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THE SILICONES AS TOOLS IN BIOLOGICAL ENGINEERING*

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Abstract—The paper discusses the requirements of a material for implantation in body tissues and deals briefly with the shortcomings of some traditional materials in this application. The silicone rubbers are then introduced, and attention is drawn to properties, peculiar to these rubbers, which makes them highly suitable for biological implantation. Extensive reference is made to many examples of such implantation.

1. INTRODUCTION

THE term engineering has undergone considerable change since the days when it was associated with the operation of an engine. Among other present meanings, it is now defined as applied science concerned with utilizing the properties of matter to supply human needs. By this criterion, the term biological engineering, or, as often used in the United States, bioengineering, is a valid one. Bioengineering is a new field, and as such, one that is in considerable flux. The vast proliferation of medical knowledge, combined with an even vaster expansion of knowledge and technology in other fields, gives the progressive research physician tremendous new tools with which to work. But he must have the aid of a middle man—one who has a knowledge of engineering as well as medicine—the bioengineer.

One of the greatest problems facing the bioengineer is that of connecting foreign elements to the body. Almost anyone can make a valve, but how can one make a valve that can be permanently placed in the heart? There are many ways to monitor motion, temperature, pressure or electricity, but how does one do this continuously on a normal subject—not one surgically assaulted and under anesthetic? The bioengineer thus finds himself separated from his objective by the physiological barriers set up by the body as protective measures. He must find some detour around these obstacles. One means is by the use of materials which the body does not regard as inimicable, or which it ignores.

Few materials qualify in these respects. Certain metals cause little foreign body reaction, but are hard and unyielding. Since most of the body is soft and undergoing constant motion, erosion becomes an immediate and major problem, so that such metals can be used only where motion is minimal, such as when screwed firmly to bone. Organic materials have enough relation to the organic substances used in the construction of the body so that tissue defenses are rallied immediately, resulting in rapid rejection of most plastics and rubbers. A key problem, then, is the finding of a material that is not hard and which does not cause the body to set up undesirable responses. Until the advent of the silicones, there was, for all intents and purposes, no material with which to solve this problem.

The silicones are a combination of the organic and inorganic families. By utilizing a chain of silicon and oxygen atoms (with its obvious relation to inorganic silica) to which he attaches organic groups, the chemist is able to blend the inertness of quartz with the ability of the plastics to be fabricated. The silicones have

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never been found in nature. Apparently the bond of carbon to silicon is not a naturally occurring phenomenon. Anthropomorphically (and not very scientifically) one could say that the body has never had to build a defense against the silicones; it seems to ignore them and to act as though they were not present. This lack of recognition on the part of the body is, fortunately, combined, in the silicones, with a lack of chemical reactivity: they do not oxidize readily, nor do they have many chemical reactions with other materials. They do not contain plasticizers, antioxidants, antiozidants, nor any of the other host of additives used in the plastics and organic rubber fields. There is, therefore, a material now available which will not cause erosion, which the body ignores, and which does not deteriorate with time. The bioengineer has a substance that can act as the intermediary between the body and the many foreign materials he wants to use.

SCALES [1] in 1953 defined the properties necessary for an ideal soft tissue substitute:

(1) not physically modified by soft tissue;
(2) chemically inert;
(3) no inflammation or foreign body reaction;
(4) noncarcinogenic;
(5) produces no state of allergy or hypersensitivity;
(6) capable of resisting mechanical strains;
(7) capable of fabrication in the form desired;
and (8) capable of sterilization.

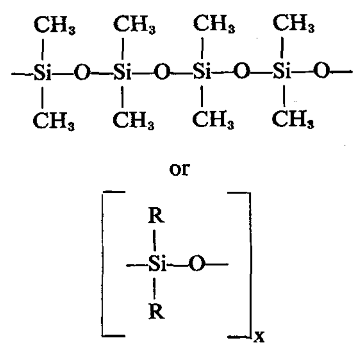
The silicones have been found to have these properties to a degree sufficient to make them, at present, the most useful of all available non-autogenous materials for long-time subdermal contact with the human body.

2. THE SILICONES AND SILICONE RUBBER

Let us look at what these silicones are: first it should be explained that they are not a single entity, but rather a large family of chemically related materials. They can take many forms: they can be watery liquids, oils, or viscous fluids; they can also be rubbery materials almost indistinguishable from natural rubber at first sight; and they can be resins like methylmethacrylate or varnish. The silicone resins have limited applications in the field of medicine and will not be discussed further here. The silicones are also available in the form of sponge or foam rubber, adhesives and gels.

In general the silicones can be described as composed of long chains (polymers) of alternating silicon and oxygen atoms (Fig. 1) much as natural rubber, plastics, oils, etc. are made of long chains of carbon atoms. When these chains are short, the resultant silicone is a low viscosity fluid; if the chains are long, the fluid has a correspondingly high viscosity. The Si–O polymer chain has, attached to each silicon atom, two organic groups, usually methyl ($—CH_3$) groups, although phenyl groups ($—C_6H_5$) are often employed, particularly in certain of the fluids. Other organic radicals are utilized in some special silicones. Because of the preponderance of methyl groups, the silicones are sometimes called, rather erroneously, the polydimethyl siloxanes.

