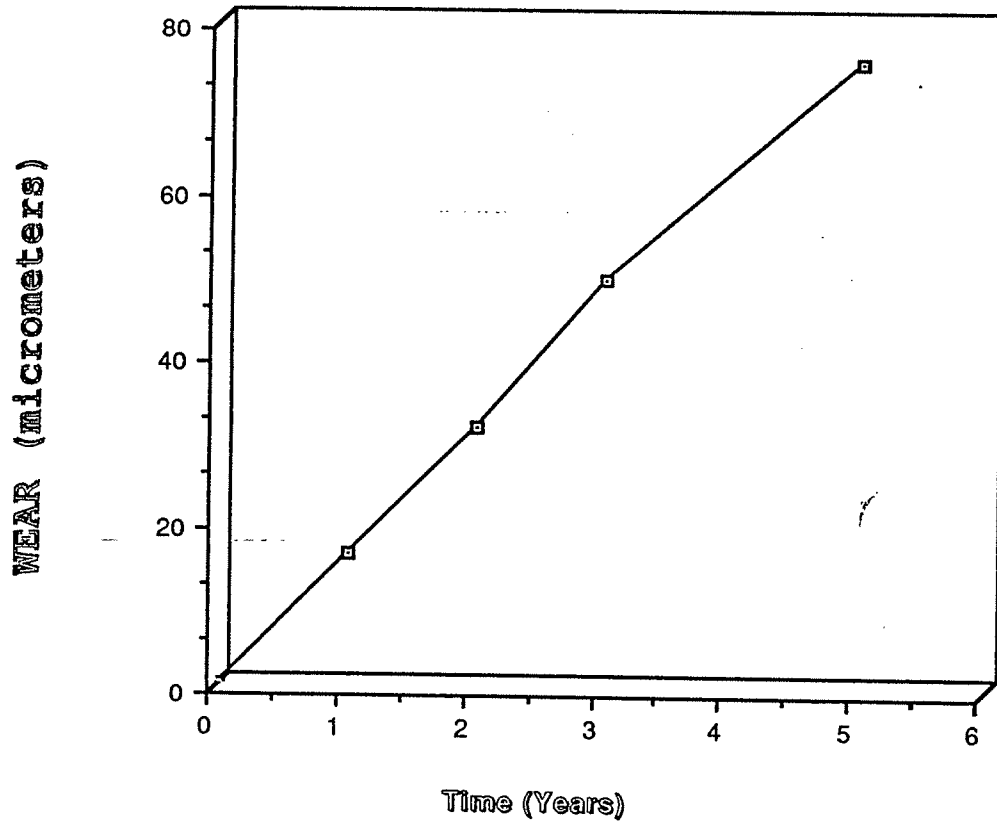
Surface Texture

Alfa (A)	Surface texture similar to polished enamel as determined by means of a sharp explorer.	Explorer
Bravo (B)	Surface texture gritty or similar to a surface subject to a white stone or similar to a composite containing supramicron sized particles.	Explorer
Charlie (C)	Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface.	Explorer

WEAR RATE OF HERCULITE OVER A FIVE YEAR PERIOD



Wear Rate of HERCULITE Over A Five Year Period



**Distribution of HERCULITE Samples
According to Amount of Wear**

