MATERIALS AND EXTERNAL PROSTHESES

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INTRODUCTION

Millions of physically disabled people in the United States use some form of appliance designed to support the body or parts of it or to restore function. Some appliances are designed to restrict motions to prevent pain or body positions which might aggravate a pathological condition. In other cases, mobility and capability must be provided.

Intensive research has been performed on the basic physiological and biomechanical problems of the disabled. Included were studies of the kinematics and kinetics of normal motion and function. Parallel research on the effects of dysfunction and disability followed the same pattern. A large collection of data is now available specifying some of the biomechanical capabilities and limitations of the handicapped alongside a body of similar data on normal function toward which the designer might aspire in his attempt to link disabled man and machine, the artificial limb or prosthesis, or the orthopedic brace or orthosis. Nevertheless, more fundamental data are needed; fortunately, several laboratories in the United States and abroad are deeply involved in such programs.

One of the largest problems in the United States at the present time is the increasingly large number of amputations necessarily performed for conditions associated with aging. Such amputations are performed on persons who usually have other physiological or psychological problems, some not associated with the condition which caused the amputation. Indeed, our Research Program has found its greatest challenge in providing a rehabilitation potential for these people.

The popular literature has treated many of the powered systems used as functional replacements or supplements controlled by electrical outputs of muscles. Formidable engineering and educational problems still exist before wide-scale application of these designs and then only on a relatively small sample of the disabled. The more serious clinical problems which

*This paper was presented at the New York Section of the Society of Plastics Engineers, Inc., Conference on "Plastics in the Medical Sciences." The Conference was held September 21–22, 1967, at the Americana Hotel in New York City.
persist relate to the largest part of our disabled population, the geriatric group. Sophisticated functions are not needed here. Required are simple, lightweight, durable, and comfortable appliances providing limited function.

Our Government-financed Research Program, which started in 1947, is primarily constituted of orthopedic surgeons, mechanical and electronic engineers, physicists, physiatrists, physiologists, therapists, and the specialists in limb and brace design, construction, and fitting—the prosthettist and orthotist. We have also enjoyed the full time support of one or two materials experts, but more often we have recruited help from the materials industries on an ad hoc basis. These infrequent contacts have nevertheless been extremely gratifying and reasonably productive. We continue to look for additional assistance from these specialists.

A limitation to stimulating industrial interest is the relatively low volume potential of our products. But our pleas for interest from the commercial group and our solicitations for technical counsel and guidance (and even a few free test samples) have been fruitful, perhaps because of the need to diversify product applications or more so, a dedication to our humane objectives. Since our Research Program is not the most richly funded, we are not too proud to accept what help we can get wherever we can get it.

THE PROBLEMS

Although most artificial limb and orthopedic brace components are mass-produced in several small factories in the United States and Europe, the assembly of these and the construction of the major elements of an appliance are still custom procedures, performed in small "fitting" facilities. Such hardware as artificial elbow joints, knees, feet, and ankles, and leg brace bars and joints, torso and cervical appliances, and even some supports and shoes for orthopedic foot conditions can be reasonably well standardized in design and size for production purposes. The production volume of most individual items is relatively small; each of the manufacturers designs production processes for relatively small-volume efforts. In some instances, permanent tooling is used but a reasonable amortization of tooling investment produces a higher price than for items of similar complexity in the market.

Providing essential functions which must be incorporated in the limb or brace often requires the development of rather complex devices. For example, modern artificial knees use fluid piston-cylinder systems in which a resistance to the angular motion associated with the knee flexing and extending can be "programmed" to produce a pattern simulating normal motion. Moreover, such fluid devices provide a desirable velocity-sensitive resistance pattern, producing a property called "cadence-responsiveness" or a helpful higher resistance to knee angular motion at higher walking speeds. Several
such devices are now being mass-produced but are assembled into wood parts to be used in limb shop use, since most fitting facilities are accustomed to using wood. Mechanical problems have resulted since the precise orientation of axes of the sophisticated fluid device cannot be maintained in wood.

