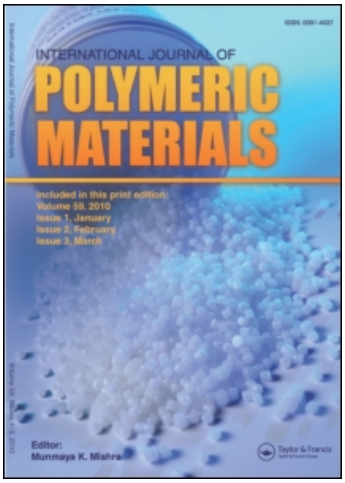

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Polyurethane Elastomers in Surgery†‡

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Review of polyurethane elastomers and several applications as surgical implants.

INTRODUCTION

From the basic work on polyurethanes by Bayer[1,2] in the 1930's came the development of a variety of hard and elastic polyurethane materials whose end-use form ranged from fibers, to foams, to sheets, to adhesives, to coatings. The urethane elastomers were of particular importance, because of their excellent strength, tear, and abrasion properties, as well as their good oil resistance. This sparked much activity in the field, and so by the middle 1950's a number of companies were marketing a variety of urethane elastomers.[3] Many of the earlier elastomer formulations were based on the reaction between a diisocyanate (such as 1,5-naphthalene diisocyanate), a polyester (such as polyethylene adipate) and a diol for chain extension. Later, polyethers began to be used. For example, an Adiprene type elastomer[4] utilized the polyether, polytetramethylene glycol, 2,4-tolylene diisocyanate and an aromatic diamine as the chain extender.

With this large increase in the types of commercially available polyurethane elastomers, it is no wonder that the surgeon, in his search for materials and devices to assist him in rebuilding the body, would be attracted to this generic

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family of materials. As a result, a large number of uses have been reported: for example, endotrachial tubes;[5] synthetic blood vessels;[6-12] heart valves;[8 13] burn dressings;[14,15] adhesive cements in bone repair;[16-19] tissue adhesives;[20-22] mammary prostheses[23] and other subcutaneous cosmetic applications;[24] and more recently for intraortic balloons;[25,26] artificial hearts[27] and assist devices;[28,29] artificial kidney membranes;[30] etc.

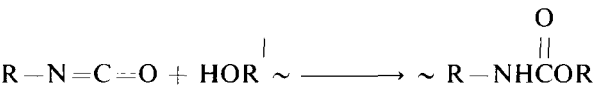
However, many of the early implants of polyurethane elastomers, especially the vascular implants, gave poor results and as a result, many surgeons who didn't understand why the failures occurred were left with the feeling that polyurethanes were not suitable as implant materials.

The reasons for these failures were based on ignorance of the chemical structure of the polymers and criteria for their proper selection, as well as on how they must be handled, cleaned, sterilized, etc. For example, a number of investigators[6-10] explored the use of polyurethane elastomer foams as blood vessel grafts. Their results were uniformly poor, with thrombosis, inflammatory tissue response, and general lack of acceptability by the body. In contrast, Marinescu *et al.*[11] found that the polyurethane they used (B.F. Goodrich polyurethane VC sponge) was fully accepted by the organism in studies lasting 7 to 10 years and that as gradual biological digestion of the polymer occurred, it was replaced by normal vessel tissue. Marinescu states that these failures result from technical errors in preparing the grafts and that polyurethanes have been discarded too soon. It has only been recently, with the increase in government funding on blood compatible biomedical materials that a better understanding of implant materials and their interaction with the physiological environment has occurred.[31] It is interesting to note that from these studies three new polyurethane elastomers have emerged with much potential for vascular repair and various cardiovascular devices.[27,28,32]

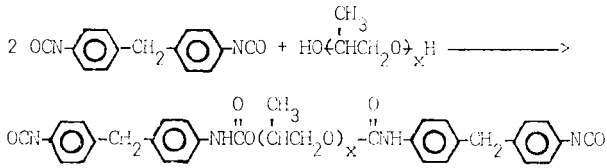
The purpose of this paper is to briefly review the chemistry of polyurethane elastomers, their interaction with the physiological system, and the criteria needed to optimize their use in several types of implant devices. Much of this is based on studies in our own biomedical polymers research laboratory.

