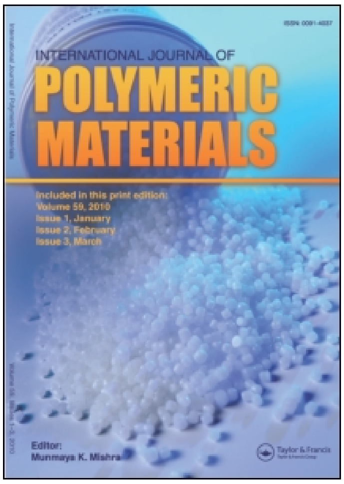

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The Effect of Catalyst Concentration of the Cured Properties of a Medical Grade RTV Silicone Elastomer†

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Mechanical properties, degree of swelling, structural uniformity (by electron microscopy), lipid uptake and implantation effects were studied on samples of silicone elastomers made with various catalyst concentrations and effects are presented.

INTRODUCTION

The medical grade room temperature curing silicone elastomers have found widespread utility as biomaterials with associated applications. These materials have been successfully used in external prostheses, for encapsulations, for coatings, and many biomedical applications.[1–5] A portion of their acceptance is based upon the simplicity of application, a two liquid system which only requires weighing, mixing and using. Because of the utility of these systems, the molecular weight of the polymer must be low enough to insure fluidity in the presence of fillers and catalysts. The mechanical strengths are normally lower than those of the corresponding heat cure systems, but for many applications their convenience outweighs their reduced mechanical properties. Variations in the cured properties of these materials were observed in these laboratories during routine applications while following normal usage directions.

[†] Presented at the Symposium on Elastomers in Medicine at the 105th Meeting of the Rubber Division, American Chemical Society, Toronto, Canada, May 9, 1974.

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The purpose of this work was to investigate the effects of catalyst ratios on those processing variables which could lead to a better cured polymer and which could reasonably be controlled as a matter of routine.

EXPERIMENTAL

Dow-Corning Corporation's Silastic 382, cured with stannous octoate was selected for this study. This material was found to have $M_w = 101{,}000$, $M_n = 64{,}000$ and a molecular weight distribution $M_w/M_n = 1.6$ by gel permeation chromatography. The compounded polymer and catalyst were used as received. All room temperature cures were performed at 25°C for a minimum of 96 hours.

Formulation

One hundred grams of the compounded polymer was weighed to ± 0.1 grams. The catalyst was weighed to ± 0.0002 grams. Blending was accomplished with a broad blade spatula by steady mixing for three minutes. After any appropriate pre-cure treatment all batches were poured into molds, measuring 330 × 96 × 3.2 mm, and cured at room temperature. The curing environment was normally room air, although some samples were cured under dry air or nitrogen for 48 hours. The appropriate post-cure treatment was then undertaken. Catalyst concentrations of 0.125, 0.250, 0.500, 0.750 and 1.04% were investigated.

Pre and post-cure treatment

Table I lists the various pre- and post-cure treatments reported in this study.

TABLE I
Pre- and post-cure treatment

Pre-treatment	Post-cure treatment
Vacuum	None
None	Gamma irradiation (^{60}Co)
None	Gamma irradiation + fast neutrons
None	Gamma irradiation + fast + thermal neutrons
None	Ultrasonic vibrations
None	Thermal f(time)
Vacuum	Thermal f(time)

Vacuum treatments were carried out in vessels where the freeboard volume was 20 times the volume of the freshly blended polymer. The large freeboard volume allowed for rapid escape of entrapped air. Vacuum treatments were carried out until excess frothing ceased.

The total dose of pure gamma radiation (^{60}Co) was 10^6 rads. Gamma irradiation in the presence of fast and thermal neutrons was accomplished in a light water pool reactor with a total gamma dose of 10^6 rads using cadmium as a shielding material. Ultrasonic treatments were accomplished in boiling water at 24,000–28,000 hertz and 100 watts for four hours. Thermal post-cures were carried out in a forced convection oven at $T \pm 2°C$.

Mechanical testing

All mechanical tests were made using an Instron Mechanical Tester on standard ASTM "dogbones". Sample size varied from five to fifteen "dogbones".

Degree of swelling

The degree of swelling of silicone rubber was determined in different solvents at 25°C. About 0.3 g of each sample was weighed accurately and immersed in a large excess of solvent. The solvents were acetone, benzene, heptane, 1,4 dioxane, methanol and methylene chloride. After a predetermined period of time the rubber was removed, the surface solvent was blotted with Kimwipes, and weighed in a stoppered bottle. Weight of sample was recorded at 15, 30 and 45 seconds after the removal of sample from the solvent. The swollen weight was determined by linear extrapolation to zero time. The above procedures were repeated until the equilibrium swollen state was reached (usually 72 hr.). Finally, the solvent was removed from the samples under reduced pressure at room temperature and the dry rubber was weighed. The amount of extractable polymer was then determined by the weight difference between the original rubber before experimentation and the dry rubber.

