THE VETERANS ADMINISTRATION'S STANDARDS PROGRAM IN PROSTHETICS, ORTHOTICS, AND ORTHOPEDIC AIDS

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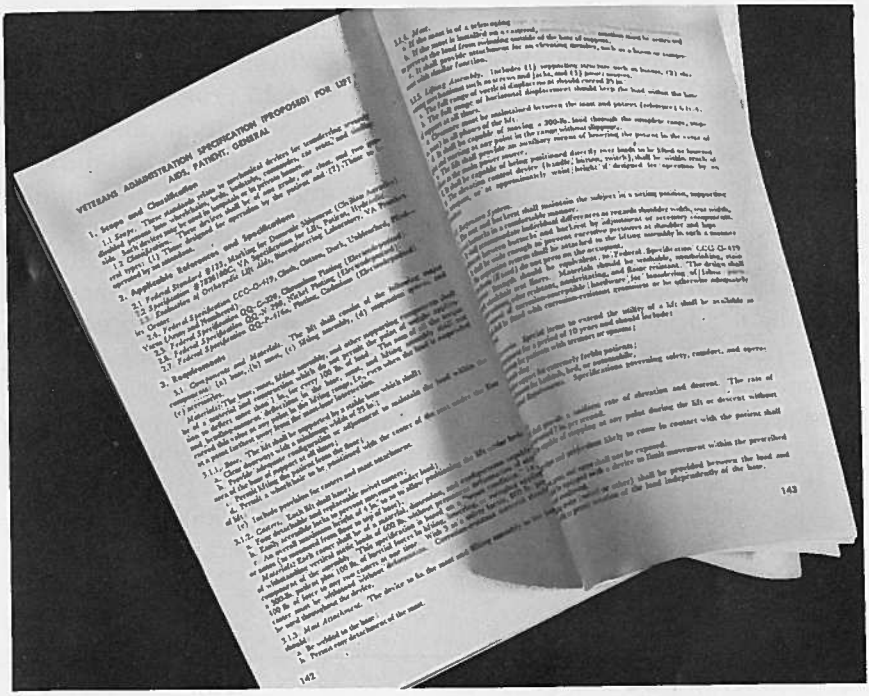
INTRODUCTION

The Veterans Administration is increasingly employing standards in its Prosthetic and Sensory Aids Program. The standards now used are documents (Fig. 1) which present desired qualities and features of prosthetic and orthotic hardware and orthopedic aids and of fitted limbs and braces and then specify those attributes necessary to control their quality, safety, and performance. Standards for sensory aids are also being developed.

Many people interested in prosthetics and orthotics practice may not be too familiar with the present program in which clinicians, especially prosthetists and orthotists as well as the hardware manufacturers themselves, help assure that not only beneficiaries of the Veterans Administration but all disabled will benefit from appropriate controls over the function, the safety, and the quality of manufactured prefabricated components. Standards covering the quality of fit use controls over the fitter on the basis of criteria formulated by the American Board for Certification. VA clinical inspection procedures based on standards of fit developed by university and VA research and educational programs are employed as well. University upgrading courses for fitting of new types of appliances are also part of the VA standards.

The Veterans Administration effects its Standards Program administratively through the Veterans Administration Supply Service and its contracts with manufacturers and fitters, and technically by use of clinical examinations of appliances fitted to patients as well as laboratory testing programs at the VA Prosthetics Center. The Government through VA, therefore, is not only able to establish requirements but is also able to followup and assist manufacturers and practitioners in following the standards.

The nature of this whole program is described here. This description should be of interest to the Federal agencies involved in procurement of limbs and braces and to other agencies concerned about the safety, quality, and function of products produced for disabled patients.



VETERANS ADMINISTRATION SPECIFICATION (PROPOSED) FOR LEG AND PATIENT: GENERAL

FIGURE 1.—A Veterans Administration Standard.

This program will be of special interest to clinicians, especially the prosthetists and orthotists and to manufacturers and suppliers who need to work with these standards. The system is not designed as a policing one so much as one organized to assist manufacturers and fitters achieve uniformly high standards, assuring all patients of function, comfort, safety, and durability.