Artificial feet have been standardized in a number of sizes. These have been preshaped to fit standard shoes, so little or no custom fitting is needed. Through the proper selection of synthetic materials and their resistances to deflection, a simulation of normal foot-ankle motion is provided. Selection of materials in this case is based on the proper load versus deflection properties for the sizes and cross sections needed to shape the component. Since most prosthetic and orthotic components will be used by patients who require a lasting, dependable function, either for ambulation or for grasping, ordinary structural design criteria apply. For the lower extremity, the components must transfer vertically directed loads in excess of body weight as well as absorb reasonably high bending moments. Components for prosthetic and orthotic appliances should also have low weight so that their use is not too energy-consuming for the handicapped person. In most cases, these devices must simulate normal parts of the body in shape and contour or when incorporated externally to an existing body part as in a brace or when incorporated externally to an existing body part. Thus, the prefabricated manufactured components require high strength to density ratios, special hygienic qualities, high resistance to wear and fatigue, and especially in some orthopedic braces, high resistance to deflection under load.

A most critical part of the problem in design of prostheses and braces is the part of the appliance which will be in contact with the disabled person—the limb or brace socket. This is the critical interface between the body and the appliance. Through proper design and contouring, this interface must transfer supporting loads to the best load-tolerant body areas, for controlling forces between body and appliance, providing a "biomechanical fit," a relationship between mating body and appliance surfaces which can produce physiological problems, to transfer supporting loads to the best load-tolerant body areas, for controlling forces between body and appliance. Sockets are designed and constructed using a "biomechanical fit," a relationship between mating body and appliance surfaces which can produce physiological problems, to transfer supporting loads to the best load-tolerant body areas, for controlling forces between body and appliance. Sockets are designed and constructed using a "biomechanical fit," a relationship between mating body and appliance surfaces which can produce physiological problems, to transfer supporting loads to the best load-tolerant body areas, for controlling forces between body and appliance.
tee, for example, can, through a properly designed distribution of pressure in the stump socket, have position consciousness of the limb in space and a “feel” for the extent of weight bearing during ambulation, providing better control of man over device.

Thus, this socket or interface represents the most important part of the appliance. It must be designed for control and functional requirements. It therefore must be formed to the special shape of the stump or body so that pressures may be distributed reasonably uniformly to allow the amputee or disabled person to be comfortable during use. Special provision must still be made for higher loads on load-tolerant surfaces. The socket therefore must be custom made for the stump or body part involved, controlling the shape over special anatomical features. Contouring must provide closer fits where such are required for control and looser fits, but still some pressure, where body parts cannot absorb the high loads. And the gradations between high pressure and low pressure areas must be such that sharp pressure changes do not exist. Most importantly, since it is worn directly against the body, the ability to clean the socket and maintain proper hygiene is essential.

Thus, the materials problem in socket construction is somewhat different from that of other common products. Since the socket must be custom formed, present methods use plaster-of-paris casts from which plaster replicas are made. These are modified by careful and expert sculpturing to provide the required pressure variations in the final contour. Over these modified molds, the socket is constructed using polyester or epoxy resins in laminations of nylon, cotton, or Fiberglas stockinet.

SOME ACCOMPLISHMENTS

The typical artificial limb or brace of years ago was made of leather, wood, and high carbon steel. Each of these materials has its limitations, particularly in lack of durability. More importantly, they are difficult to protect against absorption of perspiration and other moisture which cause not only deterioration of the material but hygiene problems. As examples, Figure 1 shows a typical artificial arm of twenty years ago and Figure 2, an artificial leg formerly constructed for amputations below the knee.

Since World War II, laminates using polyesters or epoxies with fabrics made of synthetic or glass fibers have been increasingly used for limb sockets and for some prosthetic and orthotic structures. But a major effort was required to retrain artificial limb and orthopedic brace makers familiar only with wood and metal-working. Figure 3 shows the process that is now quite common in forming plastic laminate components over plaster-of-paris molds. Also common presently is the use of such plastic laminates in combination with wood for the limb structure. As examples, Figure 4 shows the modern plastic-covered wood limb for a below-knee amputee and Figure 5, a different limb type made completely from plastic for
amputations through the ankle. In each of these examples, the socket as well as the structure provided by the shank are made using nylon stockinet-polyester laminations. Occasionally, in highly stressed areas, Fiberglas may be provided in the lamination to give extra reinforcement.

Figure 6 shows a recent attempt to use a rigid polyurethane foam in place of wood in a shank for an artificial leg. No great success has accrued from this particular substitution even though it would overcome the limitations of wood particularly when the sophisticated fluid-controlled knee systems are used. Difficulty was encountered in attempting to form a durable and cosmetic finish over the polyurethane foam. In Figure 7 a mass-produced artificial knee is shown in which a rigid polyurethane foam was employed.
FIGURE 3. Typical plastic lamination procedure using plaster-of-paris modified replica of the stump as the inner part of the mold to which a separator is applied and a polyvinyl alcohol sleeve as the outer portion of the mold. Stockinet has previously been pulled over the plaster-of-paris inner mold.

