PLASTICS IN AMERICAN PROSTHETICS

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Introduction

Prior to World War II, the use of plastic materials in our American industry was so small that it was hardly noticeable. Perhaps the most universal application was in the making of cellulose nitrate and cellulose acetate body jackets. Since cellulose nitrate (celluloid) is always a source of danger to the patient by the nature of its inflammability, it was succeeded by the less flammable but not so flexible, cellulose acetate. All of you probably are aware of this technique which is pursued as much today as then. The low cost of equipment and supplies and the simplicity of building the appliance by coating successive layers of cotton stockinette with a solution of cellulose acetate in acetone probably is the reason for its continued use. The plastic material in this technique has one basic short-coming which no doubt prevented its greater application into other braces. This and other deficiencies of some plastics should be understood to fully appreciate the new developments which began during the war and has now blossomed throughout the prosthetic world.

Two Types of Plastics

When thinking of plastics and to comprehend them, we must first know and understand why and how all plastic materials fall into one of two groups. These two groups have chemical and physical characteristics which identify them. While some physical properties are common to both, the determining factor lies in the molecular structure of the material. In one group, we find materials that cover a wide range of strength, yet they all are more or less subject to the phenomenon "cold flow" and to distortion under relatively low loads at moderately elevated temperatures. This is the thermoplastic group. They are the "re-useable" materials that can be broken down into solution or softened by heating and reformed *repeatedly* without altering the material chemically. Their molecular structure is *not fixed* or fully stabilized by cross linkage. Examples of these are cellulose acetate and cellulose nitrate used world wide for photographic film, the acrylics, sparkling transparent products trade-marked "Plexiglas" and "Lucite" as well as the blends of acrylic and nylon in "Nyloplex" or "Plexidur" and the vinyls and polyvinyls used in dolls and cosmetic restorations. These and many more plastics that can be readily dissolved by the organic solvents and/or softened or melted at elevated temperatures for casting or reforming are in the same family. Typically, they exhibit one or more of the following properties: low strength, dimensional instability, "cold flow" and are subject to attack by organic solvents such as acetone. These offer advantages to low cost forming operations, low pressure molding and to many fabrication techniques.

In contradistinction, the second group, the "thermosetting plastics", prior to World War II, had many drawbacks to *low cost, small run* production. They required, for manufacturing, expensive high pressure dies and machinery suited only for mass production. Perhaps the most popular thermosetting plastic was a phenolic trade-named "Bakelite". It typifies the physical properties of the thermosetting group, namely good dimensional stability and resistance to distortion at elevated temperatures. It cannot be broken down by heat or solvents for re-use. Once the end product is obtained, the chemical structure cannot be altered just as with an egg when once fried, it cannot be reverted to its former state. Herein lies the ideal feature for prosthetics. We need components that will hold their shape under weight bearing in warm ambient temperatures and provide a pleasing durable exterior as well as interior finish. Since thermosetting resins are stable chemically and practically inert in their polymerized (cured) state, they are in fact no causitive factor for a dermatitis. In spite of these known facts, the use of thermosetting plastics was handicapped by the expensive manufacturing costs involved.

Introduction of Polyester Resins

The turning point came in 1942 when the Bakelite Corporation developed the first thermosetting low contact pressure resin, the unsaturated polyester. Early in 1943, Northrup Air Craft Corporation, who had only recently begun to tackle the prosthetic problem, began experimenting with plastics for a new arm socket material. It seemed logical to them that the type of material best suited for this was one that could be cured in its permanent shape or form on a model of the stump. This was the ideal, if expensive dies or equipment were not required. It is history that their experience with this new resin proved successful. Truly, the unsaturated polyester resin was the answer to the plastic problem in prosthetics. With the stump model as the inner mold and with a sleeve of clear stretchy plastic film pulled over the fabric, serving as the outer mold to impart a low contact pressure and as well as a beautiful finished surface the objectionable high cost features of thermosetting resins was a thing of the past. When the resin is cured, the inner plaster model is broken out and the outer film removed, leaving a beautiful, durable "shape retaining" socket.