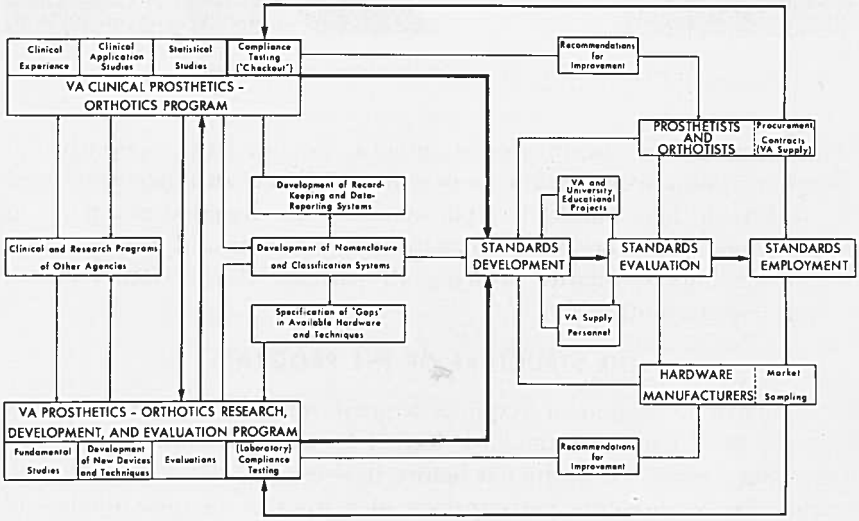
THE STRUCTURE OF THE PROGRAM

Standards development requires a great number of inputs from a number of sources. A standard drafted by the Government, like any new item, should be evaluated before it is employed. The process of evaluation requires the participation of a number of individuals and organizations outside the Government. Finally, employment of the standard does not mean that it is a rigid document which cannot again be changed by additional inputs or by changes in the technology.

Figure 2 shows how the Veterans Administration's Prosthetics-Orthotics Standards Program operates. The VA Prosthetics and Orthotics Clinical Program and the VA Prosthetics-Orthotics Research, Development, and Evaluation Program are closely interlinked in that many of the activities of one overlap those of the other. People specializing in

research are encouraged to be involved in clinical activities, and those who are primarily in the clinics participate actively in research, development, and evaluation programs. Moreover, both programs are allied to the clinical and research programs of other agencies in the Government and to other groups both in the United States and abroad through the correlating function of the National Research Council's Committee on Prosthetics Research and Development.

The experiences and the knowledge from both the clinical and research programs contribute heavily to standards development. For example, clinicians and researchers need to work together to establish an appropriate language to be used not only for standards but for educational programs. From the development of nomenclature and classification systems one can note gaps that exist in the present technology. The language systems also assist the clinical program, especially in the development of record keeping and data reporting systems. The data so obtained will in turn assist in discerning clinical problems and thus guide research, development, and standards work, and determine the priorities in these.



THE STRUCTURE OF THE VA PROSTHETICS–ORTHOTICS STANDARDS PROGRAM

FIGURE 2

All of these are products of the development of an appropriate language for a standard. Such a language is useful not only in clarifying the standard and its coverage but also in providing through the standard an educational mechanism to facilitate teaching the technol-

ogy based upon a logical organization of technical material. As will be seen in a later discussion, the standard can be useful in guiding prescription and the rationale underlying employment of various types of items covered by the standard.

With the inputs from clinical experience involving an array of devices and techniques and the knowledge and experience obtained by research, development, and evaluation personnel, a draft standard of appropriate language can be developed. This draft must, of course, be exposed to the people who will have to work with it. Thus, an evaluation process includes the manufacturers of hardware, especially for the type of standard applying to them and the prosthetists and orthotists, for both the hardware standard and the fitted appliance standard. Their critiques are important. The standard must be practical. In addition, educational specialists in the field of prosthetics and orthotics must be consulted to review the appropriateness of the standard, especially in its organization of the subject matter and in its language to training programs for all levels of clinicians. Most importantly the standard must be reviewed by VA supply specialists for its adequacy in procurement programs of the Veterans Administration and the Government.

Finally, a standard is employed. The purpose is control of quality and safety of both the hardware provided by manufacturers and their distributors and the assembled appliances provided by the prosthetists and orthotists in fitting VA beneficiaries and other clients.

Compliance testing of hardware is performed within the prosthetics-orthotics research and development program of the Veterans Administration. This is done by sampling the market and conducting laboratory tests. Results of such tests are published within the Veterans Administration for the information of procurement personnel. Moreover, results of the tests are fed back to manufacturers. If indicated by some negative results of compliance testing, engineering design recommendations are also provided.

The standards which apply to the fitters are particularly critical. Information on standards is made available to these people through contracts administered by the VA Supply Service. Compliance testing is performed in the clinics of the VA hospital system in a process normally termed "checkout." Here again recommendations for improvement, as a result of clinical inspections, are fed back to the prosthetist and orthotist for their guidance whether as part of an indicated change in one of their products or for general improvement on all products.

The system is a closed one with constant feedback to the drafter of the standards. Once the standard is adopted, it is employed routinely for the items covered. Nevertheless, there is recognition of the vibrancy of the Research and Development Program; new items constantly appear which may require special evaluations not covered by existing stand-

ards. The people involved in standards development are the ones involved in evaluations or clinical application studies of such new items. As a result a new standard may necessarily have to be established to cover the completely new item or possibly an existing standard can be slightly modified so that the new item is included.