The volume fraction of rubber in the equilibrium swollen state was then calculated using the density value of 1.165 for the rubber and the density of the appropriate solvent. The value ϕ was related to crosslink density of the number average molecular weight between crosslinks (M_c) by the Flory-Rehner equation.

Heat of wetting

A precision calorimeter was used to measure the enthalpies of immersion in acetone at 25°C for samples of cured "silicone rubber". Construction and operation of the calorimeter have been described.[6] The application of thermodynamic information available from enthalpies of immersion has been treated in detail.[7]

Samples were cut into pieces approximately 5 mm × 10 mm × 1 mm. Other samples were ground to powder in a tissue grinder. Particles were estimated to have approximately 0.5 mm diameter.

All samples were in contact, for several hours, with boiling methylene chloride followed by boiling acetone before drying for 48 hours at 130°C.

Sample bulbs with an internal volume of approximately 5.0 cm^3 were blown from 7 mm Pyrex tubing. The bulbs were able to withstand vacuum outgassing at 130°C and were easily broken in the calorimeter.

Scanning electron microscopy

Micrographs of the polymers were obtained using a JSM-2 scanning electron microscope.

Lipid uptake

To evaluate the lipid uptake of different room temperature cure silicone rubbers the pseudo blood plasma medium described by Kahn[8] was used. The specimens were immersed in this pseudo-plasma medium in glass containers. A pH of 7.3–7.6 was maintained by daily addition of NaOH solution. The containers were immersed in a metabolic shaking incubator which was kept at 37°C.

The specimens were periodically taken out and washed with distilled water. The specimens were then wiped in order to remove the surface layer of solution. The difference between the weight of a specimen at a given time and that of the original weight was taken as lipid uptake.

Implantation studies

In order to test the effect of cure modes on "Silastic" after implantation and conversely to monitor any adverse body reactions due to the different cure modes, mammalian implantation studies were conducted.

Three immature New Zealand White rabbits (one male and two female) were subjected to chronic implantation of 1 × 2 cm sections of the different polymers. Implantation was done aseptically under general anesthesia induced and maintained by Halothane and oxygen. A 10 cm skin incision was made over the dorsal midline, extending from about the 12th dorsal spinous process to the sacrum. The skin lateral to the incision was undermined by blunt dissection and four sections of the material were placed in the undermined subcutis, one piece on each corner of a rectangle approximately 2–4 cm lateral to the skin incision. The skin was closed in a routine manner and the animal allowed to recover from anesthesia. No medication was given postoperatively.

The animals were fed a routine diet of rabbit lab chow (Purina). They were euthanatized, one on the 101st day and two on the 113th day after surgery, and the polymer samples removed for pathological examination.

RESULTS AND DISCUSSION

Effect of post-cure on mechanical properties

The linear polymers (Silastic 382) employed in this study are classified as polydimethylsiloxanes which utilize a form of a silane, siloxane or silicate ester as a crosslinking agent.[9] The catalyst has been shown to be essentially stannous octoate. The reaction mechanism leading to crosslinking has not, to our knowledge, been completely classified. Therefore, differences in the cured and post-treated polymer responses are best discussed in terms of bulk properties.

The most obvious form of post-cure treatment is thermal. Heating would be expected to force the crosslinking reaction to completion. Figures 1 and 2 show the resulting mechanical properties upon heating the room temperature cure samples at 100°C and 150°C for four hours. In these and in subsequent graphs, the standard deviations are reflected in the size of the symbols used. All comparisons will be made to the room temperature cured material. Figure 1 reveals that heating the samples at 100°C for four hours results in an increase in tensile strength at all catalyst concentrations. Figure 2 shows the same trend for the elongation. The curve obtained at 150°C indicates that the crosslinked system begins to lose mechanical integrity at this temperature. The minimum exhibited by these results at a catalyst concentration of 0.50% was reproduced many times for different treatments and truly reflects the bulk properties of this polymer system. The low values obtained at 0.125% catalyst concentration tends to reach the same value as for the 0.25% when left to cure for 30 days at room temperature. The effects of post-treatment on cured properties will be discussed in more detail after presentation of additional information.

Figures 3 and 4 show the effects of different radiation treatments on the mechanical properties of the elastomers for different catalyst concentrations. A total dose of 10^6 rads of pure gamma radiation would not be expected to cause extensive scission or crosslinking of the polymer. One gamma particle interacts at a time with one electron or one atom. Scission may be considered to be a one on one interaction whereas crosslinking requires a double event. Figures 3 and 4 show that the gamma flux has caused a slight degradation of mechanical properties.