For quite a few years cotton stockinette, usually in combination with fibreglas mat or cloth for reinforcement, was the major laminating material. Four layers of cotton stockinette with fibreglas reinforcement or four nylon without the glass is adequate for the average arm socket. Light or heavy duty requirements may dictate changes in this. Leg shanks of six nylon layers are of sufficient strength for the average adult.

One of the U. S. Army Amputation Centers during the War provided hundreds of Veteran amputees with below knee prostheses containing sockets of polyester resin, with gauze and felt as the filler material. Many of these were worn for ten years or more. Impervious to perspiration, these sockets remained clean and intact while the remainder of the prosthesis wore out.

Use of a Promotor

In this early stage of development, the resin was cured by the addition of small amounts of a peroxide catalyst and the application of heat, 115° C. (240° F.) for one to two hours. Because the heating phase would produce steam from a wet plaster model, the models had to be thoroughly dried before hand. This was not a severe problem, but did require heating the plaster form in an oven for about twenty-four hours.

The inconvenience associated with oven drying or dehydrating a plaster model was obviated when the use of a promoter was introduced. Now, the gel-time and curing time may be controlled at will by the judicious addition of a promoter. This chemical suppliments the internal heat creating action of the catalyst by intensifying the heat, thus producing a cure without external heat.

Flaxible Resin

The first polyester resins available were of the rigid type. But soon flexible varieties were introduced which can be mixed in various proportions with the rigid to produce a wide range of flexibility in the finished socket. Blends of around forty to sixty percent flexible with the rigid were the common practice in use with cotton stockinette and fibreglas.

The rigid resin lacks the ability to absorb shocks to any great degree, but it has good strength. The flexible resin is much more pliable than the rigid, but lacks the strength. Tests show that within the range mentioned (40-60 to 60-40) a cured plastic with a cotton fabric would be produced which had ample strength, coupled with a reasonable resistance to shock. It has been observed that nylon produces a more flexible laminate than does cotton and hence can be used with a higher percentage of rigid.

Color Pigments

The combination of cotton or nylon stockinette and resin produced an amber color which, though not matching any human skin shade, was not unpleasant. As you may know, now various color pigments have been developed which when added in amount of 1 to 4%, depending on the shade, produce an excellent cosmetic effect. Arm component manufacturers and the universities that were teaching upper extremity prosthetics agreed to accept the standards developed by the U. S. Army Prosthetic Research Laboratory for color pigments. This has resulted in a rather uniform usage throughout America, which permits the use of stock arm set-ups (forearms and elbows for above elbow arms) from one source with the socket made at another. This practice is so common today that probably less than 10% of the plastic forearms used are made by the prosthetist.

Plastics in Leg Prostheses

The first large scale use of plastics in legs was at the U. S. Army Bushnell General Hospital where hundreds of below knee sockets of cotton reinforced polyester resin were fitted. These sockets were inserted in fibre shanks in such a way that they were removable. Since many of the army amputees were measured and even fitted five to six weeks after definitive surgery, a large number of seconds sockets were required for reason of early stump shrinkage. A new socket was routinely made in two days, an unheard of schedule for a large volume, prior to the use of plastics. Today, it is not uncommon to see flesh colored or white plastic sockets in wood, fibre, or metal legs. They can be sanded or relieved and quickly recoated to a beautiful finish and it is reasonable to expect them to out-wear the remainder of the prosthesis.