CHEMISTRY OF POLYURETHANE ELASTOMERS

Polyurethanes are defined as those polymers which contain the urethane linkage $-NHC(=O)O-$. While this linkage can be obtained by a number of reactions, the one of importance for this discussion, is from the reaction of an isocyanate with a hydroxy compound:

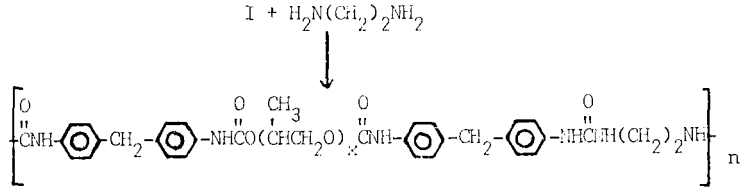


The chemistry of this reaction for polymer formation has been well described.[33,34] Polyurethane elastomers, however, are copolymers, both linear and crosslinked, in which the urethane linkage may actually constitute only a small part of the total number of linkages in the polymer chain. This is particularly true with the linear block copolyurethane elastomers in which distinct "hard" and "soft" segments are needed to develop the properties associated with these Spandex-type elastomers. These linear polymers are usually based on an aromatic diisocyanate, a hydroxy-terminated polyether or polyester segment, and a diamine as a chain extender, and are usually prepared by a two step or pre-polymer process. In the first step, the hydroxy-terminated macrosegment is reacted with the diisocyanate to form a diisocyanate capped prepolymer (I).



I

In the second step, the capped prepolymer is chain extended by reaction with a diamine.



In these block copolymers, there are a number of hetero-atom linkages: ethers, urethanes, and ureas. For example, in the above structure, if one assumes a molecular weight of about 1000 for the polyether; then the ratio of ether to urethane to urea linkages is 17:2:2.

The crosslinked elastomers may even have a greater variety of linkages, such as biuret, allaphonate, isocyanurate, etc., in addition to the ones mentioned above depending on the ratio of reactants and the catalyst used. Since the nature and amount of these linkages can greatly effect the polyurethane properties, it is little wonder that results varied so considerably from one investigator to another. Meaningful results can only come when these variables are controlled so that well defined structures are used consistently.

Of particular importance at this time, are the linear urethane elastomers since these can be readily fabricated into a variety of forms. The properties of these materials are determined by molecular factors such as intermolecular forces, chain flexibility, and chain conformation of both the hard and the soft segments and by the bulk structure of the elastomer. Block copolymers are known to form domain-matrix structures.[35] This arises mainly from the incompatibility of the two block polymer segments. In general, the hard segments form domains and are dispersed in the more amorphous soft segments. This two-phase system gives rise to the unique properties associated with block copolymers. As the block size gets smaller, and therefore the number of blocks per chain molecule increase, there is a change in domain size and purity. This is the case with the linear polyurethane elastomers. As a result, observation of the microphase separation by electron microscopy of the stained surface becomes increasingly difficult. However, recent work by Cooper *et al.*[36] did show two-phase morphology with a multiple block copolymer, with domains of the size of 30–50 A°. However, the elasticity properties of these linear materials leave no doubt to the existance of a domain structure.

A variety of properties can be obtained by varying the chemical structure of the intermediates used in the synthesis of the copolyurethanes. Structural parameters that can be varied are:

1) The structure and chemical type of the flexible macrosegment (polyether, polyester, etc.).

2) The size, i.e. molecular weight of the flexible macrosegment.

3) The structural arrangement of the isocyanate-capped prepolymer (may be a capped monosegment, a dimerized segment, etc.).

4) The structure of the diisocyanate used in the prepolymer reaction.

5) The structure and chemical type of the coupling segment.

This allows the polymer chemist to tailor the chemical, physical and mechanical properties of the resulting block copolyurethane for any particular end-use. For example, a copoly*ester*—urethane elastomer is usually stronger and has a higher modulus than a copoly*ether*-urethane of corresponding molecular weight. This results from the higher intermolecular forces exhibited by the polyester segment. One could then decrease these properties by, for example, increasing the molecular weight of the polyester segment. The increased chain flexibility with the longer soft segment would act to lower the strength and modulus of the elastomer. Conversely, one could lower the molecular weight of the polyether segment to increase the strength and modulus of the copolyether-urethane elastomer.

Another way to modify the shape of the stress–strain curves of copolyurethane elastomers is by using capped dimer segments instead of capped mono segments. For example, two 1000 molecular weight polyethers coupled together via a diisocyanate will give a stronger copolyurethane elastomer than

the corresponding copolyurethane elastomer based on a 2000 molecular weight polyether; yet both will have a similar initial modulus. The increased amount of hydrogen bonding from the urethane groups in the soft segment coupler would act to strengthen the material without unduly stiffening it.

