VETERANS ADMINISTRATION PROSTHETICS CENTER RESEARCH

INTRODUCTION

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For many years, a major function of the research personnel of the VA Prosthetics Center has been the development of fully adequate yet realistic standards for both the fitting of limbs and braces and the quality of mass-produced components and hardware used in constructing such appliances. Occasionally, the standards development program is delayed due to other commitments of the Center but never have we failed to realize that this is an essential function in the national program.

Highly important in standards development is the formulation of realistic specifications. The process depends on a comprehensive understanding of the true functional and cosmetic requirements of the man-machine complex and the techniques and production systems necessary for construction of the appliances and manufacture of their parts. A sound, basic grasp of these functional needs is only available in people experienced both in prosthetic and orthotic fitting and in research on the fundamental requirements of devices designed for prosthetic or orthotic application. Moreover, the controls over quality of external functional or cosmetic restorations or replacements for the body not only require unusual laboratory testing procedures but also require daily clinical surveillance in the field.

Orthopedic and prosthetic appliances represent generally a combination of materials and hardware or components, a socket construction and assembly process, and a fitting regimen. Standards for all elements of this combination must be set. Most assuredly, the specifics of the several standards cannot be checked on a sample appliance in one central laboratory. Representative samples of materials and mass-produced hardware are now checked at the Center on the basis of standards established here. This works well, but even these require atypical testing procedures and equipment. But proper fit and alignment can only be checked on a 100 percent basis on each subject with

his varying needs. The Veterans Administration has a mechanism for doing this through its individual field station clinical checkout program based on VAPC established standards of quality which in turn have been developed from specifications of checkout taught in university prosthetics educational programs. In collaboration with the Research and Development Division of PSAS, these checkout procedures were recently taught to our VA Prosthetic Representatives throughout the country. Moreover, the prosthetics industry has established its own standards of quality for its fitters through its certification program; such standards are equivalent to VA's own.

In this report, we offer a review of some key points about setting functional standards for mass-produced artificial limb and brace components. Given are several examples which emphasize the functional specifics of a standard rather than the detailed design specifications which hinder and restrict development. Evaluation and compliance testing against this type of functional standard require a sophisticated procedure which cannot normally be handled by manufacturers themselves or by any facility which does not have both the special equipment and the necessary people knowledgeable in applications of external replacements for the body through actual clinical involvement.

We look on our VA standards development program and its associated compliance testing as serving not only VA beneficiaries but the disabled in general. We feel that the standards for quality of prosthetic fitting set by the universities and the Veterans Administration and the standards for mass-produced components developed and administered by the Veterans Administration can accrue benefits to all agencies or institutions responsible for prosthetic and orthotic appliance procurement. Manufacturers cannot duplicate the unusual facilities available to us; nevertheless, they are free to submit all devices to us prior to mass production. We trust that the prosthetic industry and agencies which procure appliances recognize this VA program . . . a service to all.

This report, although emphasizing the standards program with examples given on the artificial foot and the prosthetic knee, sets forth some other concepts which help us in developing *future standards,* for a standards program should not be characterized by temporal provincialism; it must be flexible and dynamic. Our evaluation programs directly feed the standards development program; as new items are checked, particularly those with new functions, a standard can be quickly rewritten so that the disabled can soon benefit from the improved functions.

Our development programs are based on fundamental analyses of needs which often the standards program clearly points out as a missing element in appliance design. The most significant example now is the above-knee prosthesis structure designed to incorporate a number

of functions, now represented by an array of knee mechanisms on the market.

Many other items are covered in this report. Some are basic studies which relate directly to the design of hardware or complete appliances. The fundamental work on the effects of compression on the lower extremity should eventually result in new standards for elastic hosiery. Also highlighted is our consideration of a rather different approach to controlling prosthetic function through the use of EMG signals. In the lower extremity, with which we have become primarily concerned, we offer a new approach not duplicating the work of others. We believe that there is a major role to be played by EMG sources of control, but that before too great a definitive design program for large scale use of EMG is launched, it is well worth exploring all possible systems for such control.

Most significant in measuring the effectiveness of an R&D effort are the actual production and the availability of new hardware and manuals which give detailed descriptions of new techniques. We can report that we have assisted the University of California-Biomechanics Laboratory in getting the pneumatic above-knee swing-control system ready for production. Moreover, the adjustable below-knee standard prosthesis is now being manufactured. The VAPC single-bar brace is also being prepared for production. In addition, manuals for the use of Polysar in direct forming on stumps are being offered to the prosthetics field.

