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POLYMER COMPOSITES FOR USE IN ORTHOPEDIC SURGERY*†

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Abstract—Ever since Movin in (1950) and McKee in (1951) introduced the use of acrylic cement for fixation of hip prosthesis components a number of investigators have proposed various hip prosthesis designs using this cement fixation concept (Neale, 1967). This study was undertaken to support the hypothesis that certain dental materials could provide a more satisfactory bone-prosthesis bond than that presently possible with acrylic bone cement.‡ Two restorative resins were found to have superior strength and resistance to thermal degradation when compared to acrylic bone cement. Tests of acrylic cement combined with apatite fillers suggest that restorative resin–anorganic bone composites would exhibit improved strength and toxicity properties and would also promote improved bonding due to resorption of the surface anorganic bone particles with subsequent bone infiltration and anchorage. Relatively high degradation of acrylic bone cement in accelerated aging tests suggests caution in using this material for implantation.

STRENGTH STUDIES

DUCTILE materials are frequently assumed to fail by the maximum shear theory of failure (Spotts, 1959) and since the bone–cement interface is subjected to shearing and bending forces it was decided to determine the shear strength and bending modulus or stiffness of the various prospective cementing materials in order to asses their suitability as prosthesis seating and stabilizing materials.

A specially designed shear and bending tool was constructed to handle small samples. Reliability of test results is considered to be excellent due to close agreement with published data for the Plexiglas samples and the fact that twice as many samples were tested as required by ASTM procedures. The samples were prepared from specially designed Teflon molds.

PROCEDURE FOR STRENGTH TESTS

The Teflon molds were constructed in order to prepare uniform test samples. The average dimensions of the samples were 2 – 1/4 in. × 1/2 in. × 1/16 in. however precise readings were taken with a micrometer and these readings were used to calculate the shear areas and the cross-sectional moments of inertia. Samples of the materials Kadon, Adaptic, and Concise were prepared along with CMW cement samples and also samples of various CMW composites. The filled composites consisted of 80 per cent by weight of CMW and 20 per cent filler. The fillers included sugar particles approximately 200–300 μm in size, $NaHCO_3$ particles approximately 10 μm in dia., citric acid particles approximately 200 μm in size, and apatite crystals ranging from approximately 10–225 μm. The apatite

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‡Acrylic cement is manufactured by C. M. W. Laboratories, Ltd., Preston New Road, Blackpool FA39TP, England.

rock was pulverized into small particles and then screened through a standard Tyler number 60 sieve. It was thought that the gradation of apatite sizes would provide the higher strength advantage of using small particle fillers and also permit bone infiltration after *in vivo* absorption of the larger surface particles such as occurs with the plastic–anorganic prosthesis of Hodosh (1969). The test results appear to bear this assumption of greater strength and they also correlate well with the findings of Bowen (1964) that intermittent grading increases the strength of the composite. The improved strength of graded filler composites might be explained by Mooney's equation relating sedimentation volume and the viscosity of suspension of spheres (Nielsen, 1967).

After the various samples were prepared they were then carefully tested on the bending test apparatus and then shear tested on a Wykeham Farrance press. The crosshead speed was 0·045 in. per min and the shear force was indicated by a calibrated Proving Ring. The shear area was determined by multiplying the circumference of the punch by the thickness of the sample.

RESULTS OF STRENGTH TESTS

The wide variation in strengths of some of the composites shown in the following tables attests to the significant role that filler particles can play in altering the basic properties of a polymer plastic such as CMW acrylic cement. Also it can be seen that the materials Adaptic and Concise show considerably higher strength values than the other materials.

THERMAL DEGRADATION STUDIES

The desire to be able to predict the success of a prospective implant, prior to implantation, has spurred much interest recently in quick screening tissue culture studies and accelerated thermal aging tests. Short term thermal degradation tests are very useful for screening out extremely toxic materials and for evaluating biocompatibility of prospective implant materials particularly when correlated with tissue culture tests.

Table 1. Average shear strengths, psi

Plexiglas	8700*	CMW-citric	5643
CMW	7208	Adaptic	11730
CMW-apatite	6363	Concise	8995
CMW-sugar	5764	Kadon	7020
CMW-$NaHCO_3$	5867		

*Rohm & Haas Co. 9000 psi.