FIGURE 4. Modern plastic artificial leg made for below-knee amputee.

in place of wood. Again, finishing problems impeded clinical applicability of this particular item, although an important weight gain resulted.

The use of plastic laminates produced a revolution in artificial limbs and to a lesser extent, in orthopedic brace practices. Improved durability and hygiene of product resulted. Appearance was preserved longer. Some early difficulties were encountered with sockets made from plastic laminates since when reshaping was required after the final fitting of the limb, the required carving would expose fibers which could be irritating to the body. However, by using an inner lamination of Dacron felt and polyester, the socket wall could be slightly reconstructed to provide adjustments in fit without fiber exposure. Figure 8 shows such a socket.

Other innovations in socket design and construction, shown in Figures 9 and 10, are incorporations of flexible polyurethane and silicone foams to provide a soft support for the more sensitive tissues on the end of the amputation stump. Readjustment of the contour of the bottom of the socket in these designs can be readily performed by removing the foam and then refoaming.
Other applications of plastic laminates were made in appliances for the torso and for the upper-extremity artificial limb. In Figure 11 a high bilateral arm amputee is shown with artificial arms primarily constructed of plastic laminates. This particular pair of prostheses contains extrinsically powered systems previously mentioned. Figure 12 shows the use of plastic laminates in a body jacket for torso support. Process control in construction of this appliance yielded a rigid structure where needed and a flexible portion in front for the opening and closing required in donning.

Recently, our Program has concluded a major part of clinical experimentation with a completely new concept of prosthetic rehabilitation of amputees. Immediately following surgery, a socket is formed (usually in the surgical suite) to allow attachment of a simple prosthetic appliance permitting early weight bearing and ambulation, in some cases one day postoperatively. The socket is formed of plaster of paris. Figure 13 shows a step in this process.

The use of such simple prosthetic structures recently stimulated an entirely different approach to artificial limb design. Present artificial leg structures are “crustacean-like” in that loads are transferred through a hollow shank of wood reinforced with a plastic laminate. With the introduction of the tubular-type “pylon” for immediate postsurgical prosthetic management, con-
FIGURE 6.—The use of a rigid polyurethane foam for the shank of an artificial leg. This material can be readily shaped but finishing with a lamination of polyester and nylon stockinet was not too successful.

FIGURE 7.—Artificial knee which uses polyurethane foam in place of the conventional wood.

consideration was given to using such a “skeletal” structure and a suitable plastic cosmetic cover for artificial limbs. This would permit the amputee, from time of primary surgery to time of discharge, to have the same prosthesis structure; only the socket would change as postsurgical progress was made. Figure 14 shows the type of limb structure which can be used immediately after surgery as well as through and including the time for a definitive or “permanent” limb. Such metal structures would also solve the problems resulting from incorporating complex mechanisms in wood structures, as is done presently.

A very significant part of immediate postsurgical prosthetics management is the employment of a rigid plaster-of-paris socket as a dressing over the surgically traumatized stump. Many clinicians who have worked with this procedure have stated the desirability of having a transparent dressing to permit observation of the stump without removing the socket. Repeated
removal of the socket in this technique would cause problems. Sockets made of a transparent material would permit not only observation of stump healing during the immediate postsurgical prosthetics procedure but could give a fitter an impression of pressure distribution in this procedure as well as in general prosthetics practice. Figure 15 shows such a transparent socket. A qualitative estimate of pressure distribution is obtained when the distortion of stump tissues is observed through the transparent wall.

Other innovations in the use of certain synthetic materials have recently been made. A synthetic balata recently made available by the Polymer Corporation of Ontario, Canada, has been used to form sockets for artificial limbs without the use of the intermediate plaster-of-paris replica and the
FIGURE 10.—Formation of cap at bottom of socket using flexible silicone or polyurethane foams. After the foam composite is poured, the amputee’s stump is placed in the socket. During the foaming process, excess foam is discharged through ports provided in the socket wall. An intimate fit of the stump end is provided by this process.

FIGURE 11.—A high bilateral arm amputee using artificial arms powered partly with carbon dioxide. The use of power allows many functions unattainable if the designer had to depend on power from the body of the amputee himself. Plastic laminate sockets and structures are used throughout.