Silicone rubber is made from high viscosity silicone polymers. Fillers and vulcanizing agents are compounded with the base polymer. The former are usually silica and give the rubber strength, while the latter, under the proper conditions, changes the plastic or fluid mass to a true rubber. This process of vulcanization cross-links the polymer chains lightly so that



(R can be any organic group)

FIG. 1. Composition of silicones.

they cannot slip completely away from one another, as they can in a fluid. The vulcanizing agent most commonly used in the heat-vulcanizing type of medical grade silicones rubber is dichlorobenzoylperoxide. It is interesting to note that this material, when heated, causes the vulcanization of the silicone rubber but is then fugitive; it does not become part of the rubber molecule, as does the sulphur used in vulcanizing natural rubber. Hence medical grade silicone rubber utilizing this system of vulcanization eventually contains only the silicone polymer and the reinforcing silica filler.

The room-temperature-vulcanizing or RTV silicone rubbers use an organo-metallic catalyst that causes vulcanization when it is stirred into the rubber base. There are many of these catalysts, but the only medically acceptable one is stannous octoate. This causes vulcanization to take place in a few minutes. The other catalysts, usually various organo-tin compounds, will cause the rubber to vulcanize over a longer period of time, but are toxic. We are aware of massive sloughs where these have been used subdermally. For this reason special care should be taken that only the medical grades of RTV silicone rubber be used for medical purposes.

It is probably wise at this point to define terms that have caused confusion:

silicon is an element, a hard, black, crystalline solid, Si in the chemist's shorthand;

silica is SiO_2, sand and quartz rock are the commonest sources;

silicones are the polymeric, organo-silicon compounds just described;

siliconize means to coat with silicone—this will hydrophobe a surface, but it does not change the substrate, siliconized rubber is not silicone rubber;

Silastic® is the trade-mark for Dow Corning silicone rubber and not a generic term for all silicone rubber.

The past five years of intensive application of the silicones to medical uses has demonstrated that there are four primary reasons underlying this development.

(1) *Heat stability*. For the physician this means that they can be autoclaved or dry-heat sterilized with impunity, eliminating the uncertainty of cold sterilizing methods. Also the high and low temperatures encountered in medicine will not cause the silicones to become either soft or brittle.

(2) *No deterioration with time*. The medical grade fluids do not evaporate or turn gummy, and silicone rubber does not deteriorate. Samples of the latter exposed for more than fifteen years in the South Florida Testing Station show little change from their original properties. Recent work [2] has shown no significant change in the physical properties of thin silicone rubber sheets after implanting in rats for seventeen months. In the eight years since the first silicone rubber hydrocephalus drain was installed, no reports of change in the rubber have been encountered.

(3) *No adherence*. Literally nothing will stick to a silicone except certain other silicones. They therefore can be used for efficient drains and for the prevention of adhesions. If adherence to body tissue is desired, an artificial stroma can be attached into which the tissue can grow.

(4) *Lack of tissue reactions*. Properly prepared, medical grade silicones elicit less tissue reaction than almost any other non-autogenous material. It has been stated [3] that following implantation of Silastic silicone rubber, with subsequent histological studies, the entire process of tissue reaction can be interpreted as "a normal healing response in a sterile wound".

It should be emphasized that the subject we are discussing is that of the *medical grade* silicones. These have been adapted for medical applications from a large number of industrial grades of silicones. These industrial grades contain a wide variety of additives to do specific jobs for industry. The medical grades we are discussing are specially compounded for this use, have a wide background of implant work, and are made under the exacting specifications demanded by their ultimate use. Some of the industrial grades have been tested for medical applications and have been found to be toxic;

the vast majority have never been tested and should, therefore, be considered suspect.

We cannot overemphasize that *only properly prepared medical grade silicones should be used for medical applications.*

Much of the literature contains references that do not specify which silicone was used. Because of the wide variety of silicones available, it is strongly recommended that specific description be made in order to guide subsequent users.

As was mentioned before, the medical grade silicones probably elicit less foreign body reaction than almost any other non-autogenous material. However, if they are not properly prepared, this quality can be lost. Dust, lint, fingerprints, etc., on the surface can cause foreign body reactions which can be mistakenly attributed to the silicone. If the ultimate in lack of tissue reaction is desired, the difference between cleanliness and sterility should be recognized [4].

Many, if not most, of the cold sterilizing solutions and gases will absorb into the silicones and will, unless extreme care is taken to get rid of them, subsequently cause tissue reaction when the piece is implanted. For this reason, cold sterilizing methods are not recommended. Autoclaving under standard conditions or dry-heat sterilizing for several hours at 300°F are preferred. Neither will damage the silicone, although the pressure changes encountered in autoclaving can collapse the cell structure of the sponges, since they have an essentially closed-cell structure. Almost all reports of tissue reactions attributed to silicones can be traced to the use of non-medical grades or to improper preparation, particularly the use of cold sterilizing methods.

