needs to be known about the magnitude and patterns of forces that are necessary and safe to orthotic applications. Workers in kinesiology and gait laboratories around the country are endeavoring to find more answers to diagnostic problems and to collect useful data for orthopaedic assessment and even surgical treatment. New materials offer the orthotist new versatility. The pneumatic orthosis, a new concept, is ready for full development. Electrical applications are at an embryonic stage in the stimulation of paralyzed muscles, inducing therapeutic exercises, and providing afferent or feedback systems. New interest has developed to improve powered mobility devices to replace the conventional electric wheelchair for the high level spinal cord injured patient. Specially adapted vans can be operated safely by paralyzed, limb deficient patients and other severely handicapped. In view of the potential offered by computer applications and rapidly improving robot technology, environment control devices are on the threshold of great advances. So much remains to be done in prosthetic-orthotic research that even the casual observer must be concerned.

At the same time that public research dollars have decreased, private research dollars have not increased sufficiently to fill the void. Obviously, research needs offer a challenge to orthopaedic surgeons who must increase the amount of personal time and funds given for research. At least one encouraging sign of private sector philanthropy exists. Bristol-Meyers/Zimmer U.S.A. has donated 1.2 million dollars to the Orthopaedic Research and Education Foundation (OREF) for the 1983–1984 Campaign. To date, more than 150 orthopaedic surgeons have given $1,000 each to OREF for the current campaign. This is in sharp contrast to the previous years' total of $200,000 from all sources. Other members of the industrial community should duplicate and even surpass the example set by the Zimmer group.

If this instance of giving by the orthopaedic surgeons and a prime industrial supplier is replicated by prosthetic-orthotic practitioners and members of the corresponding industrial manufacturing community, the funding for prosthetic-orthotic research can be adequately raised to support needed research programs.

From Research Lab to Consumer: The Manufacturers' Point of View

Carlton Fillauer, CPO*
Charles H. Pritham, CPO†

The matter of transferring new developments from the researcher to the consumer is one that has bedeviled the American prosthetic-orthotic establishment for years. The researcher, the agency that funds the research, the manufacturer, the clinician, and the patient are all, of course, interested in seeing new products brought to market, and all stand to benefit. Financially, the manufacturer is the one who stands to benefit the most from the successful introduction of a new product. Only by such means does a manufacturer expand his base and increase earnings. If the incentives are greatest for a manufacturer, the risks are also proportionately greater. In making a decision to produce a new product, the manufacturer must weigh the risks against the potential benefits and make a decision about committing his resources. It should be obvious that once resources of time, effort, and money are lost backing an unsuccessful product, they are lost forever. What is not so obvious is the fact that the loss is threefold.

Potentially, at least, the resources expended for backing a losing product could have been invested in a successful one, turning a loss into a profit. Also, in making the decision to back a new product the manufacturer commits his prestige and credibility. A positive result resounds to his credit, attracting new attention to products currently being produced and assuring a positive reception for future products. A negative result has the opposite effect, tarnishing the image of other items in the manufacturer's product line and damaging his credibility. That the investment in a new product can be a high one should not be discounted, therefore.

A small group of highly skilled and motivated individuals (or an inventor working alone) can, with a relatively low investment in machinery, produce complicated prototypes efficiently and with a low rejection rate. When the time comes to produce the same object in large numbers, the factors are fundamentally different. Production workers are seldom so skilled or motivated. Oftentimes, to overcome bottlenecks in production and to achieve consistent results, a product must be redesigned. The cost of this redesign must be borne by the manufacturer. To achieve productivity and consistent results, the manufacturer will develop tools, dies, and molds with which to produce a device. Resorting to such an alternative can enable relatively unskilled personnel using inexpensive materials to produce products of great appeal and excellent quality. While the material costs of such objects can be measured in the cents, the cost of the molds and dies can frequently run in the thousands of dollars each. If it is necessary to produce the device in a range of sizes and in right and left, the cost can be prohibitive. It should also be borne in mind that the researcher or inventor frequently has only partially tested the prototype and further testing and development must precede redesign for production. The direct expense of manufacturing an object, however, is only a portion of the cost.

In order to sell a product it must be promoted and advertised. The total expense of attending a convention (often far from home), renting space to exhibit, and obtaining a suitable display is not cheap. Commissioning the art work and copy of an advertisement, and obtaining space for it in a journal are, similarly, of considerable expense.