One could also increase the stiffness (or modulus) of the elastomer by changing the structure of the diisocyanate used. For example, in going from 1,6-hexanediisocyanate, to 2,4-toluene diisocyanate to methylene bis(4-phenylisocyanate) to 1,5-naphthalene diisocyanate, one would observe an increase in the stiffness of the resulting elastomers. In this case, one is effecting not only the flexibility of the isocyanate molecule, but the conformation, and thereby the packing of the chain segments in the hard segment.

One can also modify the properties of the copolyurethane elastomers by varying the chemical type and structure of the chain extender. In general, slightly better properties are obtained with materials chain extended with diamines than with diols. However, one can vary the structure of the diol or diamine (aliphatic *vs.* aromatic *vs.* alicylic, and whether odd or even numbers of carbon atoms) and effect larger changes in hardness, glass transition temperature, strength, modulus, etc. of the final polyurethane elastomer.

These same structural parameters can also influence the chemical stability of elastomers. Of particular importance in implant studies are hydrolytic stability and lipid adsorption.

In general, anything that increases the water adsorption of the copolyurethane elastomer will increase the susceptability of labile condensation linkages to hydrolysis. In this regard, the more labile polyester segments can present problems. Thus for longer stability, the polyethers would be preferred. However, it should be kept in mind that these results can be shaded and modified by variations in the molecular structure of the various reactants.

Lipid adsorption can also be affected by the polymer structure though at present less is known on the relationship of polymer structure to the plasticizing effects of lipid adsorption on the mechanical properties of the urethane elastomer.

Oxidative degradation, although slight, can discolor urethane elastomers based on aromatic diamines. This is particularly true when the stoichemetry of the reaction is such that excess diisocyanates are used. By using aliphatic diisocyanates or alkylaryl diisocyanates such as xylylene diisocyanate, this can be avoided. A mixture of the meta/para (70%/30%) xylylene diisocyanates have been reported to give properties as good as 2,4-Tolylene diisocyanate, but with less tendency to yellow.

As a result, one can design into the multiple block copolyurethane elastomer about whatever physical and mechanical properties needed for a particular end-use. The question therefore becomes, what properties do we need for the implant. In approaching the problem of the use of a particular polymer for any

implant use, one must know the effect of that particular polymer upon the body from the cellular to the systemic level, and the effect of the body on the implant. While answers to these questions are not available at this time, considerable amounts of empirical information is available on a variety of materials in the body and in related physiological environments to at least make it possible to outline the characteristics that must be considered for each implant material.[31] These have been paraphrased as follows:

1) The polymer can be obtained as a pure material.

2) It will have the needed chemical, physical and mechanical properties to perform its function.

3) It can be fabricated into the desired form without being degraded or adversely changed.

4) It can be sterilized without changes in properties of form.

5) It will not have its properties adversely altered by the biological environment.

6) It will not induce thrombosis or abnormal intima formation, nor interfere with the normal function of blood.

7) It will not induce adverse inflammatory and foreign body response.

8) It will not be anti-leukotaxis.

9) It will not be carcinogenic.

These characteristics can be affected by the surface structure of the polymer, the total quantity of the polymer, the toxic or irritational qualities of the breakdown products or additives absorbed during fabrication, cleaning or sterilization of the polymer as well as by an improper implant design or improper procedure for implantation.

At the moment there are no completely suitable methods for determining the *in vivo* performance of materials, especially for materials in contact with blood. Some of this is because device design, implantation procedures, location of implant, animal species, etc., all influence the overall material performance. The rest often is a result of inadequate monitoring procedures to continuously determine what is happening. Therefore, one is forced to develop model situations (both *ex vivo* and *in vitro*), to isolate and study the events that might occur at the molecular level as the polymer is brought in contact with the living system and to couple these with carefully designed studies on device fabrication and implantation.

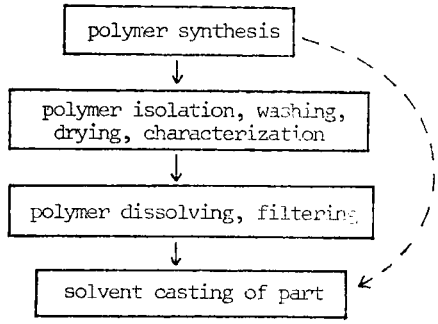
FABRICATION OF POLYURETHANE ELASTOMERS

The copolyurethane elastomers can be fabricated into a variety of shapes and forms by several different methods. Each of these methods has their own

problem which must be controlled if we are not to adversely affect the results of the implantation.