Plastic BK

Many prosthetic facilities now provide all plastic below knee shanks and sockets for their best prosthesis. Combine this type with the new American SACH (Solid Ankle Cushion Heel) Foot and you have a light weight, trouble-free prosthesis. Here are the usual steps followed: First the socket is fabricated and fitted. Since it is rather difficult to alter the alignment or height (length) in a finished *plastic* limb more precaution is taken initially to avoid the necessity of a major alteration later. The use of a walking alignment device is highly desirable before the shank model is formed. When the stump is tapered, the finished shank, in order to have reasonable cosmesis should be built up as a double wall arm socket using a build up model of bees wax. This second step is the only difficult and time consuming part, for once the model is made with a jig of some sort incorporated to hold the knee joints true, the plastic part is routine, and comparable to that in arm work. Of course, the knee joints and ankle block would be laminated into the shank free of rivets or bulges.

Plastic Laminate Substitute for Rawhide

About five years ago, we began to substitute for rawhide on wood prosthesis, a laminate finish consisting of one layer of nylon stockinette over a layer of fibreglas cloth. The primary objective was to develop a protective finish which would cut down the delay experienced with rawhide in soaking, drying and lacquering. Also, the outer surface coating on the rawhide has never been ideal in resisting abrasion and once the coating was worn, there was no waterproof protection to the wood. Typical of this condition was the ankle section near the joint line and the medial proximal border of thigh sockets. So as a secondary advantage, we felt that the plastic finish would correct these problems.

Once the laminating technique has been mastered for arm sockets or for any component there is little problem in adapting it to covering wood. The usual preparatory shaping and sanding operations for rawhide apply to the new method. Then all holes and slots must be filled or covered with an impervious material such as Celastic, a reinforcing material used in shoe construction. Since all pin holes or cracks which might permit air or the resin to pass through the wood must be sealed, it is our practice to coat the inner surface of the shank or socket with a seal—others apply the sealing coat to the outer surface. Both shank and thigh pieces are mounted inverted on padded mandrels-holding sticks in a vise and kept vertical until the resin has gelled. This is to prevent the resin that runs beyond the wood components from getting inside the socket or shank. Usually the resin mixture, made up of 80% rigid and 20% flexible, is promoted to set in 10 to 15 minutes. Trimming can be accomplished after the parts have been heated for 10-15 minutes at 93°C. The heating speeds up final cure and softens the resin sufficiently to permit easy cutting around holes and socket margins. If a means of heating the parts is not available, the trimming can be done cold, but with more difficulty. To facilitate cutting a neat opening around the joint hole in the knee block, we insert hardened, steel bushings into the knee joints prior to the "lay-up" of the fabric. Then after the resin hardens, the contour of this steel bushing can be seen so that a hole cutter with a small pilot drill can be used to make a neat cut out for the joint strap on the shank.

During the past year, the Veterans Administration made numerous comparative tests of the nylon-polyester finish against the usual rawhide and found that it had many advantages. Now the University courses on A. K. Prostheses include this method in their instructions. It is safe to assume that in a few more years, the use of rawhide will drop significantly if not into complete disuse.

Soft Sockets

We have mentioned that a plastic laminate can serve as a potentially durable and easily formed below knee socket. There is also a modification of this that involves another special plastic which holds good promise. This is a combination unit of a soft rubber-like liner of plastisol over which a rigid supporting shell is built of nylon and plastic resin similar to a plastic socket. For years a soft socket material has been sought for this purpose. The ideal degree of resilience and permanence without packing down after prolonged wear has not been found in a material easily formed, that is non-toxic and resistant to perspiration. However, we have found a new plastisol formulation that comes close to the ideal. It is a rather viscose liquid which will convert to a rubber-like material when heated to 177°C. for a few minutes.

Using a dehydrated plaster stone model of the stump that has been preheated to 149°C., a liner of any thickness can be built up by repeating the process of coating the model by dripping or application with a spatula and curing it in an oven for 15 minutes then recoating while hot. Once the desired thickness, 5-10 millimeters is reached, there remains only the removal of the liner for trimming before encasing it in a plastic laminate over the same stump model. We find that the soft liner needs to extend only three and one half inches down into the socket to cover the weight bearing area of the stump. We have patients who received a plastisol socket three years ago and are still satisfied wearers of this type of soft socket.