The post-cure treatment involving fast and thermal neutrons resulted in

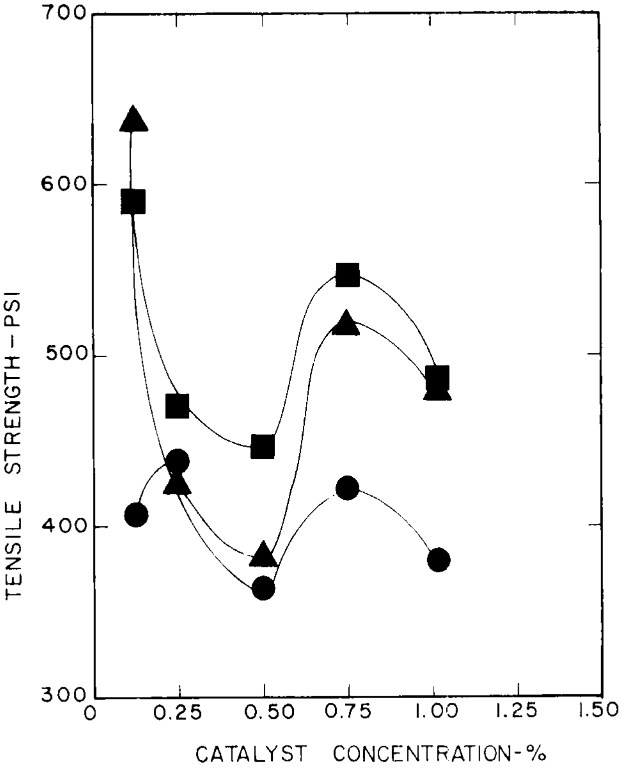


FIGURE 1 Tensile strength as a function of catalyst concentration: ● no post-treatment; ■ 100°C, 4 hours; ▲ 150°C, 4 hours.

improved mechanical properties in the catalyst concentration range 0.125 to 0.75%. The final radiation event associated with fast neutrons would be either a thermal spike or a displacement spike depending upon the model employed. Each of these represents the formation of a significant localized volume of radiation induced structural rearrangements. A sufficient amount of energy is generated to induce segmental motion and thus promote additional cross-linking.

Ultrasonic treatments at 100°C gave essentially the same results as those polymers receiving a thermal treatment at 100°C, indicating that the ultrasonic field utilized in this study had little if any effect upon the final polymer properties. A series of runs were made whereby the initial liquid polymer blend, at catalyst concentrations of 0.125, 0.25 and 0.50%, was subjected to a vacuum treatment prior to room temperature curing. After thermal and radiation post-cures, the resulting mechanical properties' curves were perhaps 10% higher and had the same shape as those not receiving the vacuum treatment. Therefore,

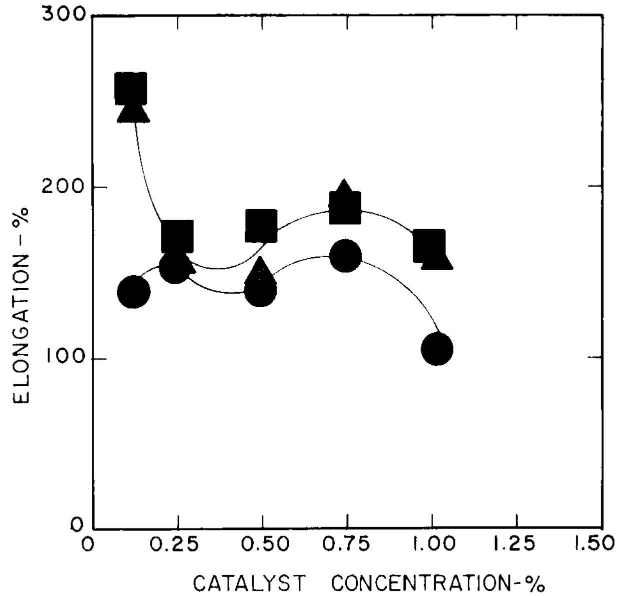


FIGURE 2 Elongation as a function of catalyst concentration: ● no post-treatment; ■ 100°C, 4 hours; ▲ 150°C, 4 hours.

the shape of the curves shown in Figures 1–4 cannot be attributed to gross amounts of entrapped air which should increase as the catalyst concentration increased due to gel time considerations.

The following discussion is a possible explanation of the mechanical properties of the cured material as a function of catalyst concentration and crosslinking mechanism. Since the silicone polymer is hydroxyl terminated and the catalyst is stannous octoate, the crosslinking agent is probably tetraethoxysilane or some other tetrafunctional silane. It is assumed that the stannous octoate reacts with the hydroxyl groups on the polymer to form an active complex which then reacts with the crosslinking agent. As long as the catalyst concentration is low, there is a small amount of active complex present with respect to the concentration of the crosslinking agent. Statistically there is a greater probability of the active complex reacting with an unreacted molecule (in excess) of the crosslinking agent than with a site on a reacted one. This reaction does not lead to changes in mechanical properties since the molecular weight of the polymer is increased only by the molecular weight of the crosslinking agent. However, after this initial reaction, the same statistical arguments given above hold and the active complex has a higher probability of reacting with crosslinking agent that has reacted only once than with one that has reacted two or three times. These first two reactions lead largely to the