The selection of the proper silicone and its proper preparation are only the first steps in the successful use of silicones for implant purposes. While they are perhaps the best available substitute for natural tissue, it should be remembered that they are, nevertheless, still non-viable materials. They cannot heal themselves, sharp edges will not disappear, and through rubbing can cause erosion of the tissues, and they remain forever what might be called, paradoxically, extra-corporeal implants; that is, they do not become part of the living tissue. Care should be taken that the silicone implant be buried as deeply as is feasible, preferably under a layer of fat, and it should not be in an area where trauma, constant motion, or tissue tension can cause erosion. The springiness of a small curled piece of silicone rubber can erode through the tissue as it uncoils. Because of the nearly total absence of fibroblastic activity around a silicone implant, the potential movement of the implant is unrestrained.

Table 1 lists the most commonly used medical grade silicones at the present time. Because it is felt that complete nomenclature is necessary so that non-medical grades can be avoided, the list includes both the present name of these materials as well as the earlier nomenclature found in some of the older papers. This nomenclature was

Table 1. Medical silicone nomenclature

Dow Corning silicone fluid	*(Older number)*
360 Medical Fluid	
20–1,000 centistokes	200 Fluid
555 Fluid	
20 centistokes only	Unchanged
Silastic® silicone rubber	
(a) Heat vulcanizing	
Soft-Silastic® 370	S-6508
Medium-Silastic® 372	X-30146
Hard-Silastic® 373	X-30294
Coarse Cell Sponge	Unchanged
Fine Cell Sponge	Unchanged
(b) Room temperature vulcanizing (RTV)	
Solid-Silastic® 382	502
Foam-Silastic® S-5370	Unchanged
Soft Solid-Silastic® S-5392	Unchanged
Adhesives	
Medical Adhesive Type A	Q-30149
Medical Adhesive Type B	269 Adhesive

changed in order more clearly to separate the medical from the non-medical grades. Most silicone fluids have two numbers describing them: the first indicates its chemical nature (360 Fluid is dimethyl), and the second describes its viscosity in centistokes (water has a viscosity of one centistoke). You will note that the silicone rubbers are divided into two groups, the heat vulcanizing and the room temperature vulcanizing types. The heat vulcanizing types are more widely used, are stronger and tougher, and generally are furnished in the already vulcanized form. The room temperature vulcanizing (RTV) types are fluid in the raw state and are vulcanized by the user. These RTV silicone rubbers are used primarily where heat cannot be tolerated. It should be noted that the medical fluids will not set up by the addition of a catalyst, only the RTV rubbers. The Medical Adhesive Type A sets up from a grease-like raw state to a silicone rubber by reaction with moisture. It will adhere to many materials, but not well to tissue and certain plastics. Medical Adhesive B never sets up, rather it stays sticky like adhesive tape.

Typical electrical and physical properties of silicone rubber are illustrated in Tables 2 and 3.

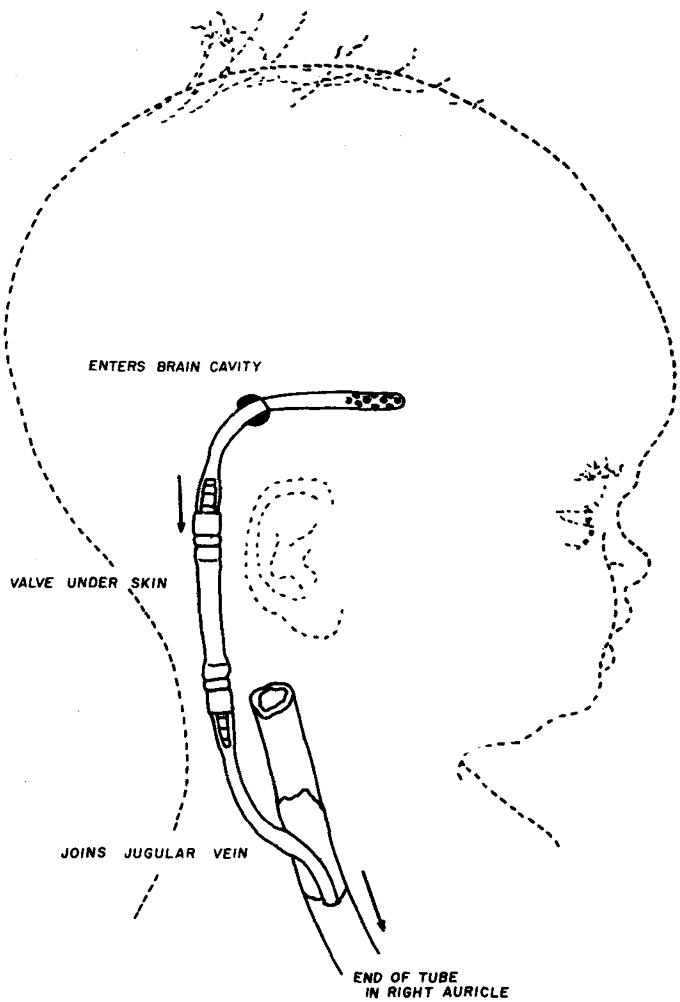


FIG. 2. Holter hydrocephalus shunt. Made of Silastic® silicone rubber, it carries the brain fluid to the heart. Courtesy of the Holter Company, Bridgeport, Pennsylvania, U.S.A.