Making these items available represents the successful completion of major research and development on them. Of course, additional evaluation will always be performed, for evaluation never ends. But these all represent products of the VA research program which will soon be used to help disabled people.

And in their use, which includes how they are produced and how they are fitted, we will continue to enter the picture through our VAPC compliance testing program and VA-wide clinical checkouts. If any item or procedure falls below VA standards at any time, it will soon be noted and prompt action taken to eliminate deficiencies, usually first by technical assistance to the manufacturer or fitter. Thus our standards program is not characterized as a "policing" effort but more so as a framework for helping the prosthetics industry achieve improvements and high quality at minimum cost to all.

I. LOWER-EXTREMITY PROSTHETICS
   A. Basic Studies
      1. Effects of Compression of the Lower Extremity
      2. Work and Energy in Walking
      3. Sources for Control of Prosthetic Function

B. Development (Components)
1. Adjustable Below-Knee Standard Prostheses
2. Standard Above-Knee (Multiplex) Prostheses
3. Torque Absorber
4. Cosmetic Covers

C. Development (Techniques)
Direct Forming of Below-Knee Sockets

D. Evaluation (Components)
1. UC–BL Pneumatic AK Swing Control System
2. Wagner Above-Knee Assembly (#319)
3. Teufel Protective Nylon Sheath
4. Hosmer Above-Knee Pylon

E. Evaluation (Techniques)
None

II. UPPER-EXTREMITY PROSTHETICS

A. Development
Humeral Rotator

B. Evaluation (Components)
AIPR (American Institute of Prosthetic Research)
Externally Powered Components

C. Evaluation (Techniques)
Direct Forming of Below-Elbow Sockets

III. LOWER-EXTREMITY ORTHOTICS

A. Development
None

B. Evaluation (Components)
VAPC Single-Bar Ankle Brace

IV. ORTHOPEDIC AIDS

A. Development
Spence-gel Foot Appliance

B. Evaluation (Components)
Stryker Floatation Pad Field Study

C. Evaluation (Techniques)
None

V. TESTING

A. Standards Development Program (Knee Mechanisms and Foot-Ankle Assemblies)

B. Compliance Testing
1. SACH Feet
2. Teufel Leg Wool Stump Socks

C. Materials Testing
Polypropylene

VI. OTHER PROJECTS

A. Wheelchair Field Study

B. Cetrone Contoured Support Belt
VII. OPERATIONS REPORT FOR FIRST HALF, FISCAL YEAR 1967
A. The Orthopedic Shoe Service
B. The Prosthetics-Orthotics Service
C. Special Service for Vietnamese Wounded

REPORT

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I. LOWER-EXTREMITY PROSTHETICS

A. Basic Studies

1. Effects of Compression of the Lower Extremity. As described in the previous issue (BPR 10–6, pp. 223–228), a series of studies has been undertaken to develop a valid description of the forces applied by elastic hose and to develop reliable physiological measures of their compression effects. The influences of gravitational forces on circulation were studied first; then the effects of local compression of the lower extremity were investigated. In the previous issue we indicated that pulse rate and *diastolic* arterial blood pressure were the most reliable indices among the simpler physiological measures of the gravitational effects on blood circulation in normal men, that is, orthostatic effects. In a second phase, we have applied compression forces directly over the lower extremity by using the VA Prosthetics Center pneumatic casting bag. Pressures in the bag were systematically varied from 100 mm. Hg (approximately 2 p.s.i.) to 25 mm. Hg (.5 p.s.i.) (Fig. 1).

Data on two normal subjects indicate that the pulse rate and the diastolic blood pressure as measured at the dorsalis pedis artery vary with changes in both gravitational force and in localized compression force. However, compression forces could not be quantitatively related to the simple physiological measures employed in this study, i.e., altering the applied pressures did not produce predictable changes in arterial pressures or pulse rates.

Although reasonably reliable, our findings indicate great variability of response in each subject as well as from subject to subject. This corroborates the earlier findings of Spencer et al., who state: "Even healthy persons show large differences in response to passive tilting in their cardiovascular behavior . . . , and in their ability to compensate for orthostatism in repetitive and successive tilts (1)."