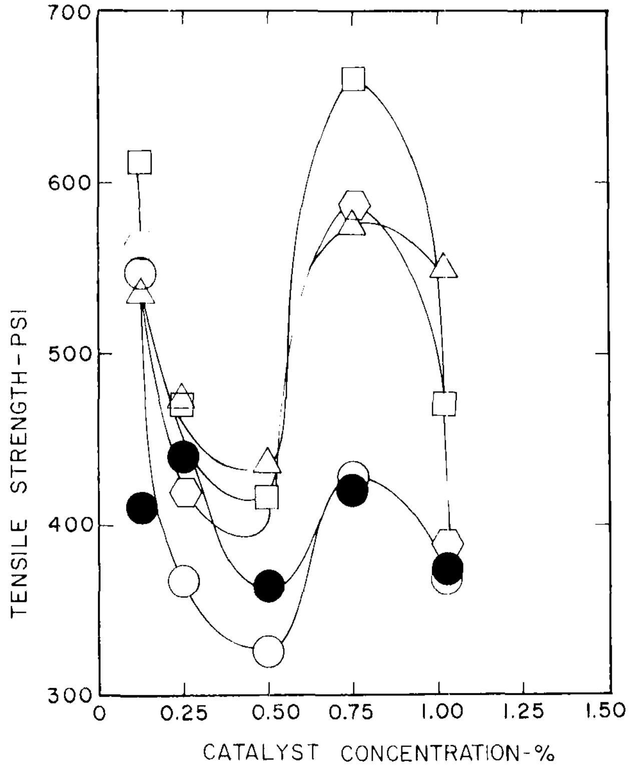


FIGURE 3 Tensile strength as a function of catalyst concentration: ● no post-treatment; ○ gamma irradiation; ⬡ gamma irradiation + fast neutron; □ gamma irradiation + fast neutron + thermal neutron.

formation of linear chains with very little branching. Consequently, the tensile strength of the polymer increases simply because the chain lengths have been increased. This is shown graphically in the 0.125–0.25% region of the no treatment curve, Figure 1 or 3.

As the catalyst concentration is increased above 0.25%, the amount of active complex increases and results in a smaller excess of the crosslinking agent. Under these conditions, the probability of the active complex reacting with a crosslinking agent that has already reacted twice (or possibly three times) is good. Such a situation leads to branching at the expense of linear molecular weight increase. Thus, highly branched, but short, chains are formed and the tensile strength reaches a minimum at a catalyst concentration of approximately 0.50%.

At concentrations of catalyst above 0.50% the ratio of active complex to crosslinking agent approaches a situation in which both molecular weight in-

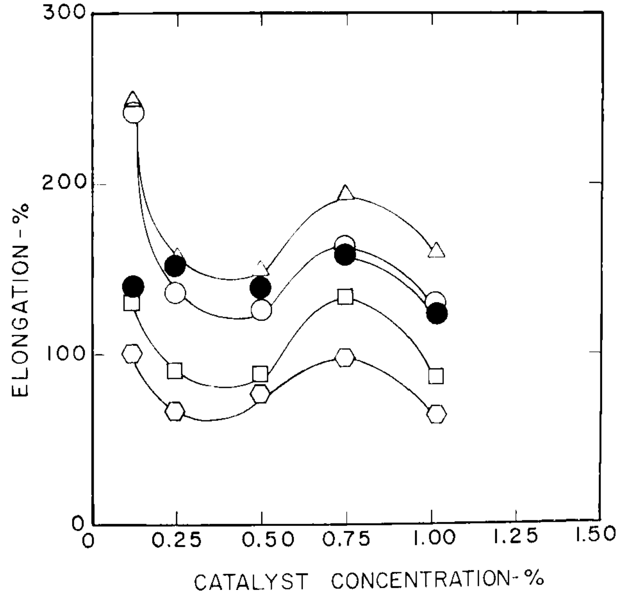


FIGURE 4 Elongation as a function of catalyst concentration: ● no post-treatment; ○ gamma irradiation; ⬡ gamma irradiation + fast neutron; □ gamma irradiation + fast neutron + thermal neutron.

crease and branching (crosslinking) can occur. This results in an increase in the tensile strength at catalyst concentrations between 0.50% and 0.75%.

As the catalyst concentration is increased above 0.75%, the ratio of active complex to crosslinking agent begins to greatly favor the third and fourth reactions of the crosslinking agent. Consequently, the system is overwhelmed by branching and rapidly undergoes gelation before good mechanical properties can be attained. This results in a decrease in the tensile strength above 0.75% catalyst.