1 Solution casting

One of the best ways to form implant parts is by casting solutions of the polymer over appropriate molds, then evaporating off the solvent in a forced draft oven. Of course, this is only suitable for linear polymers. Typical solvents are dimethyl sulfoxide, N,N-dimethylformamide, tetrahydrofuran, etc. The overall steps in the process are as follows:

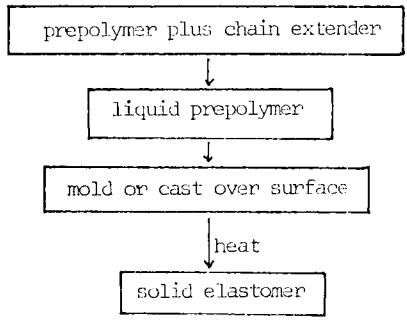


Since the polymer can be well characterized before the implant part is made, good control over polymer purity, reproducibility, etc., can be achieved. Of major concern in solution casting is removal of the solvent. This is of particular importance for solvents such as N,N dimethylformamide since residual solvent increases platelet aggregation and release reactions.[37] One must also avoid contamination from the molds, mold release agents (which should not be used) or from metal oxides which have some solubility in certain of these powerful urethane solvents.

As indicated by the dotted line in the above diagram, it is possible to use the polymerizing solution directly, thus avoiding the time-consuming isolation and redissolving steps. However, it is more difficult to maintain good quality control unless a sample of polymer is isolated and characterized prior to the solvent casting of the implant.

2 Casting

This method involves coating of molding parts with a liquid prepolymer, followed by a curing step to give the solid urethane elastomer. In general, these urethane materials are crosslinked, though some, like the Estane are essentially linear materials.



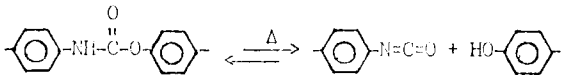
Problems with this method is that special equipment is needed for the two-part system where prepolymer and chain extender are mixed. If mixing is not uniform, a poor quality will be formed. In a one-part system, in which the manufacturer does the mixing of a "stabilized" system, this is avoided.

Since the prepolymer is usually viscous, degassing is needed to avoid entrapment of air.

In this method, however, excess diisocyanate is usually used to effect crosslinking (curing) of the final material. As a result, the final product is highly dependent on the mixing step, and on temperature control. These polymers usually have a variety of linkages—allophanat, biuret, urea, etc., beside the urethane linkage. As a result, the body sees a variable chemical structure. It is no wonder that implant results do vary if the fabricator is not highly skilled.

3 Thermoplastic molding

Some polyurethane elastomers can be fabricated into parts by traditional thermoplastic molding methods. Linear polymers such as the Estane type can be fabricated in this manner and can be highly crosslinked in the process. This is accomplished by varying the ratio of glycol to polyester mixes. However, a more interesting group are the polyurethanes containing thermolabile crosslinks. These materials often employ hydroquinone derivatives, since these all-aromatic urethane linkages dissociate thermally about 160°C, then reform on cooling to give back the crosslinked elastomer.



Again, reproducibility of reaction control, at the level needed for biological interaction can leave much to be desired. Adhesion of the thermoplastic formed material to the metal mold can present problems in part removal, and

yet the use of mold release agents to ease this problem can lead to a surface contamination problem.

4 Cellular methods

In many instances a foamed structure is needed rather than a solid surface. This is particularly true when fibrous tissue ingrowth is desired. Urethane foam densities can range from 0.05 to 0.65 (the solid materials range in density from 1.10 to 1.30).

The common way to form a foam is to generate CO_2 *in situ* by utilizing the reaction of the isocyanate with water.

$$R-N=C=O + H_2O \longrightarrow [RNH-\overset{\overset{O}{\|}}{C}-OH] \longrightarrow \underset{R-NH_2 + CO_2\uparrow}{}$$

The amine ends are more reactive than hydroxy ends, and thus one can adjust the ratio of reactants so as to achieve the final polymer (usually crosslinked) in a relative short time period. Other agents such as chemical blowing agents that release N_2, or low boiling liquids, such as trichlorofluoromethane have been used to form foams. The amounts used usually range from 7 to 30%, though amounts as high as 60% have been used. Fluorocarbon are also often used as auxillary blowing agents when CO_2 is generated. They tend to help the foam to be less brittle and softer. Since many of these then utilize the isocyanate-hydroxy reaction to form the final crosslinked copolyurethane elastomer, catalysts must be used to accelerate this reaction. Many common catalysts include tin, cobalt, or titanate organic compounds, tertiary amines, etc. All of these have potential toxicity in the body if not removed from the implant material.

Surfactants are often used in many commercial foams to control pore size. Silicones and silicone-polyether copolymers are often used. Again, while concentrations are low (approx. 0.5%), they could affect the surface properties of the implant.