PROSTHETICS-ORTHOTICS STANDARDS

The United States Government is a large consumer of all kinds of manufactured goods. Products procured by the Government are governed by official standards and specifications established to control the quality of the products for the benefit of the United States taxpayer and to effect an equivalent quality in the products purchased by other consumers, especially individuals. Setting of standards too low and loose specification of requirements lead to excessive cost as well as to inadequate product applicability. The system for establishing standards and specifying requirements in the field of prosthetics and orthotics was originally set forth by the late Otto Rothman (1).

The definitions previously offered by the VA Prosthetics Center (2) are worth quoting:

"*Standards* present the qualities or values which represent desired goals or conditions.

"*Specifications,* part of the standard, relate to the attributes required to attain the standards.

"A *test procedure,* also a part of the standard, is used to determine the presence or the extent of an attribute as a measure of the degree to which a standard is reached.

"For example, a standard for a prosthetic knee mechanism is that *'it provides a normal range of knee rotation.'* The related specification would *'require that the knee rotate through a minimum of 120 deg. in the sagittal plane.'* The test procedure would be to *'use a goniometer and measure the range of knee rotation'.*"

Orthotic and prosthetic appliances generally represent a combination of materials, hardware or components, a fitting and alignment process, and an assembly and finishing procedure. Thus, standards not only for the manufactured devices used in an appliance but also for the results of the assembly and fitting must be set. Standards for items classified as orthopedic aids such as wheelchairs or the lift aid shown in Figure 3 do not produce similar problems, although "fit" criteria must be included as part of the requirements for the device as prefabricated. In other words, the orthopedic aid must suit the special needs of the patients for whom designed, considering all human factors.

The development of realistic standards for orthopedic aids, for the assembly and fitting of limbs and braces, and for the adequacy of constituent mass-produced components and hardware is no small task.

FIGURE 3. — A patient-lift which was tested against a Veterans Administration Standard.

The process depends on a comprehensive yet practical understanding of:

1. the functional and cosmetic requirements of man-machine complexes, based on both sound fundamental and practical clinical principles,
2. the proper nomenclature based on an appropriate functional classification system and,
3. the techniques and production systems necessary for construction of the appliances and manufacture of their parts, based on both direct involvement in clinical practice and comprehensive knowledge of production processes.

"A sound, basic grasp of the functional needs is only available in people with clinical exposure, preferably continually involved in prosthetic and orthotic fittings (3)." Moreover, an involvement of some of the same people in research and especially evaluation programs requiring detailed knowledge of the basic functional requirements and production engineering concepts is necessary.

THE PROBLEMS OF NOMENCLATURES

Nomenclatures, essential parts of a standard and of classification systems needed to develop standardization, have always been problems, particularly in bracing. Appliances have been given names, usually of people or organizations, which signify nothing functionally and thus impede understanding of an appliance's usefulness. The Veterans Administration, the American Orthotic and Prosthetic Association, the Committee on Prosthetics Research and Development, the American Academy of Orthopaedic Surgeons, and the University Educational Pro-

gram have recently treated the formidable problem of nomenclature and classification, starting with the lower-extremity brace. New York University has worked with others on problems in spinal bracing terminology. The Committee on Prosthetics Research and Development developed the PTB below-knee prosthesis classification system of Figure 4, and the VA offered the above-knee quadrilateral socket prosthesis classification system of Figure 5.

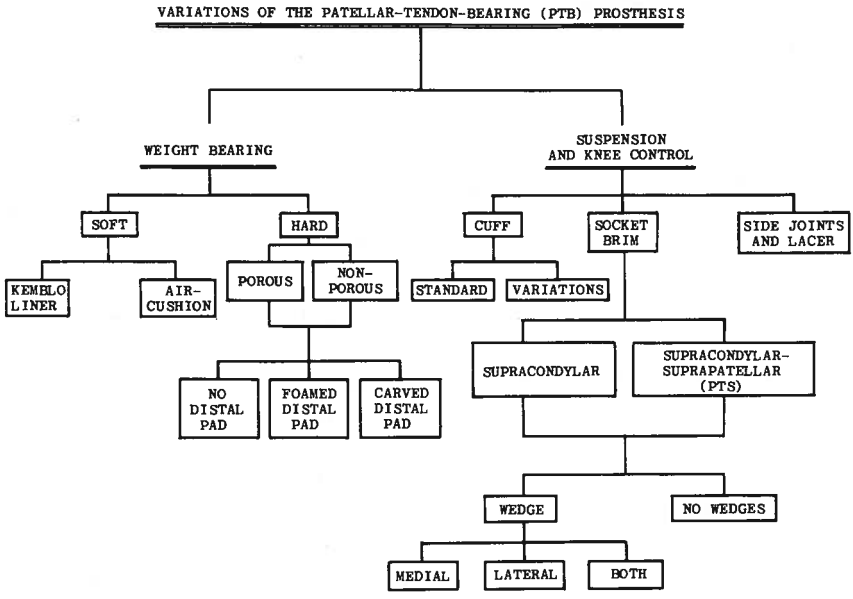


FIGURE 4

Apparent in the activities of these several groups is the need for definition of the functional and design attributes of variations on prosthetic-orthotic systems by establishing sensible nomenclatures and then by classifying existing hardware and appliances functionally. Pathology or dysfunction in a patient if properly specified in biomechanical terms can then be related directly to the function offered by the prosthetic-orthotic system, an assist to educators and their students and eventually to clinical practice.