Table 2. Typical electrical properties of silicone rubber

Electric Strength†	
V/mil	450–600
kV/cm	160–240
Dielectric constant	2·9–3·6
Dissipation factor	0·0005–0·02
Volume resistivity Ω-cm	10^{13}–10^{15}

† ¼ in. (0·625 cm) electrodes, rapid rise of 500 V/sec, on specimen 1/16 in. (0·156 cm) thick.

The appropriate ASTM test methods were used. These properties are not materially changed by many hours aging at 250°F, by extended immersion in water, or by repeated autoclaving.

3. USES

The versatility of the silicones in surgical practice provides a good index of their capabilities. The following are examples taken from many medical and surgical specialties. Some of these are in general use, while others are still experimental. All illustrate some property of the silicones that could be directly or indirectly utilized by the medical engineer.

The Holter ventriculo-caval shunt, called more commonly the Holter hydrocephalus valve [5], illustrates what is probably the most extensive use of silicones in the human body. This shunt is made of Silastic 372 Medical Grade Elastomer and serves to drain excess fluid from the brain cavity into the heart (Fig. 2). It is implanted entirely subdermally. One end is placed in the brain, the tube extending through the skull behind the ear, and passing into the throat where it enters the jugular vein. It continues inside the jugular vein to the heart, where it discharges the brain fluid into the right auricle. This application illustrates dramatically the lack of tissue reaction inherent in the silicones, since it is in contact with brain tissue, bone, muscle, and skin and finally is permanently bathed in venous blood. Another ventriculo-caval shunt, the Pudenz valve [6] serves a similar function but is of a somewhat different design. It is also made of Silastic 372 silicone rubber. These two valves have been implanted in perhaps 45,000 children over the past eight years.

The majority of the implantable pacemakers for artificially stimulating the heart are encapsulated with Silastic silicone rubber, which acts as both electrical and physiological insulation (Fig. 3). The Chardack pacemaker [7] utilizes three kinds of silicone rubber. Silastic RTV 382 is used to encapsulate the power unit because the mercury batteries will not tolerate heat. Silastic 372 is used to cover the wires and to make the seal where the wires enter the heart. Silastic Medical Adhesive Type A, is used to seal the junction between the unit and the Silastic coated wires.

The Schuder micromodule pacemaker [8] is also coated with Silastic RTV 382. It is about the size of one's thumb nail, is attached directly to the heart, and is actuated by a radio frequency pulse. Levitsky and Glenn [9] have also developed a radio-operated pacemaker. Both the receiver, which is implanted in the chest, and the antenna, which is attached exteriorly to the skin, are encapsulated in a heat-vulcanizing stock, Silastic 372. The wires attaching the receivers to the heart are also insulated with Silastic 372.

Digital plethysmographs operating by means of a tiny mercury-filled rubber tube surrounding a finger or toe have been improved by Parks* by the use of Silastic 373 silicone rubber tubing.

Table 3. Typical physical properties of silicone rubber

	Heat vulcanizing types	RTV types
Durometer	30–80	50–60
Tensile strength		
lb/in.²	1,000	500
kg/cm²	70	35
Elongation	300%	150%

* Parks Electronics Laboratory, Beaverton, Oregon, U.S.A.