POLYURETHANE IMPLANTS

A variety of polyurethane implants are under investigation in our laboratory. These involve vascular grafts, sutures, surgical adhesives, nerve cuffs, ureters, urethras, fistula catheters, artificial heart devices, membranes for artificial lungs and kidneys, and artificial skin or burn dressings. Several of these are discussed in some detail below.

1 Peripheral nerve repair

The advances in peripheral nerve repair have lagged behind the advances made in other fields of surgery.[38-40] Even though significant advances in basic research on mechanisms of nerve regeneration and nerve anatomy physiology have been made during the last 10 years, these discoveries have given the surgeon only a few new or better techniques of nerve repair.[38,41,42]

Currently, good nerve repair appears to involve these factors: (1) close approximation of the two severed ends;[43] (2) correct rotational alignment of the ends;[43] (3) as little trauma and handling of the nerve as possible;[38,44] and (4) shielding the injured ends from extraneural tissue ingrowth within the field of axonal regeneration.[45,46] Newer developments in nerve repair show that removal of tension in the immediate area of the severed ends and the avoidance of sutures in the faster regenerating, peripheral areas of the nerve cross section give better clinical and laboratory results.[43]

Many surgical repair techniques and devices have been explored over the years to accomplish some of the above requirements, but the superiority of any one technique has not been demonstrated. Although some of these clinically used devices include sheaths of various materials,[45] such as tantalium, cellulosic Millipore filters, and silicone rubber material and physiological considerations indicate that these materials are relatively thick and stiff in design and are less than desirable.[44,49] These considerations include lack of true biocompatibility, mismatching of the modulus of elasticity with the development of circumfrential scarring and the diminution of function and reduced blood supply.[47,48] Also, these materials were not usable in areas of increased motion such as across joints.

A new copolyether-urethane nerve sheath device (see Figure 1) has been developed by our group which is much superior to the currently available devices in many ways. It is transparent, and thus visualization of the marking vessels and nerve bundles enables correct rotational and longitudinal apposition of the nerve. The mechanical toughness and elasticity of the polymer enable us to make a thin sheath which will collapse around the nerve by surface tension of the physiological solutions. This decreases the dead space, plasma accumulation, surgical debris and space available for fibrous tissue ingrowth. Also, a more loosely fitting device can be put on with essentially the same sheathing function. The polymer sheath is very elastic ("springy"), both longitudinally and circumferentially, so that when the nerve swells during the acute healing stages (sometimes 2–3 times the normal diameter), constriction and collapse of the nerve does not appear to occur, unlike the silicone and metallic devices reported in the literature.[45] This polymer is also very tear resistant (unlike the silicone rubbers of the same thickness) and 4–0, 5–0 and 6–0 sutures, even on cutting needles, have been used without tearing the material.

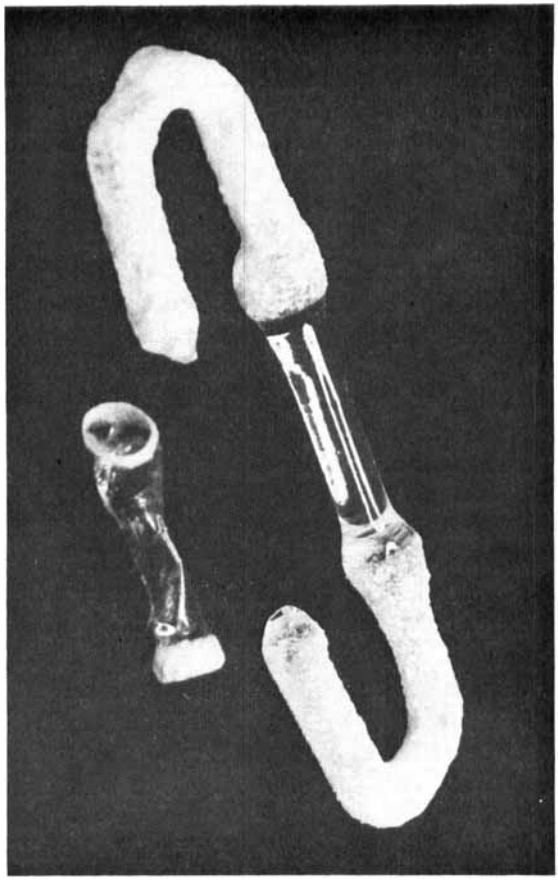


FIGURE 1 A polyurethane artificial epineurium, or nerve sheath, and the implant still on its glass mold.