The organization that makes all this possible (research and development, production, and promotion) can fre-

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quently be quite large and demand a sizable indirect labor force to administer the resources and personnel involved. The total expense of all factors involved in developing a new product is a figure to be reckoned with and can be justified only if the product has the potential of selling in sufficient quantities to recoup the original investment and earn a favorable rate of return. It is in connection with this that the greatest stumbling block is encountered. Whatever the merits of a design may be, a manufacturer can not afford to devote the resources to its development if it will not sell in a large enough volume to enable him to sell it at a reasonable cost.

Despite the optimistic expectations of a developer, the market for his new object is seldom as large as he hopes. All researchers and developers seeking federal research money are asked to project the number of individuals for whom their work will be applicable. As all involved will admit, it is a fundamental fact of the way that health care is funded in the United States and the way that health care statistics are gathered that the best of projections are crude estimates. What statistics are available point to the fact that the total market for any one product is small. This market is rendered smaller because not all members of that market are in the marketplace at one time, or even interested in the new product.

A new product must compete for a share of the market with existing products that do the same thing. It should be kept in mind that few, if any, developments are so radically different as to have no potential competiton for market share. The price at which established products are sold limits the price for which a new product can be sold. For a new product to rapidly gain market share, it must be reasonably priced versus the competition, potentially much better than the competition, and current users must be very dissatisfied with the competing product.

On a practical level, the people to whom a product must be marketed are not the ultimate consumer, but the prosthetist-orthotist who will render that product into a form suitable for a particular patient, and who must also frequently convince the physician to prescribe the device.

At any one time, there are said to be about 2,000 practicing prosthetists-orthotists; that is hardly a mass market. Prosthetists-orthotists as a group are not the easiest group to introduce to a new product. Most of them have experience with one or more products that, despite the manufacturer's best efforts, were released before all the problems were worked out. Like the car buyer who chooses not to buy a car during its first model year, they prefer to wait and see. Others, while interested in trying a new product are "waiting for just the right patient." On the other hand, a disconcerting number are all too ready to rush in without thought.

Battling for preeminence in every prosthetist-orthotist's lexicon of adages to live by are the two:

1. If all else fails, read the instructions.
2. Don't force it, get a bigger hammer.

Every manufacturer can recount instances of practitioners who provided a device to a patient for whom it was specifically contraindicated, or who neglected one or more crucial precautions in fabricating the completed device. This can result in a wave of negative word of mouth publicity despite a manufacturer's best efforts to promote a new product and educate the profession about its proper use. The end result may be passive indifference, or active rejection whatever the positive merits of a new device are when it is properly prescribed and utilized.

A developer of a new object has a vested interest in making it work successfully and will go to considerable pains to make it do so. It is a well recognized fact that a product, when transferred to even the best motivated and prepared practitioners, seldom works as well as it does for the developer.

In summary, then, the following points can be made:

1. The following factors are sizable expenses:
   a. Research and development of the original idea to a workable prototype
   b. Production design
   c. Tooling
   d. Manufacturing

Questionnaire

1. Do you believe the amount of public funds available is adequate for prosthetics and orthotics research?

   Yes _____ No _____

2. Do you believe appropriate research and development is conducted?

   Yes _____ No _____

3. In each of the three categories below, indicate your personal priorities for research that needs funding. (1 being the highest priority)

PROSTHETICS

_____ External power for upper extremity prosthetics
_____ Sensory feedback upper extremity prosthetics
_____ Improved body power for upper extremity prosthetics
_____ Better lower extremity prosthetics for geriatrics
_____ Extra-ambulatory advance performance lower extremity prosthetics for younger amputees
_____ Alignment and gait analysis for lower extremity prosthetics
_____ Cosmesis
_____ Other _____

ORTHOTICS

_____ Upper extremity orthotics
_____ Lower extremity orthotics
_____ Spinal orthotics
_____ Gait analysis for lower extremity orthotics
_____ Seating
_____ Other _____

GENERAL

_____ Materials
_____ Fabrication technology
_____ Basic science as related to prosthetics and orthotics
_____ Other _____

4. Additional Comments: _____

_____

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e. Quality control and testing
f. Marketing

2. Considerable uncertainty surrounds the business of gauging market size and reception for a new product.

3. However well an object sells, the field of prosthetics and orthotics can hardly be said to constitute a mass market of sizable proportions.

4. Experience has repeatedly shown that it takes three years to achieve a profitable volume of sales once a new product is introduced.

The result of these facts is that the manufacturers of items for use in the prosthetic and orthotic market are confronted with the need to make sizable initial investments for a rather small market that is oftentimes slow to adopt new products of even the greatest merit. Considerable uncertainty surrounds the decision to make the investment and it can take many years for a return on the investment to be realized and the decision to be vindicated. Given these facts, it is understandable that manufacturers differ from developers and their backers about the utility and acceptability of many developments, and that they are slower to adopt new products than others might wish.