Epoxy Resin

Not to mention, in passing, the existence and use of another similar but unrelated plastic resin would leave this paper incomplete. This reference is to the postwar family of epoxy resins which were developed through the Mellon Institute in Pittsburgh, Penn. in their efforts to develop a new plastic for orthopedic appliances. The first name used was the designation C-8 but now that several companies are manufacturing expoxies, we find various trade names like Epon. The epoxy resin is a phenolic like Bakelite but there the similarity ends. In many characteristics it resembles and can be used in laminations as the rigid polyesters. It is a room temperature cure resin usually sold commercially in two liquid parts. Cure time cannot be controlled as readily as with the polyesters, but it can be speeded up by the application of moderate heat. Until very recently flexible epoxy resins were not available. Also the curing agents were highly toxic and many cases of dermatitis developed on those handling the raw resin. Last but not the least of the deterant factors in its wide spread use has been its relative high cost which is more than double that of the polyesters.

The chief asset of the epoxy is its excellent adhesive ability which makes it especially valuable in making strong fibreglas laminates and repairs to prostheses of all materials.

Three Recent Innovations

1. Several improvements in the use of polyester resins are just being anounced. One is an additive to prevent discoloration of the laminate resulting from exposure to sunlight (ultra violet). Arm prosthesis wearers who often work in the open notice a distinct yellowing of the plastic in only a few months exposure. Now by adding 2 to 4% Ultra Violet absorber to the resin this can be prevented.

2. It is our practice to coat all wood inner socket walls with the rigid "air cure" resin used in our plastic sockets. Within a very short time a heavy coat is tack free and ready for wear. To obtain a similar thickness with a lacquer would take several hours. We add a silica power (it can be used with any resin mixture) which increases the viscosity appreciably while not affecting its wetting ability. This permits application of thick coatings that will not run. When "filling-in" a socket is necessitated by stump shrinkage, a ¼ to ½ inch thick buildup can be made by adding a 5-6 percent silica to a resin mixture containing cork, wood dust or suitable filler like Bentone. This thixotropic mixture can be contoured to the socket interior and the material will not run to the lowest level. When the resin is cured, it can be sanded smooth and coated to blend into the socket without an offset.

3. Current research work is being directed toward the development of an easily fabricated porous socket with equivalent strength and durability of the present laminae. Such a socket has been made with microscopic

porosity sufficient to carry off moisture equal to the rate that it is produced by the skin. The end result will be a cooler appliance with diminished perspiration around the stump.

Summary

It is no longer problematic whether or not leather, wood and other materials used as the basic structure of prostheses will be supplanted by plastics. Real advances have been made on all fronts and they are continuing at a rapid pace. Tangible advantages in the methods of construction as well as in comfort to the patient are self evident to even the casual observer.

Without a doubt the trend to plastics began with the development of low contact pressure polyester resins in 1942 and advanced with the war effort. The subsequent research program in prosthetics assured the full exploitation of its potential and the dissemination of its uses through publications and the postwar university prosthetic courses.

Just about overnight, all upper extremity prostheses were converted to plastic by the appeal of the new found qualities of the new resins. All new components, wrist units and elbow mechanisms, have been designed exclusively for bonding to plastics almost to the exclusion of leather, wood, metal and fibre.

The now conventional technique of laminating nylon and other fabrics with a contact pressure resin enables the prosthetist to fabricate a wide range of end products. He can readily control size, shape, color, weight, strength and shock resistance and incorporate into his laminated prosthesis a whole new armamentarium of components. The amputee patient benefits by these new materials with a more durable appliance that can be made from (*prefitted*) *test* sockets. Interior and exterior finishes are excellent from the points of view of skin contact and cosmesis.

Though research has developed many techniques and procedures as a guide, the ultimate success of the "masterpiece" depends upon the knowledge and skill of the prosthetist in his handling of materials and in fitting the patient. Plastics, we believe, now provide the versatility and mechanical properties necessary to better accomplish the goal of biomechanical rehabilitation.