We have used our device and repair technique for experimentally severed common peroneal nerves in rats, rabbits, dogs and cats. Small 6–0 monofilament sutures, used to secure the sheath to the proximal and distal ends of the nerve, were placed in the epineurium and not into the nerve proper. The result is a repair which can be easily seen and checked for proper alignment and tension. The tension is checked by gently pulling the two ends apart; the elasticity and strength of the repair will allow approximately a 3–4 mm separation which promptly recovers when the stress is removed and the lacerated ends of the nerve, as seen through the tube become practically invisible. Thus, transient stresses and motion of the nerve repair will not result in permanent separation of the nerve which causes longer healing time and poorer final results seen with rigid suturing techniques.

All these factors appear to enable us to use this device not only as a sheathing material to contain the nerve and separate it from the surrounding fibroblastic tissue, but as the primary joining material in peripheral nerve repair. Preliminary short term results would indicate that many of the problems currently encountered in peripheral nerve repair might be eliminated by this technique.

2 Replacement for segments of urethra and ureters

Surgical treatment of urethral strictures has, for the most part, been aimed at constructing a tube of host mucosa or skin to partially or completely replace the stricture. Restricture formation is frequently a problem. Silicone rubber patch grafts have been successfully used in humans[50,51] and a 9 cm length of urethra was completely replaced with a silicone rubber tube in one man.[52] However, there have been too few trials with humans to fully determine the potential or problems associated with this polymer. In the dog, 2–4 cm of membranous and pendulous urethra have been replaced by a silicone rubber prosthesis[53–55] and also with Teflon and collagen tubes[54] with variable success. To date, silicone rubber has been the most successful polymer with urethroperineal fistula and pseudopapilloma formation at the suture line being the main complications.

Ureter repair in humans has traditionally been with bladder flaps, ileal conduits, ureterostomies and transureteroureterostomies. Problems with these have primarily been insufficient length of material to surgically rebuild in an ideal manner. Also, infection is apparent in cases where access is made through the skin. Experimental work in animals has been with abdominal wall fascia,[56] fallopian tubes,[57] polyvinyl,[58] vitalium,[59,60] freeze dried arteries and veins,[61,62] tantalum,[63] polyethylene,[64–66], Teflon[67,68] and silicone rubber[69,70] tubing. Polyethylene and silicone rubber have been successfully implanted into the dog ureter for long periods of time, although encrustations do occur. Ureteral valves have been devised from Teflon and silicone rubber[71–73] and stainless steel,[74] but have not met with success due to encrustation and failure of the valves with resultant hydronephrosis.

A new block copolyether-urethane-urea device has been made in our laboratory to replace the ureter and urethra (see Figure 2). Three coordinated investigations are underway to evaluate the potential of selected polyurethane materials in repair of the genitourinary system.

The first stage of the G-U study to test the ability of the polyurethane to withstand encrustation involved implanting small pieces of the polyurethane inside rat bladders. The urine of the laboratory rat on a herbivorous diet is a severe test for encrustation. Results to four months' duration have shown little or no encrustation on the polyurethane while the silicone rubber became encrusted.

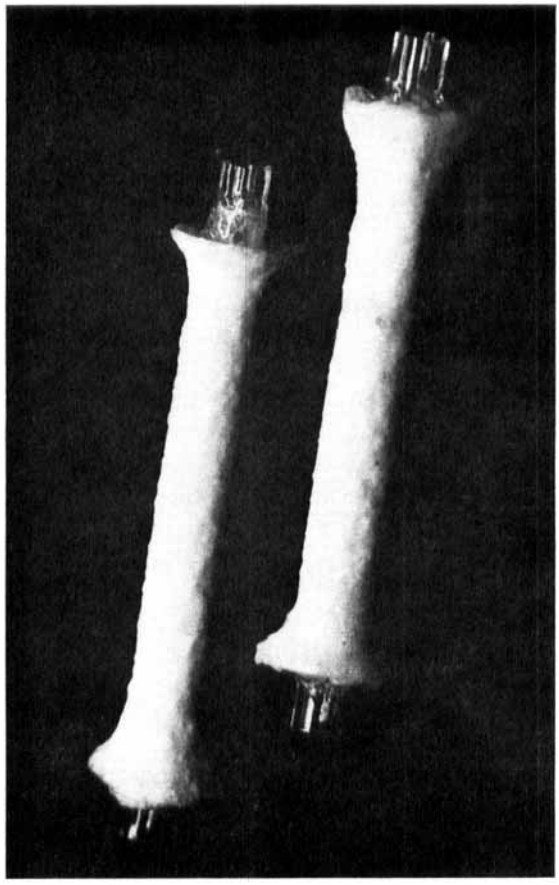


FIGURE 2 Polyurethane ureters.