Table 2. Average flexural moduli, psi $\times 10^{-5}$

Plexiglas*	4·08†	CMW-citric	2·42
CMW	3·11	Adaptic	20·20
CMW-apatite	3·84	Concise	11·70
CMW-sugar	3·60	Kadon	3·70
CMW-$NaHCO_3$	3·70	PMM‡	4·25

*Commercial brand of polymethyl methacrylate.
†Rohm & Haas Co. 4–4·5 $\times 10^5$ psi.
‡Polymethyl methacrylate.

Accelerated aging tests have been designed by Mason (1966) and Homsy *et al.* (1969). These tests consist of spectrophotometric determination of C–H type moieties that result from high temperature (120°C) degradation of materials immersed in a saline "pseudo extracellular fluid." The test data in ppm for toxic materials are presumably much greater than that for a relatively inert material. Medical grade Silastic 372 and 382, which are known to be quite inert, are often used as the control materials in such tests. Table 3 compares the composition of various pseudo extracellular fluids.

A similar accelerated aging test has been

Table 3. Compositions of pseudo-extracellular fluids

Ion	Physiological*	PECF*	Tis-u-Sol†
NA^+	145	145	137·6
K^+	5	5	5·8
Cl^-	113	118	142·3
HCO_3^-	30	30	
HPO_4^-	2	2	1·1
Mg^{2+}			1·6
SO_4^{2}			1·6

*Adapted from Homsy (January, 1970).
†Travenol Labs, Inc., Morton Grove, Illinois 60053, U.S.A.

designed for this study with the excellent cooperation of Bio-Technics Labs of Los Angeles in order to make preliminary assessments of the chemical inertness and expected tissue reactions for the candidate implant materials of this study.

PROCEDURE FOR THERMAL AGING TESTS

Each sample was weighed, diced, and carefully measured under a microscope in order to provide 400 cm^2 of surface area per sample and then 50 ml of Tis-u-Sol (physiological irrigating solution) were added to flasks containing these samples. The surface area to fluid volume ratio was maintained or dilution factors were applied to the spectrophotometer test results for samples of limited quantity. Use of this surface area to fluid volume ratio of 400 cm^2 to 50 ml enabled comparisons with the results of Homsy (1969) that were based on the same ratio.

The dental materials and CMW bone cement had to be polymerized in special Teflon molds and then thin sectioned on a Gillings Bronwill Semi-Automatic machine. After this the sections were lapped to a thickness of 0·050 in., carefully cleaned, and then diced and weighed to provide the desired surface area of 400 cm^2.

After the samples were thus prepared they were then subjected to 120°C and 30 psia for 60 hr while immersed in Tis-u-Sol. The samples were then evaluated by Bio-Technics Labs for thermal degradation by using spectrophotometric analysis of the pseudo-extracellular fluid. The spectrophotometer that was used was a Perkin–Elmer Infrared Spectrophotometer Model 137B.

RESULTS OF THERMAL DEGRADATION TESTS

The experimental data on thermal degradation are presented in Table 4. The results can only be compared qualitatively due to the variations that occurred and the limited number of available samples. A larger aumber of samples would have to be tested in order to establish with statistical confidence a precise figure for each material. Nevertheless certain valid conclusions can be drawn from the data.

Table 4. Results of screening tests*

Material (Sp. Gr.)	Trial series	Sample series	Check series
Kadon (1·185)		82	
CMW (1·185)		354	429
Adaptic (1·99)		23	
Concise (1·94)		40	
Teflon 7 (2·17)			
ML 733 HDPE (0·96)	14	25	
X87 Trans 70 DPVC (1·35)	40	4	
PU 5701 (1·20)		92	
PU 5714 F1 (1·20)		36	
X17 1000 (1·06)		91	22 (Homsy 21)†
PE 6009 (0·96)		54	(Homsy < 2)‡ no test made.

*Parts per million equivalent isoamyl alcohol.
†Homsy (1969).
‡Homsy (September, 1970).