Flexible Prosthetic Socket Techniques

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The continuous development and availability of new materials of various kinds, e.g., elastomers, copolymer thermoplastics, and composite materials have brought a potentially revolutionary development in the design, configuration, and fitting principles of prosthetic sockets, especially for above-knee prostheses. All of this may result in greater patient comfort, physiological, and psychological advantages.

Improvements in socket comfort with concomitant physiological and psychological benefits are not only due to the materials themselves, but rather, the inherent characteristics of the various materials used permit socket configurations heretofore not possible. For example, socket fenestrations over selected or entire stump surface areas are now possible. The desirability and principle of permitting greater flexibility over muscular areas than is possible in a rigid, laminated socket were appreciated more than 25 years[1] ago in the fitting and design of the "Flexicage" socket[2] which consisted of nylon cords strung between the proximal brim and the distal end of the socket. McCollough, et. al.,[3] as early as 1968, attempted fenestrations over selected socket areas. These attempts, however, were not generally successful because of the potential and real problems with window edema and the properties of the material used. These problems now have been overcome through the availability of materials which can be used as elastic or semi-elastic inserts, preventing window edema, yet permitting removal of the outer rigid socket shell in selected areas.[4,5]

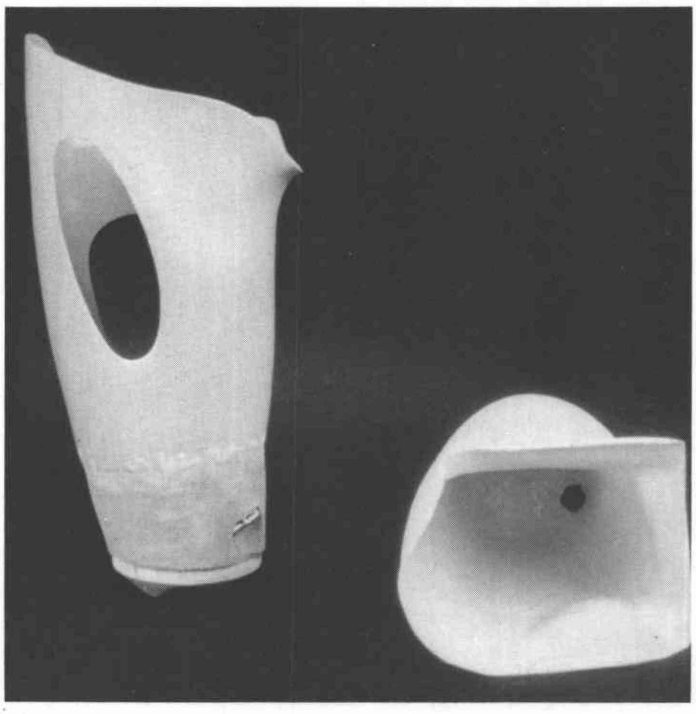

Figure 1.

Below are described several approaches allowing flexible or semi-flexible stump containment, while maintaining the essential biomechanical characteristics required for interface stability to transfer body weight through the prosthesis to the ground, and for dynamic and safe control of the prosthesis.

Two systems are curently used at the Institute of Rehabilitation Medicine at NYU Medical Center (IRM-NYU) to provide the characteristics described above. The first system consists of an inner socket laminated of Perlon fiber and silicone elastomer contained in a rigid plastic laminated socket (Figure 1). The laminated silicone elastomer has nearly perfect memory and permits fenestrations of the rigid outer socket over the posterior area (Figure 2), rectus femoris (Figure 3) and the adductor group, without causing window edema. This design permits greater muscle expansion than the designs described below because of the elasticity of the silicone material. It also provides enhanced sensory feedback, particularly when sitting, i.e., the patient is able to feel the surface of the chair or seat. The soft liner is also a boon to improved comfort, particularly in geriatric amputees and those with a history of general socket discomfort.

The second design utilized at IRM-NYU is a Surlyn™ inner socket (Figure 4) which permits removal of even more of the hard outer laminated socket (Figure 5). The reason larger areas of the hard socket can be removed is the lesser flexibility of Surlyn™. Thus, more rigid material can be eliminated without compromising the integrity of known biomechanical principles (Figure 6).

A more recent design developed in Iceland and further refined in Sweden and at New York University, known as the ISNY socket, consists of a medical rigid frame only, leaving the rest of the polyethylene socket semi-flexible.

For below knee amputations, similar systems have been developed at IRM-NYU and in Belgium by Van Rolleghm

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