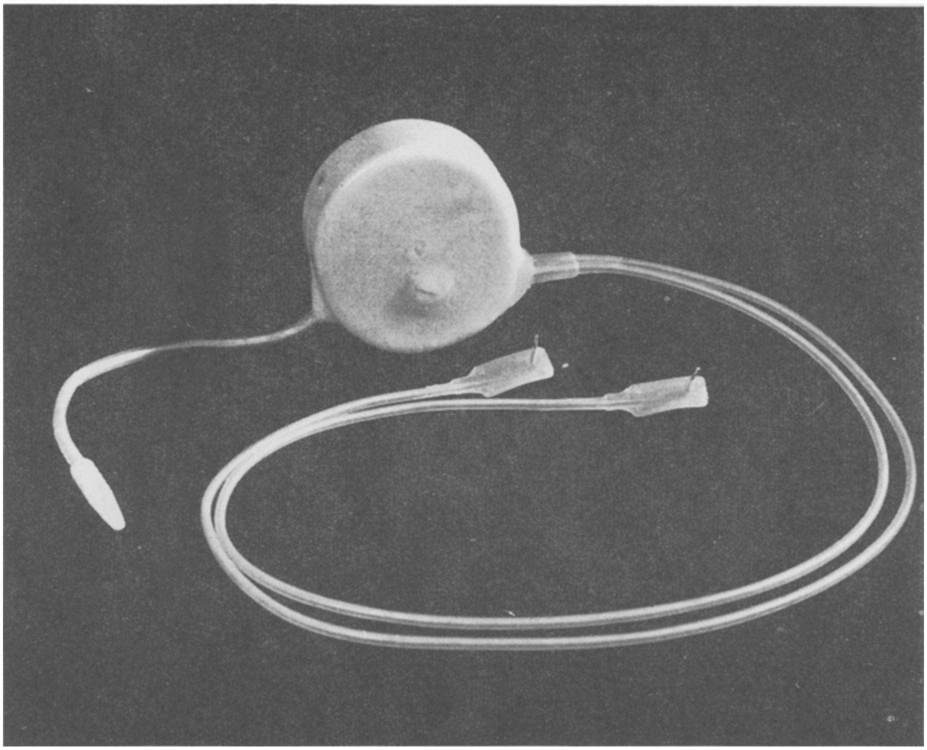


FIG. 3. Chardack–Greatbatch implantable pacemaker. This is entirely coated with medical grade Silastic® silicone rubber. Courtesy of Medtronic, Inc., Minneapolis, Minnesota, U.S.A.

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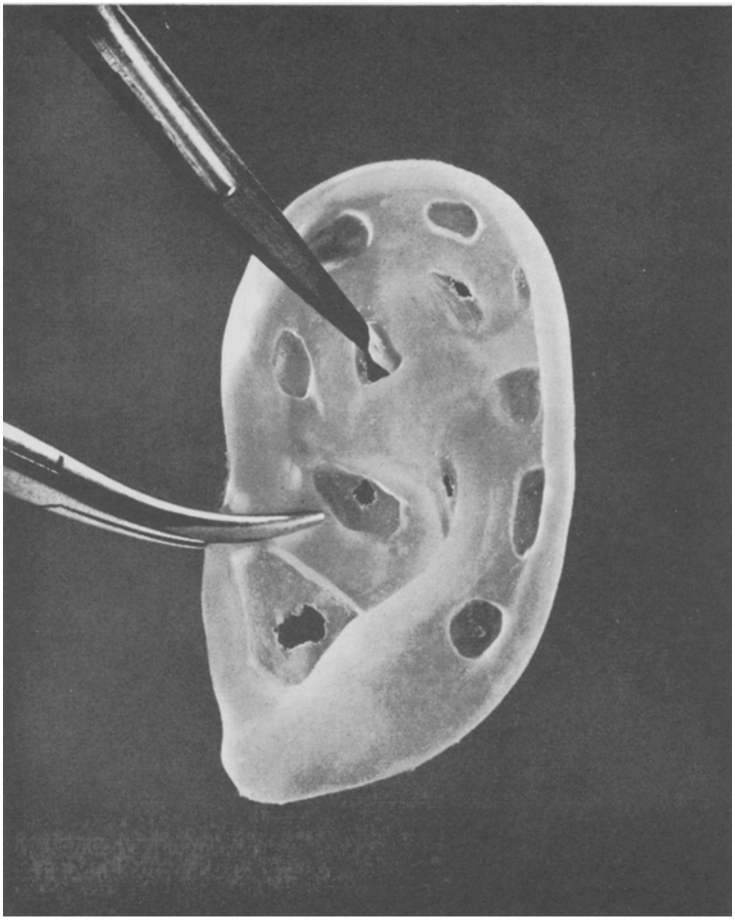

FIG. 4. Implantable Silastic® Otoplasty Prosthesis. This acts as artificial cartilege for rebuilding missing ears.

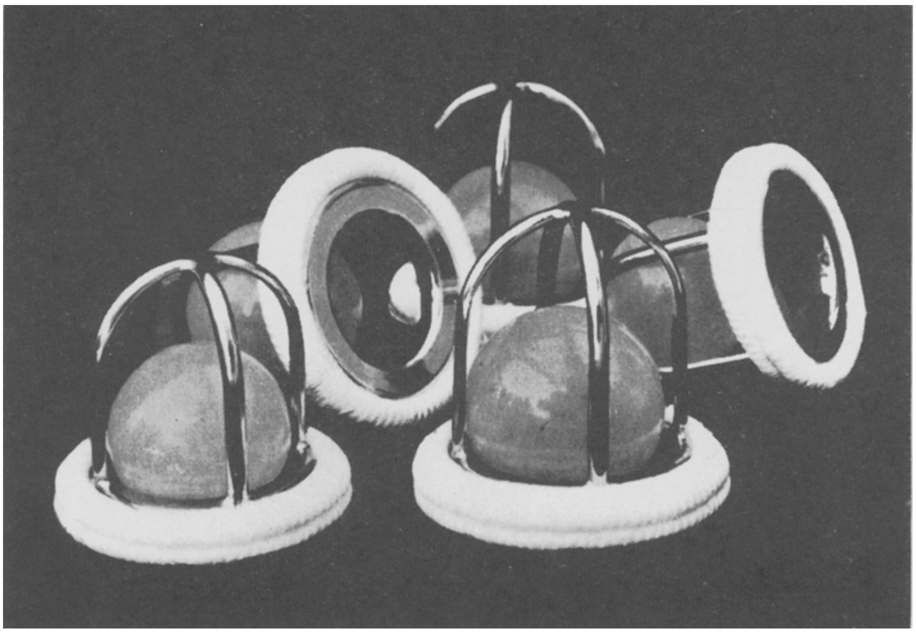

FIG. 6. Starr–Edwards heart valve. Made of a medical grade Silastic® silicone rubber ball in a metal cage with an artificial stroma of Teflon cloth around the base. Courtesy of Edwards Laboratories, Inc., Santa Ana, California, U.S.A.