The second stage of the study (in progress) involves replacing 2 cm of ureter or urethra of dogs with the polyurethane device. The ends of the polyurethane tube act as internal splints by being inserted 3 mm into the ureter or urethra, and also serves to keep the suture line away from the urinary stream. Early results show mild hydronephrosis, but good function on intravenous pyelogram at one month.

3 Vascular grafts

The earliest materials investigated as arterial prostheses were solid walled tubes of glass and metal.[75,76] However, because of general lack of success it wasn't until 1952, with the introduction of the concept of the porous

prosthesis by Vorhees *et al.*,[77] that interest was renewed in vascular implants. Since that time many materials, including synthetic polymers, have been evaluated in both laboratory and clinical settings. Most of these have been rejected because of aneurysmal degeneration and rupture, thrombosis, and distal embolization. Currently only the Dacron woven and knitted grafts enjoy popular clinical use. However, their use is limited to vessels greater than 6–8 mm in diameter[78,79] and even these larger arterial prostheses are subject to thrombosis at any time.[79]

The mechanism of failure and clot formation has been well documented by Weslowski[80] and efforts have been made to alter the physical characteristics of the grafts by increasing the biological porosity in an attempt to retard the thrombosis potential. Some success recently has been experienced by Hasegawa and co-workers using expanded Teflon as a small artery prosthesis.[81] Here also, success appears to depend on minimizing the thrombogenic nature of Teflon[79] by utilizing a porous structure.

The problem is even more acute in venous replacements where almost universal thrombosis has occurred in the infrarenal inferior vena cava;[82–85] and only limited success elsewhere. There have been some promising reports recently with copolymer grafts of methylmethacrylate on woven Teflon[86] and also with grafts made of the expanded Teflon (Gore-Tex),[87] though other investigators have achieved only 50–60% patency rates using the same material.

Because a truly non-thrombogenic polymer was not readily available, investigators explored various techniques to render traditional materials non-thrombogenic, such as surface bonding of heparin,[89] creation of an electro-negative potential along the inner surface of the prosthesis,[90] and a hydrophilic protein gel to protect the blood prosthetic interface.[91]

Our investigation, however, continued in an attempt to find a material which, by virtue of its chemical and physical properties, is truly non-thrombogenic. Gott reported in 1971 on his evaluation of various materials,[92] that our polyether-urethane-urea was free of thrombus at two weeks, while most of the commonly used substances clotted by two hours. In further studies on this material, both *in vitro* and *in vivo*, we have found that it does indeed have specific non-thrombogenic properties; the selective adsorption of albumin in preference to fibrinogen, γ-globulin, or other serum proteins, appears to account for its low platelet adhesion and subsequent lack of thrombus formation.[93]

Preliminary studies of both venous (10–12 mm ID) and small artery (2–4 mm ID) implantation using solid wall grafts (see Figure 3), showed no adherence of any thrombus to the graft surface, though thrombus did form at the suture line in many instances, thus eventually compromising function. We are studying this juncture problem further by implanting a series of 6 mm ID

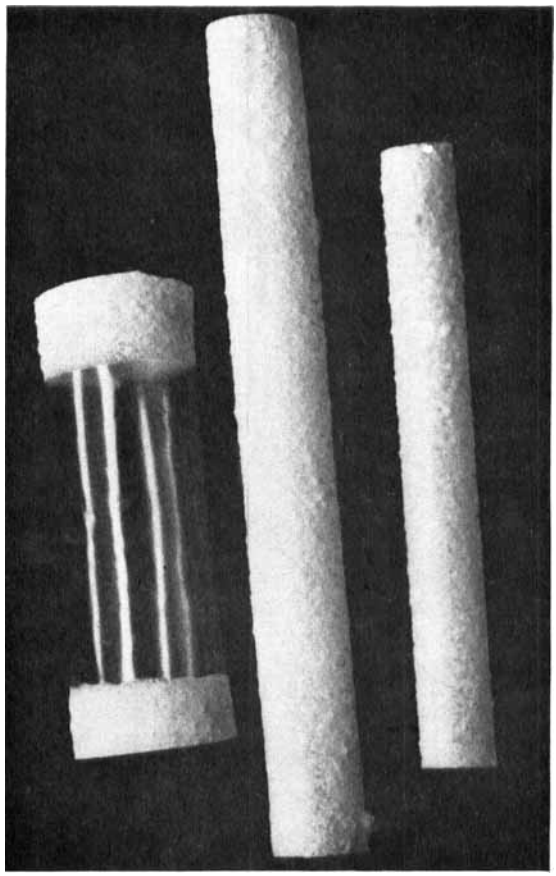


FIGURE 3 Several experimental solid-wall polyurethane vascular grafts.

solid wall polyether-urethane-urea grafts into the femoral veins in dogs with timed removal. A visualization of the chronological sequence of events, both at the suture line and on the graft surface, will help us to better evaluate the effects of blood flow and the role the cut vessel and blood elements play in initiating thrombosis at the suture line. This information is important in designing our new solid wall and foamed polyurethane vascular grafts.