It is of interest to note the elongation behavior of the system as a function of catalyst concentration. As shown in Figures 2 and 4, the overall shape of the elongation curve is very similar to the tensile strength curves. In most polymer systems, tensile strength and elongation show opposite trends. This is due to the fact that most systems involve long linear chains tied together by short crosslinks. In the system at hand, however, the crosslinks can be as long as any linear portion of the system. This is due to the fact that this system is crosslinked by bonding three or four polymer chains to a point, i.e. a single silicon atom. Thus, crosslinking, in this case, simply changes the direction of chain growth. Consequently, the elongation of the polymer follows the same behavior as shown by the tensile strength.

Referring to Figures 1–4 the results of the post-cure reactions would be depicted by a series of values that would start at the points describing the untreated polymer. An overall curve would then proceed through some maximum at about 0.125% catalyst. At the lowest catalyst concentration, the major reaction involves only the first and second sites on the crosslinking agent. In this situation, the system contains many chains which are active complex terminated. However, the system still has mobility at elevated temperatures and, therefore, post-cure treatments greatly enhance the mechanical properties through linear molecular weight increase. At 0.25% catalyst, the amount of crosslinking agent that has reacted once has decreased in favor of the material that has already reacted twice to increase molecular weight in a linear fashion. In this case, post-cure reactions can only increase molecular weight linearly or add a branch to an existing chain. Neither event would greatly change mechanical properties since the overall chain length would be changed very little relative to the chain length before post-cure, and any branch must react at both ends to form an effective crosslink. Consequently, at this catalyst concentration post cure has little effect on properties.

At catalyst concentration of 0.50% and greater, branching becomes an important room temperature reaction and fewer long linear chains are present to prevent motion. Consequently, post-cure treatments can once again improve mechanical properties.

Degree of swelling

The volume fraction in the swollen state at equilibrium was calculated:

$$\phi = \frac{1/\rho_p}{1/\rho_p + \dfrac{\text{weight of solvent}}{\rho_s\,(\text{weight of rubber})}}$$

where ρ_p = density of rubber
ρ_s = density of solvent.

The value of χ is related to crosslink density by Flory's equation:

$$\ln(1-\phi) + \phi + \chi\phi^2 = NV_1\,(\phi^{1/3} - \phi/2)$$

where χ = polymer–solvent interaction parameter which characterizes the interaction energy per mole of solvent for a specific solvent–polymer pair. The χ value was calculated by the empirical formula

$$\chi = \Delta H/RT + 0.35$$

where ΔH is the heat of swelling in calories/mole of solvent measured by means of a calorimeter.

V_1 = molar volume of solvent
N = degree of crosslinks, moles of crosslinks/cm^3 polymer.

TABLE II

ϕ values as a function of % catalyst and treatment

		ϕ					
% catalyst	Post-cure treatment	Acetone	Benzene	1,4 dioxane	Heptane	Methanol	Methylene chloride
1.04	*NT*	0.7266	0.3687	0.7080	0.2967	0.9443	0.3781
0.75	*NT*	0.7294	0.3687	0.7137	0.2930	0.9496	0.3682
0.50	*NT*	0.7290	0.3645	0.7074	0.2920	0.9884	0.3766
0.25	*NT*	0.7275	0.3708	0.7114	0.2954	0.9645	0.3702
0.125	*NT*	0.7378	0.3708	0.7119	0.2852	0.9139	0.3689
0.50	γ	—	0.3684	0.7091	0.2991	0.9564	—
0.50	*US*	—	0.3624	0.7068	0.2966	0.9550	—
0.50	*T*-150°C	—	0.3557	0.7052	0.2802	0.9510	—
0.125	*US*	—	0.3385	0.7108	0.2829	0.9659	0.3604
0.125	*V T*-150°C	0.7402	0.3535	0.7140	0.3046	0.9686	0.3635

ϕ = volume fraction of rubber in the rubber-solvent swollen state at equilibrium.
γ = gamma irradiation.
NT = no treatment.
T = thermal treatment.
US = ultrasonic vibration.
V = vacuum pre-treatment.

The larger the value of ϕ, the more crosslinks in a given polymer–solvent pair. The ϕ values shown in Table II show that ϕ is not a significant function of catalyst concentration.

The heat of swelling for silicone rubber is 125 cal/mole in benzene and 18 cal/mole in n-heptane. The χ values were 0.56 and 0.38 for benzene and n-heptane, respectively. Attempts were made to calculate the number of crosslinks by Flory's equation. The value of N for different catalyst concentrations and different post-cure treatments are shown in Table III. The Flory equation is derived for non-polar solvents. Therefore calculations were done on benzene and n-heptane only. It should be noted that the N value in Flory's equation is very sensitive to the χ value. Therefore, a slight uncertainty of χ will result in a value larger than the real value of N.

Figure 5 and Table IV show the results of the extraction experiments. Figure 5 shows the amount of material extracted for the no post-treatment samples. These results indicate that the number of chains tied up by crosslinks decreases as the catalyst concentration increases. The general shape of the curve is not consistent with those showing the effect of catalyst concentration on the mechanical properties. Table IV shows the effects of the various post-treatments on the extraction results. In general, thermal treatment tends to reduce the amount of extractables. In all cases the amount of extractables was greater than was obtained with peroxide cured systems using the same solvent systems.