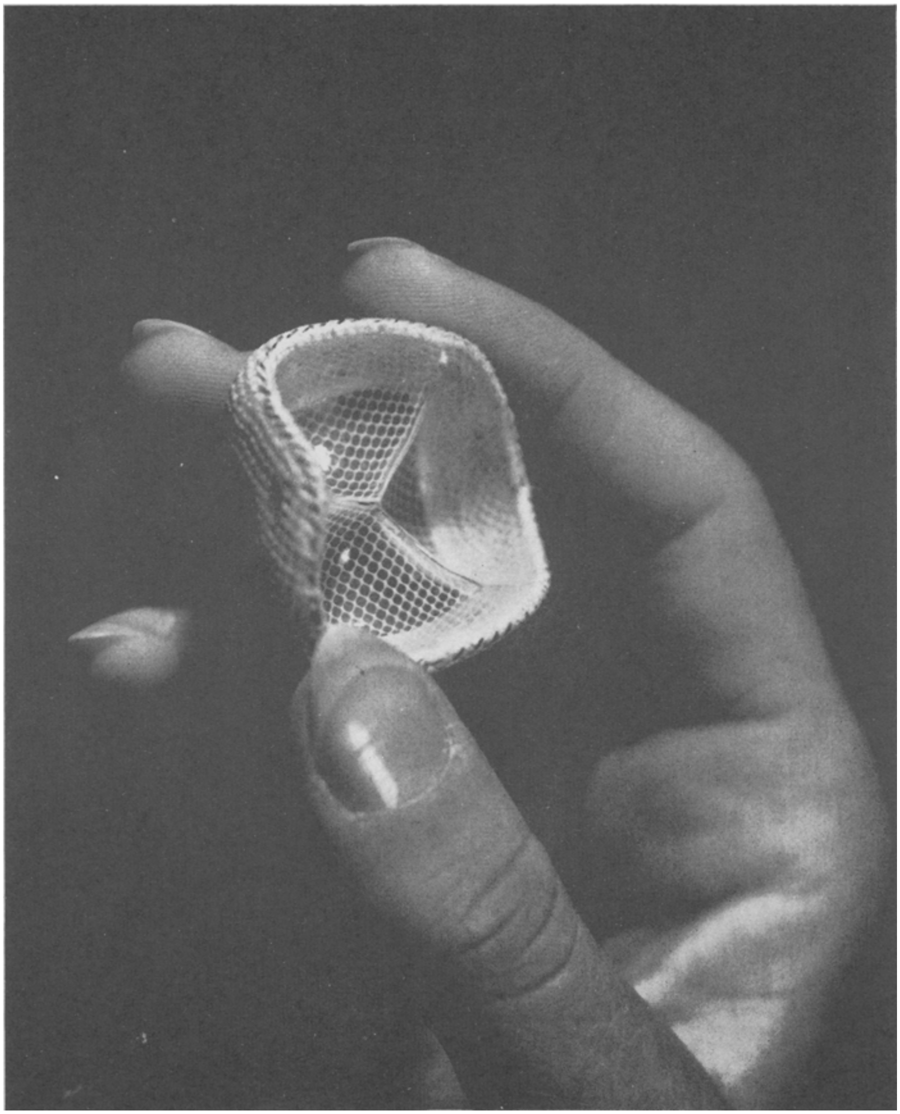

FIG. 7. Segger artificial aortic valve. A tricuspid heart valve made of medical grade Silastic® silicone rubber coated Dacron.

FIG. 8. Kolff–Akutsu artificial heart for calves. This model is made of medical grade Silastic® silicone rubber coated on to Dacron cloth. The "R" and "L" refer to the right and left sides of the heart.