4 The artificial heart

The pioneering work of John Gibbon, Jr., over 30 years ago on pump oxygenator devices[94] led to the concept of an implantable artificial heart which could be implanted within the chest as a substitute for an irreparably damaged

heart. For some time, the Division of Artificial Organs at the University of Utah, under the direction of Dr. W. J. Kolff, has been developing artificial heart devices. Much of this work has been concerned with diaphram type of devices[95,96] as well as the defining of optimum surgical procedures and post-operative care techniques. In 1971, we prepared and implanted a smooth

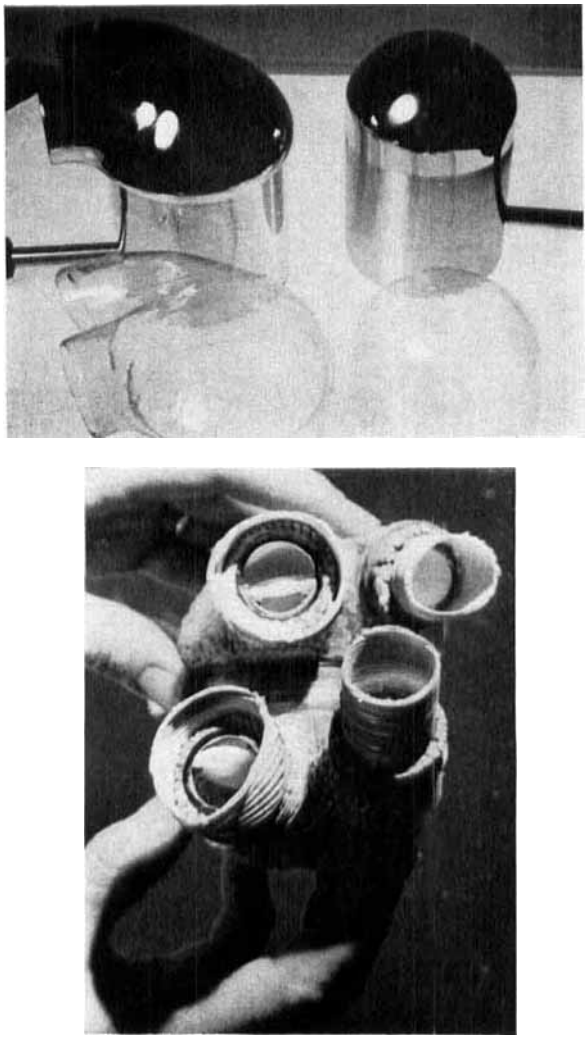


FIGURE 4 A polyurethane hemispherical artificial heart. (a) The molds and a polyurethane diaphragm and shell for one ventrical; (b) view of both ventricles after termination of implantation. Reproduced with permission of the Transactions of the American Society for Artificial Internal Organs (Ref. 27).

copolyurethane hemispherical artificial heart.[27] Although we did not get long survival with this implantation, the artificial heart on removal was as clean and shiny as when we put it in. There was no evidence of clots, fibrin deposition or platelet deposits anywhere on the copolyurethane surface. When concurrent experiments with fibril-coated silicone rubber surfaces began to give longer survival times, we shifted our studies on the copolyurethanes back to more basic studies to gain an understanding of why the polyurethanes appeared to be non-thrombogenic.

Although fibril-coated silicone rubber surfaces have allowed longer survival times (to 30 days in calfs) the material problem still appears to be a limiting factor because of clot formation and the stripping off of fibrils to form emboli. With the newer artificial heart designs[96] and improved post-operative care, it is possible that a smooth copolyurethane device might solve these clotting problems. It is hoped that sometime during this year such a device can be implanted.

Note added in proof: A smooth copolyetherurethane (Biomer) artificial heart has just kept a calf alive for 94 days at the Division of Artificial Organs, University of Utah. No changes in blood chemistry was noted. Death of the animal resulted from an infection along the pneumatic drive lines entering the chest cavity.

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