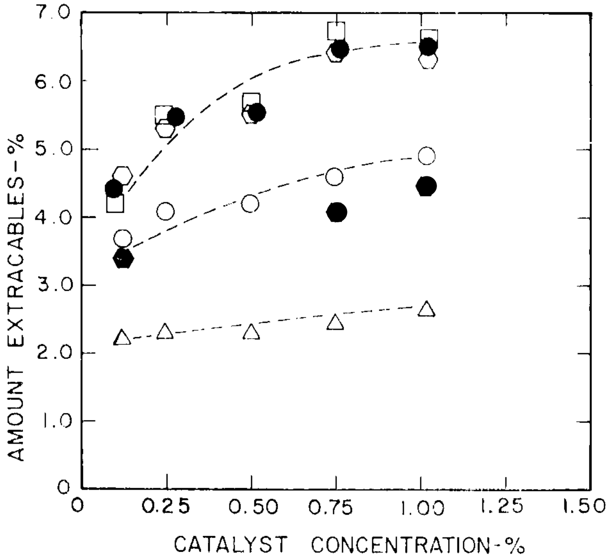


FIGURE 5 Amount extractables as a function of catalyst concentration: ○ acetone; ● methylene chloride; ⬡ benzene; ⬢ 1,4-dioxane; △ methanol; □ heptane.

Heat of wetting

The enthalpies of wetting for 12 differently prepared samples immersed in acetone were in the range 2–2.5 cal/g polymer. This data indicated that the enthalpies were independent of particle size but may be dependent upon treatment of the polymers. Further investigation is concerned with understanding the polymer-lipid interface in a variety of liquids.

TABLE III

Values of N as a function of % catalyst and treatment

% catalyst	Post-cure treatment	$N \times 10^4$ Benzene	$N \times 10^4$ Heptane
1.04	*NT*	3.19	2.87
0.75	*NT*	3.19	2.78
0.50	*NT*	3.04	2.83
0.25	*NT*	3.29	2.83
0.125	*NT*	3.29	2.60
0.50	γ	3.18	2.91
0.50	*US*	2.98	2.72
0.50	*T* – 150°C	2.76	2.49
0.125	*US*	2.25	2.54
0.125	*VT* – 150°C	2.69	3.06

N = number of moles of crosslinks per cm^3 of rubber
NT = no treatment
T = thermal treatment
US = ultrasonic vibration
V = vacuum pre-treatment
γ = gamma irradiation

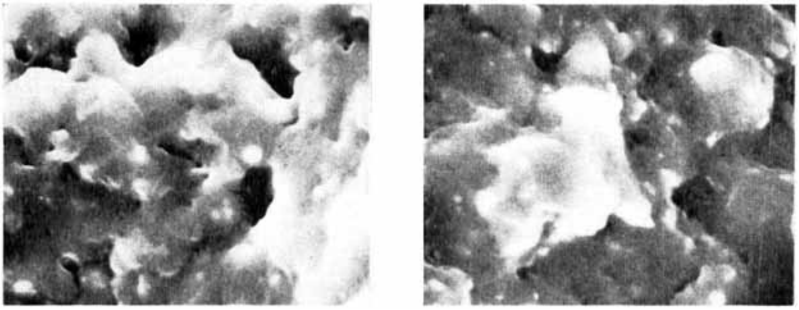
Scanning electron microscopy results

Samples cured with the different catalyst ratios were observed via SEM. In order to extend the frame of reference, cross sections of identical samples were exposed by tension rupture at room temperature (Figure 6a), by shear rupture at liquid nitrogen temperatures (Figure 6b) and by slicing with a scalpel (Figure 6c). With no "a priori" knowledge of the properties of the cured polymers the micrographs from the shear and sliced samples indicate that the uniformity of the polymer improves as the catalyst concentration increases. The same samples ruptured by tensile forces reveal the presence of crosslinked agglomerates as the catalyst concentration increases. In general these, and other micrographs from the post-cure treatments, did not correlate the findings of the mechanical testing results except at the lower and high catalyst concentrations. The surprising features of the micrographs are that the samples having the greatest amount of catalyst are freer of microvoids than the samples containing smaller amounts of catalyst. These findings appear to us to be consistent with