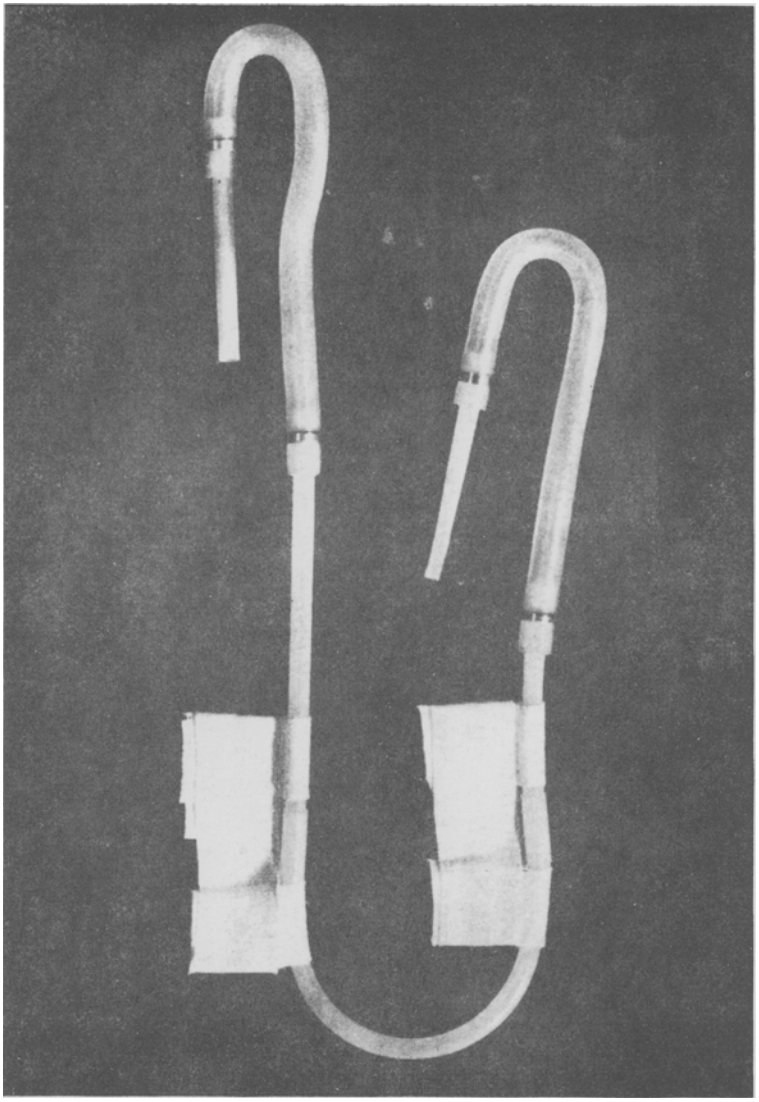

FIG. 9. Silastic–Teflon arterial–venous shunt for permanent artificial kidney. Courtesy of W. E. Quinton Instrument Company, Seattle, Washington, U.S.A.

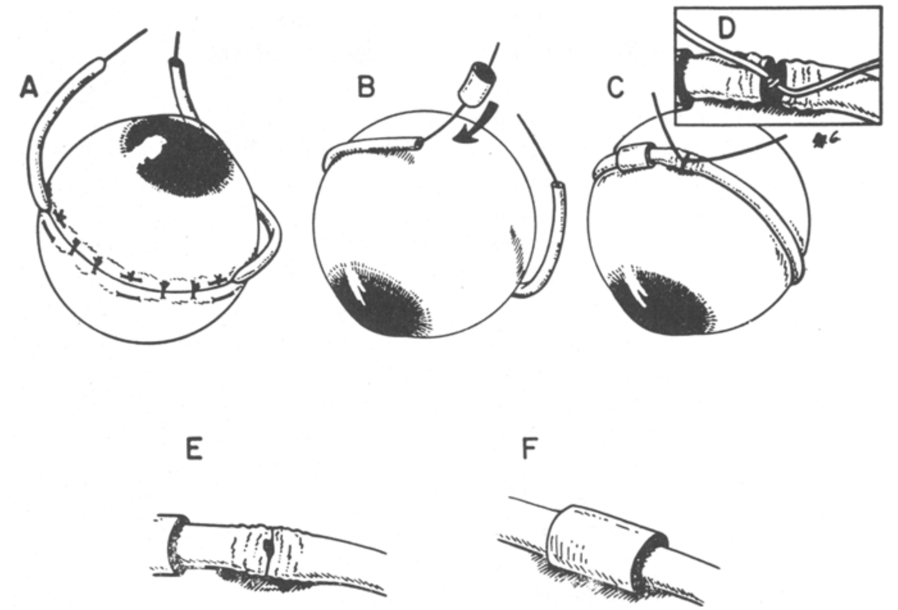

FIG. 5. Encircling Silastic® silicone rubber rod for retinal detachment repair—Everett technique.

In this case, the medical acceptability of silicone rubber is secondary to the fact that silicone rubber is not deteriorated by aging, so that the tiny tubes have a much longer life.

Silastic 372 has also been used to coat implantable strain gauges. JACOBY *et al.* [10] and McCOY and BASS [11] have used them to study the individual roles of the longitudinal and the circumferential muscles of the intestine.

Silastic 372 has been used to make many prosthetic parts for plastic surgery uses: ear armatures (Fig. 4), columellae and struts for noses, sponge for building out cheeks and chins are a few [12–19]. It also has been implanted in thousands of eyes (Fig. 5) for the correction of detached retinas [20–23]. Recently Dow Corning Medical Fluid 360, 1000 centistoke viscosity, has been used to replace completely the vitreous fluid of the eye in cases of otherwise intractable retinal detachments [24, 25].