FIGURE 12.—Body jacket formed using polyester resin and nylon stockinet. This appliance was made over a plaster-of-paris replica of the torso of the body. In this case, a vacuum system was used to draw the PVA sleeve (outer mold face) in against the replica at locations of extreme curvature. Velcro closures shown are commonly used in this and other types of appliances.
FIGURE 13.—Fitting of a prosthesis immediately after amputation surgery. Plaster-of-paris wrap over stump provides controlled pressures on traumatized stump to prevent edema. The socket is roughly contoured to permit early weight bearing and ambulation on the simplified artificial limb structure shown.

FIGURE 14.—Recent experimental approach to artificial leg design. Metal structure just above foot permits geometrical changes in orientation of socket to foot as part of the fitting process. The socket here has been formed using a polyester-nylon stockinet lamination. After the fitting process has been completed, the vinyl cosmetic cover shown is placed over the socket and metal structure.
rigorous procedure now required with the laminations. These sockets have
been formed directly on the amputation stump by preheating the material
to approximately 160 deg. F. (Fig. 16 and 17). Forming this material on
the stump causes no discomfort to the amputee or to the limbmaker. More-
over, unlike some other thermoplastic materials with which some of our
laboratories have experimented, this material exhibits reasonably sat-
sisfactory properties in shape retention and creep resistance under typical
conditions.

Effort has been devoted to developing techniques for forming porous
epoxy-Fiberglas laminations for sockets, to permit “breathing” between
stump and environment (Fig. 18). With the required intimate fits in sockets,
perspiration can obviously be a very serious problem. Moisture accumula-
tions in this tightly formed enclosure can cause difficulty not only hygien-
ically but also by producing skin irritation. But the techniques developed

Figure 15.—Experimental transparent
socket for above-knee amputation stump.
This socket was formed over a plaster-
of-paris replica of the stump using an
acrylic sheet. A butt joint which is not
desirable was needed to effect closure.
The transparency permits a qualitative
estimate of pressure distribution when
the stump is placed within the socket.

Figure 16.—Synthetic balata used to
form stump socket directly. The normal
step requiring a plaster-of-paris replica
is not necessary with this procedure.
Rather, the balata cylinder is heated and
then formed directly on the stump
using, in one experimental procedure,
the two pads shown to provide special
distortion patterns in strategic areas.
Figure 17.—A stage in the fabrication of a socket with synthetic balata for an arm amputee. Required socket contours have been formed in the plastic while on the stump.

Figure 18.—Porous epoxy-nylon lamination developed by the U.S. Army Medical Biomechanical Research Laboratory and made to permit a desirable moisture interchange between socket chamber and environment.
for porous laminations are quite rigorous; the expense involved has become a significant factor.

Recent attempts have been made to reconsider the structures now used for orthopedic braces. For example, in certain cases, simplification of the typical brace structure can be made by using a single metal bar as shown in Figure 19. Normally, the case shown would require a bulky pair of bars on each limb.

Attempts have also been made to use epoxy-Fiberglas laminates in brace structures (Fig. 20). One of the problems with such design has been lack of rigidity and strength for the bulk permissible. An enthusiasm for a brace structure of primarily synthetic composition has recently been generated by the availability of boron and other filaments for epoxy composites, structures which would provide higher strengths and the very essential higher modulus of elasticity.

![Figure 19](image1.png)  
**Figure 19.**—Experimental brace using single-bar structures on each extremity. Normally, such patients require a bar on each side of each leg. This system uses closely contoured sockets to integrate the skeletal structure of the patient to the metal structure.

![Figure 20](image2.png)  
**Figure 20.**—Brace structure formed of epoxy-Fiberglas laminate by the U.S. Army Medical Biomechanical Research Laboratory. This structure is designed to replace equivalent ones in metal.
CONCLUDING COMMENTS

A necessarily general overview of the external prosthesis and brace and the materials problems involving design and construction of such items has been presented. Much still needs to be done, particularly in orthotics (bracing). Our Program has realized that some of the major breakthroughs in clinical practice have accrued from the availability of new materials, particularly the synthetics. Since there is no materials development program primarily organized in response to the needs of external prostheses, we have often been required to depend on developments of other researchers, for other purposes. Fortunately, we have prospered from such “spin-offs.”

For example, a significant breakthrough now awaits the necessary efforts by us in the design of orthotic structures using filament composites. It is expected that the researchers in our Program will continue to work with their dependency on the researchers in perhaps more glamorous and thus better funded projects. And we will continue to be associated with the plastics suppliers in developing the use of the newer materials in artificial limb and orthopedic appliance design and construction, representing an area of technology which is relatively small in volume but huge in impact.