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Artificial Limbs

*A Review of
Current Developments*

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RESEARCH AND DEVELOPMENT

COMMITTEE ON PROSTHETIC-
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Evaluation

FRANK W. CLIPPINGER, M.D.¹

FORMAL and systematic evaluation of materials, fabrication techniques, and components is not only a desirable, but an essential, step in the field of prosthetics and orthotics. Simply having an idea, publicizing it, and letting it “succeed” or “fail” on its merits in general use does not suffice, given the variety of disciplines involved, the financial outlays required for tooling and manufacturing, and the difficulties concomitant with conveying detailed technical information in print.

We have had experience with hit-or-miss “progress” in the past. From the early nineteenth century to 1945, it was difficult to try out others’ innovations; it was not worthwhile to innovate one’s self; and, both financially and emotionally, the old, tried-and-true processes appeared to be best. It was enough to use something that was relatively effective, economical, and fairly reliable. It is not hard to see why little change occurred.

Since 1945, there has been a new, organized emphasis on the detailed study of patients’ problems, and the availability of public funds for research, development, and service has made the application of new ideas practical. Gait mechanisms, hand functions, skin difficulties, and emotional reactions to disability and cosmetic impairment have been studied in detail. New materials have appeared at a rapid rate, and new techniques for their application to the patient have evolved. For instance, plastic molding has revolutionized the technology of prosthetics.

Today, the need is not simply to provide the patient with just any device as a substitute for his impairment, but to get for him the best we can provide: the most functional, comfortable, practical, economical, and satisfying restoration of which we are capable.

The increasing complexity of prostheses and orthoses, while it may result in better function, requires more training of personnel and greater financial outlay. It is not practical to try everything on a wide scale. It is necessary to sift out the best for general use. This process is *evaluation*.

Evaluation has three phases. First, the developer must conduct studies on his own. Will his idea work when applied to a patient? Will it do any harm? Is it possible to make the component?

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Second, trial on a wider scale must be performed. This is best done by a second party who can answer questions such as: Can the developers' results be reproduced by others? Is the technique teachable and how? Will the components survive normal wear and tear? Can the process be made applicable to patients other than those for which it was specifically designed? Are modifications of design or material needed?

Third, the final test is that of acceptance by the people ultimately concerned: the patients, prosthetists, orthotists, physicians, and agencies who have the responsibility to prescribe, purchase, make, and use these products of imagination and technology.

A major problem has been that of transition from the design and development phase to the availability of new techniques and materials to the patient. It is in expediting this transition that an organization such as the Committee on Prosthetics Research and Development, through its Subcommittee on Evaluation, must be active. This is a group which can, without bias, coordinate the efforts of developers, manufacturers, and consumers.

CPRD is in the unique position of having knowledge of, and access to, many scientific and clinical programs throughout the world that will cooperate in trying new products of research. Under the auspices of the National Academy of Sciences—National Research Council, knowledgeable people can be brought together, learn a technique from a developer, try it in their local area, and then meet again for criticism and discussion. Experience can thus be obtained, the need for teaching materials can be assessed and manuals developed, and problems that were not readily apparent in the early phases of development can be identified. Above all, duplication of effort can be kept to a minimum, and unnecessary expenditures of money for development and manufacture can be avoided.

Excellent examples of the role of CPRD appear in this issue of *Artificial Limbs*. Electrically powered prosthetic elbows have become popular items for development. Several designs have arisen, all of which could have been rather costly, in terms of both time and money, to develop and manufacture. By means of the Evaluation Program, specifications have been adjusted, durability requirements established, patient acceptance assessed, and the need for various kinds of redesign noted. This has been done before anyone has committed himself to expensive tooling and the wide-scale manufacture of seemingly attractive items in an imperfect phase of development.

Modifications of techniques continually appear and are in fact a phase of the evaluation of an item; witness the continual development of casting techniques for prosthetic sockets and modification of the design of, and the clinical indications for, the Veterans Administration Prosthetics Center patellar-tendon-bearing brace. In short, evaluation is a critical part of any design and development process.

Rehabilitation Engineering is in its infancy. The next several years will show an exponential growth in the numbers of sophisticated people involved and the complex products of their brains. Identifying needs and sorting out the best and the most practical techniques and components for our patients will be a real challenge. We must be up to it.

Premodified Casting for the Patellar-Tendon-Bearing Prosthesis¹

JOSEPH H. ZETTL, C.P.², AND
JOSEPH E. TRAUB, C.P.³

METHODS for producing a functional, comfortable, and well-fitting patellar-tendon-bearing prosthesis have been the subject of considerable discussion, and in fact some controversy, since the prosthesis was first introduced several years ago. Prosthetists use a variety of techniques to cast below-knee stumps, and there is an extensive literature on the subject, not excluding the technicians' differing viewpoints. There is agreement, however, that the effectiveness of the prosthesis depends to a great extent upon how well the wrap-cast (negative) was taken and, subsequently, how precisely the male plaster mold (positive) was modified.

The positive mold is modified in order to relieve pressure-sensitive areas by the addition of build-ups, and to increase the pressure to the pressure-tolerant (or natural weight-bearing) areas of the stump by the judicious removal of small amounts of plaster. These alterations prevent vertical displacement during stance and provide for comfortable accommodation of the stump during full weight-bearing. The precise amount of plaster removed varies with the individual patient, depending upon the muscle tone and the amount and resilience of the subcutaneous tissue. The procedure is by no means a difficult one, but timing is a complicating factor.

Authorities on the subject encourage immediate rather than later modification of the positive cast in order to prevent improper interpretation of the individual stump characteristics. Consequently, the well-qualified prosthetist who finds himself with a large number of plaster positives to be modified, or the less experienced prosthetist who is just developing a keen sense of technical judgment, is at a disadvantage because, even with the best memory and with detailed prosthetic information, he is limited by techniques which involve nothing more than intelligent guesswork and which are conducive to at least an occasional error, regardless of the individual's experience and skill.

This difficulty can be overcome by modifying the cast on the patient's stump when the negative-cast impression for the permanent prosthesis is taken. This paper describes such a procedure, essentially initial socket fitting during casting, which provides a plaster negative-positive that requires only a final smoothing to be ready for socket lamination. The method includes the application of felt pads to strategic areas of the stump. Elastic plaster bandage is used for the negative plaster wrap because it effectively conforms to the irregular stump surfaces, controls tissue compression and displacement, and yields a precise stump impression. The resulting positive plaster mold resembles the stump contours accurately, thus providing the basis for a comfortable, well-fitting, and functionally acceptable PTB prosthesis.

Provision of a total-contact, hard PTB socket, without a soft end or the customary insert, is the standard procedure at the

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