Silastic 372 is used to make the ball in the cardiac ball valve [Fig. 6] devised by STARR and EDWARDS [26]. These valves have been implanted successfully in close to 4,000 patients. The same rubber is used in several other ball type heart valves. It also has been used to make many other varieties of heart valves. SEGGER [27] has devised a successful tricuspid Silastic valve (Fig. 7). HUFNAGEL [28] has made a single cusp of Silastic 372 coated Dacron that can be used singly or in combination to replace any or all of the three cusps of the aortic valve. Recently AKUTSU [29] and others have made entire artificial hearts of Silastic-coated Dacron* (Fig. 8)

Silastic 372-coated Dacron cloth is used to replace missing dura mater in the skull [30]. Tubing of the same silicone rubber has been found to be less damaging to blood than conventional rubber or plastic tubing [31, 32], and hence has been used for heart-lung machine tubing and for long-indwelling intravenous tubes [33]. It is interesting to note also that the oxygen and CO_2 transmission rate of silicone rubber is so high that it is being utilized as the membrane in membrane oxygenerators [34, 35].

Medical Adhesive Type B has been used to

* Trade name for du Pont polyester fibre.

attach silicone rubber external facial prostheses to the skin [36–39] and also for attaching collecting bags to the abdomen in ileostomy, colostomy, and cystostomy cases. This pressure sensitive adhesive not only adheres well to the skin and is not attacked by water, but also it does not cause reaction with the skin as do many of the conventional skin adhesives. On the contrary, as in the case of ileostomy bags, it actually protects the skin from the effects of the draining fluids. This same adhesive can be used to attach electrodes to the skin. Because of the excellent dielectric properties of silicones, it is, of course, necessary that the adhesive not cover the contact area of the electrodes.

Silastic RTV 382 has been used to make both physiological and electrical insulation for electrodes for longtime stimulation of nerves [38], and to seal the burr holes when trephines are used in the placing of cranial electrodes. The liquid material is poured into the burr hole, and in a few moments it hardens and the skin can be replaced.

Silastic S-5392, a similar, but softer, room-temperature vulcanizing silicone rubber, has been injected into tissue and allowed to vulcanize *in situ* [39]. It has served to build out dressed areas of the head, for mammary augmentation, and for creating a raised area in the back of the throat for cases of velopharyngeal incompetencies [40].

Because of the many combinations and permutations possible in using silicone rubber, it can be used to accomplish many procedures heretofore considered impossible. The continuous monitoring of blood exteriorized by means of a silicone rubber tube running from an artery out of and back into the skin and into a vein is quite feasible. This procedure is now used for the permanently indwelling cannula of the Scribner artificial kidney system [41]. Patients have lived for as long as two years with such cannulae in place (Fig. 9).

Silicone rubber capsules have been devised that indicate possible long term medication [42]. Certain medicinals, depending on their solubility in the silicone rubber, will, in effect, pass through the wall of the capsule and be absorbed slowly and regularly by the body. This work is still experimental and further investigation is indicated.

Recent work by GEROW and SPIRA [43] in immersing burned patients in a silicone fluid bath has created considerable interest. They report that the patients are virtually free from pain, infection is reduced, early eschar removal is facilitated, and the patients are ready for grafting earlier. Multiple painful dressings are avoided, and because the silicone is a non-aqueous fluid, maceration is not a problem. It should be possible to ultize the same system to isolate a patient almost completely from, and thereby control, his environment. This opens many doors to physiological studies previously impossible.

HUNTER [44] has made artificial tendons of silicone rubber. CARROLL [45] has used silicone rubber rods to place in the tissues to build new tendon sheaths. When healing is completed they are removed and autogenous tendons are introduced. ASHLEY [46] has used silicone rubber sheeting to prevent adhesions around autogenous tendon grafts.

4. SUMMARY

In summary, the silicones can be said to provide the bioengineer with a whole new family of materials to work with; materials which, unlike almost all other non autogenous matter, cause practically no tissue reaction.

While it is too early to assess with any degree of finality the ultimate role of the properly prepared medical grade silicones, they presently offer the bioengineer distinct advantages and seem to fulfill most of Scales' criteria for an ideal synthetic.

Further information and research amounts of the materials discussed are available from the Dow Corning Center for Aid to Medical Research, Midland, Michigan, U.S.A.

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LES "SILICONES"—LEUR ROLE DANS LE GENIE BIOLOGIQUE

Sommaire—Les propriétés nécessaires au matériel d'implantation en tissu corporel sont discutées. Une bréve critique des défections des matériaux couramment employés dans cette pratique est suivie d'une étude sur les caoutchoucs-silicone. Les qualités particuliéres à ces caoutchoucs les rendent trés appropriés à l'implantation biologique. De nombreuses références sont citées.

DIE VERWENDUNG VON "SILICONE" IN DER BIOLOGISCHEN TECHNIK

Zusammenfassung—Die Abhandlung untersucht die Anforderungen, die an Materialien zu stellen sind, die für die Implantation in Gewebe vorgesehen sind, und behandelt kurz die Nachteile einiger traditioneller Stoffe auf diesem Anwendungsgebiet. "Silicone"—Gummi wird dann behandelt und die Aufmerksamkeit auf Eigenschaften gerichtet, die von besonderem Interesse für die biologische Implantation sind. Ausführliche Hinweise auf viele Beispiele solcher Implantationen werden angegeben.