The test data in parts per million (ppm) for the plastic materials X17000 and PE 6009 were higher than the values obtained by Homsy and this is probably due to the fact that Tis-u-Sol has a much greater concentration of Cl^- ions than does the PECF used by Homsy.

A quick glance at the difference between the sample series test for the plastic material X17 1000 and CMW and the check series test shown in Table 4 indicates that the sensitivity of the i.r. spectrophotometer and/or the associated experimental setup procedure are the likely causes for the variation of the results. The same identical samples of X17 1000 and CMW were used for both test series and similar findings would be expected. The results do not conform closely to Beer's law of absorption because of the wide range of ppm encountered.

Due to the variations in the data one cannot validly conclude that, for instance, Adaptic has a greater resistance to thermal degradation than Concise. However, while recognizing the need for additional testing, it seems justifiable to state that, from the data of Table 4, the materials Adaptic and Concise, along with

Teflon 7, would likely be considerably more stable and less reactive in the physiological environment of the body than would CMW bone cement.

RESEARCH POSSIBILITIES

This present study disclosed several promising research areas some of which are itemized below.

1. Intensive research is recommended on the potential uses of dental materials as bone prosthesis materials. Tests of strength and toxicity of various composites such as Adaptic and Concise are needed.

2. Improved accelerated aging tests are needed along with tissue culture and implant studies to correlate with these aging tests. Higher aging test temperatures and shorter test times may be possible. Also multicomponent infra-red (i.r.) analysis schemes are needed to improve the selectivity of the aging rests. Studies of weight loss on heating during degradation tests are needed. The specification ASTM C706-63 may be useful as a guide.

3. Research is needed to determine if more suitable pseudo-extracellular fluids can be developed. Perhaps an ordinary salt solution would be just as effective as more expensive and complicated preparations.

4. Studies such as that performed by Levitt (1969) on sintered apatite prostheses also show much promise and additional research on producing apatite forms by standard sintering techniques and testing of these materials for strength and biocompatibility is needed.

5. Research is needed on the development of improved forms of acrylic bone cements, e.g. the use of steel meshes with acrylic (see pp. 8–5 of Lee and Neville, 1970) and hydrophilic acrylates (see pp. 11–24, Lee and Neville, 1970). Also research is needed on multicellular acrylic resins (McLoughlin, 1951).

6. Biocompatibility screening and development of porous polymer composites utilizing absorbable filler materials such as the suture materials available from Ethicon, Inc. of New Jersey is needed. Combinations of spherical and filamentary fillers would provide high strengths and impact resistance (see p. 249, Holliday, 1966).

7. Studies are needed dealing with the systemic effects of polymer degradation and other implant material degradation in the body. Tolerances should be established for these implants with regard to the amount of degradation (ppm) allowed, the effects on the local tissue environment, etc. The relation between tissue rejection of the implant and the amount and size of the degraded particles should also be determined.

SUMMARY AND RECOMMENDATIONS

It is believed that the findings of this study have demonstrated the feasibility of using certain high strength composite dental materials as bone cements and hip prosthesis seating materials. The high degradation of CMW bone cement in the accelerated aging tests suggests caution in using this material for implantation.

It is highly recommended that additional research be continued in the areas previously mentioned. Also, while recognizing the limitations of the data of this study and the need for additional testing, the following materials listed in order of preference are recommended for further consideration and study as potential materials for reconstructive surgery. Preference was based on considerations of strength, resistance to degradation, and the desirability of bone infiltration. Resistance to degradation was considered more important than strength in establishing the order of preference since all of the materials appear to have adequate strengths although the stronger materials are likely to be more suitable. Concise has a more fluid consistency than Adaptic during mixing and consequently Concise may prove to be better than Adaptic in terms of handling qualities.

1. Adaptic plus 20–40 per cent by weight of gradated anorganic bone or apatite filler particles ranging in size from 10 to 300 μm.

2. Concise plus 20–40 per cent by weight

of gradated anorganic bone or apatite filler particles ranging in size from 10 to 300 μm.

3. Adaptic.
4. Concise.
5. CMW plus 33 per cent by weight gradated ed anorganic bone or apatite filler particles ranging in size from 10 to 300 μm.
6. CMW with reservations regarding possible toxicity.

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