TABLE IV

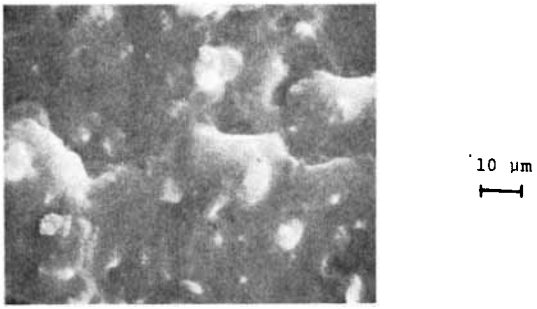
Extraction data

Solvent	% catalyst	% extractables			
		No post-treatment	Gamma irradiation	Ultrasonic vibration	Thermal 150°C, 4 hours
Benzene	0.125	4.6	—	4.2	5.1
1,4 dioxane	0.125	3.4	—	3.3	2.9
Heptane	0.125	4.1	—	4.2	3.2
Methanol	0.125	2.2	—	1.9	1.7
Methylene chloride	0.125	4.1	—	4.0	3.5
Benzene	0.25	5.5	4.0	4.0	3.6
1, 4 dioxane	0.25	2.6	3.3	3.4	3.1
Heptane	0.25	5.5	4.1	4.4	3.9
Methanol	0.25	2.3	1.9	1.9	1.7

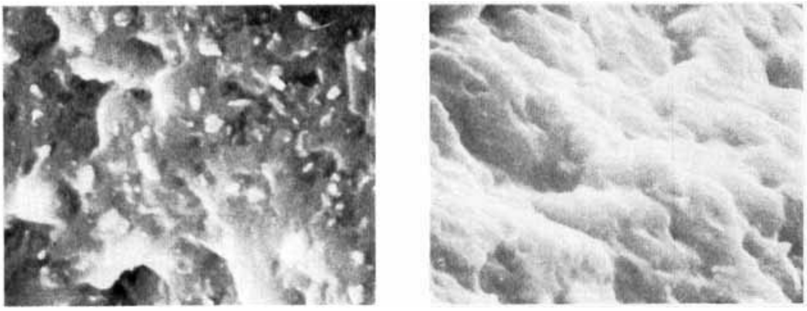


0.125% Catalyst

0.25% Catalyst



0.50% Catalyst

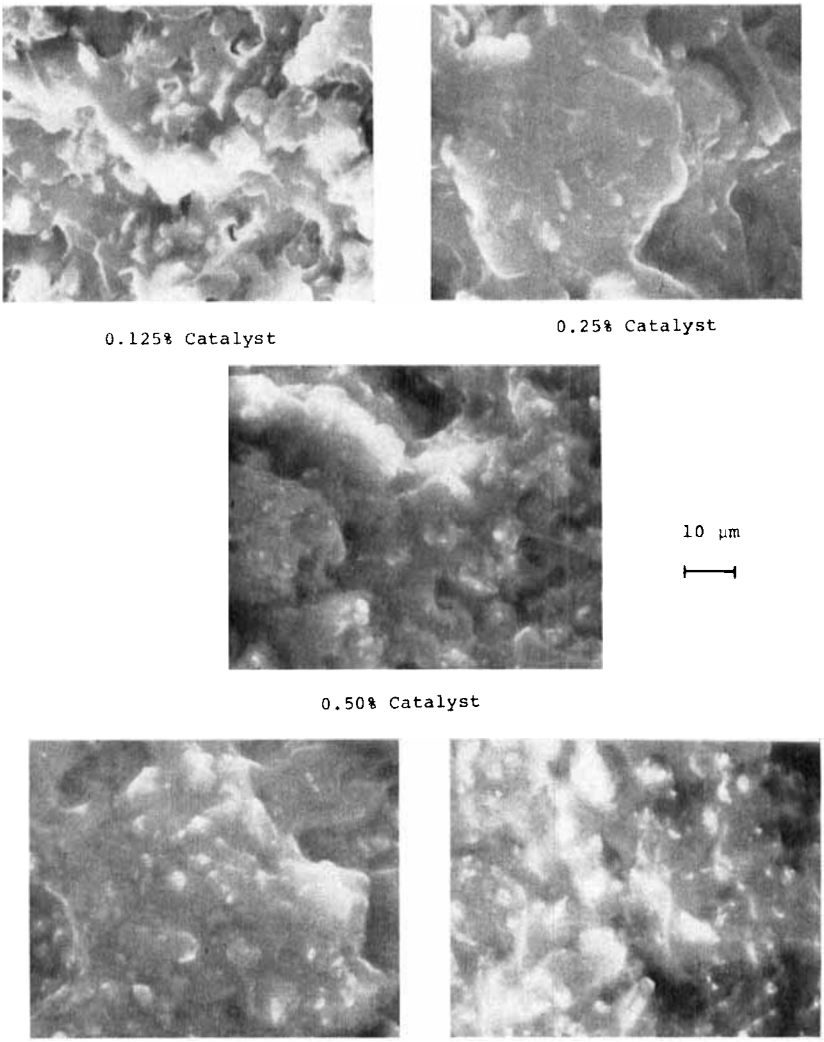


0.75% Catalyst

1.04% Catalyst

FIGURE 6a SEM micrographs of tensile rupture cross section.

the formation of linear chains postulated for the case of low catalyst concentration, and the formation of localized masses of grossly crosslinked polymer formed at the high concentrations. It is also of interest to note the agglomerates of filler and individual filler particles, some of which do not appear to be completely wetted by the polymer.



0.125% Catalyst

0.25% Catalyst

0.50% Catalyst

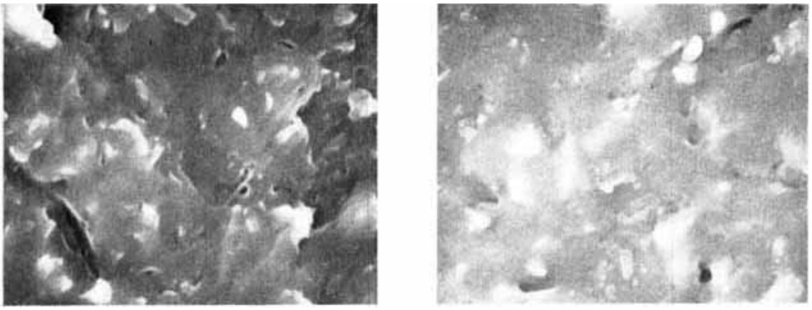
0.75% Catalyst

1.04% Catalyst

FIGURE 6b SEM micrographs of shear rupture cross section.

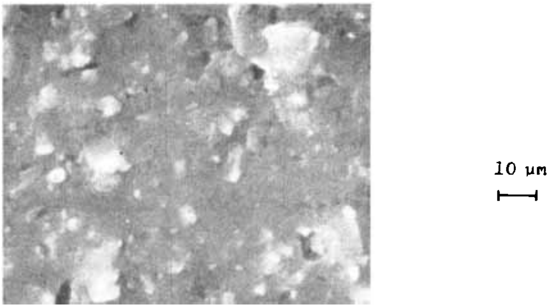
Lipid uptake

Table V shows that the lipid uptake, under the conditions of these experiments, is between 1 and 2%. These numbers are consistent with those obtained from peroxide cured systems under the same test conditions. Tests utilizing other

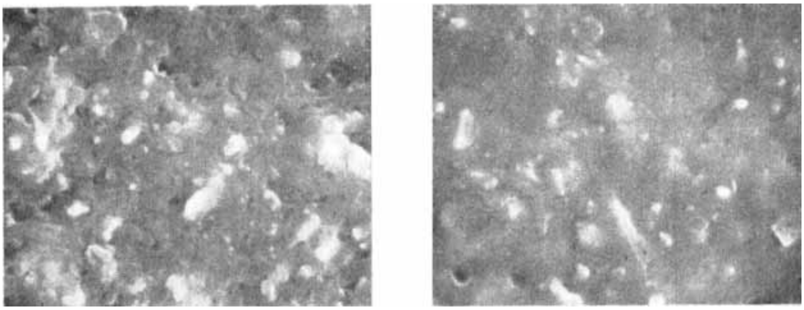


0.125% Catalyst

0.25% Catalyst



0.50% Catalyst



0.75% Catalyst

1.04% Catalyst

FIGURE 6c SEM micrographs of scalpel sliced cross section.

less conventional procedures yield different numbers but the same general trend is observed.

Implantation studies

Gross and histologic examination of all implant sites was performed on all

TABLE V

Lipid uptake as a function of % catalyst[a]

% catalyst	Wt. % lipid uptake after 28 days
0.125	1.2
0.25	1.3
0.50	1.8
0.75	1.9
1.04	1.8

[a] Samples received no post treatment. Values for post-treated samples fall within the same range.

three rabbits. Postoperative observation revealed no untoward effects and skin healing was routine in all animals.

When the tissue surrounding the implant sites was examined grossly, all sections were noted to be encapsulated in thin, nonadherent fibrous membrane, typical of the reaction to implanted silastic. Little evidence of an inflammatory reaction was observed grossly, save for occasional small vessels growing over the corners of the sections.

Histologic examination of the tissues making up the capsule and its surrounding revealed a fibrous tissue membrane of 2–20 cells thick with an occasional macrophage and polymorphonuclear leukocyte observed. The pathologic impression of all implant sites was that of an extremely mild foreign body reaction.

SUMMARY

The data reported here differ from previously reported results[10] in so much as the cured polymer properties are not independent of the catalyst concentration.

Several statements are in order pertaining to the discussion of the results of this work. There are systematic deviations which are inherent in the preparation of the samples. The time required for the polymer to reach a gel state is a function of the catalyst concentration. Since the blending time is the same for all batches, approximately equal volumes of atmospheric gases are entrapped in the liquid catalyzed polymer. The time available for the bulk of the air to escape from the polymer before gel is variable depending upon the catalyst concentration. Therefore, the results reported here reflect not only catalyst concentration and the primary treatment variables but also the composite effects of entrapped gases and moisture as a function of cure time. It should be noted that the results reported here are real and should be expected by any practical user, however, references and comparison to theory would be expected to reflect these systematic deviations and strict theoretical considerations could be misleading.

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