Because it is essential that logical nomenclatures and classification systems be organized, the American Academy of Orthopaedic Surgeons has taken an active role on the lower-extremity brace problem. To assist the Academy's committee, the VA Prosthetics Center has developed a tabulation to classify functions of existing lower-extremity brace components. Table 1 is a partial listing of functions based on the current "trade" terms as shown in the first column. Eventually a new

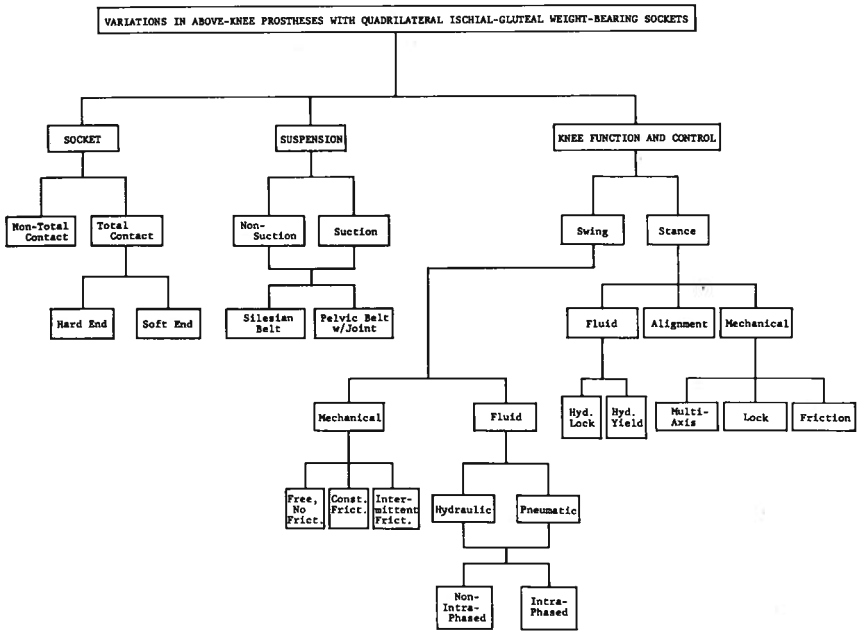


FIGURE 5

nomenclature can be developed on the basis of the functions specified.

Recently, codification of the nomenclature for prostheses and braces has become important in VA record-keeping systems. Employment of automatic data processing in the VA will enable planners to effect more accurate budgeting and to predict trends in clinical employment of various types of appliances. Moreover, data accumulated on the detailed content of fitted appliances alongside data on service life including structural and maintenance problems will permit research and development planners to determine emphases in such programs to meet the problems being experienced in the clinics. Data helpful for evaluations of new items will also accrue. In addition and perhaps most significantly, the results of fittings in an entire national network can be reviewed and analyzed for total compliance with standards of fitting quality and appliance and component durability.

Table 2 shows how the nomenclature, based on a detailed analysis of an entire appliance, is codified for a system used in the VA Prosthetics Center. The code for lower-extremity prostheses is partially based on the classification systems of Figures 4 and 5. Manufactured hardware used in an appliance are precisely identified with codes which relate to both the type of function provided as established in a hardware standard and to the manufacturer. Parallel systems are used to identify the patient, the service life of the appliance, and patient experiences,

TABLE 1.—*Sample of Functional System for Classifying Lower-Extremity Orthotics Hardware*

Components	Biomechanical function: Plane of function: Sagittal	Coronal	Transverse	Source	Materials
C. Knee control (Single or bilateral bar) —continued					
2. Knee joint (offset)	PROVIDES EXTENSION MOMENT IN EARLY STANCE PHASE. Permits flexion-extension. Prevents hyperextension. (UCLA Functional Long Leg Brace)	Prevents abduction-adduction	Prevents internal-external rotation	U.S. Mfg., Becker	Stainless steel
3. Pretibial cuff	PROVIDES EXTENSION MOMENT IN STANCE PHASE. (UCLA Functional Long Leg Brace)	Prevents abduction-adduction	No significant function	Custom made	Plastic laminate
4. Hydraulic ankle joint assembly	PROVIDES EXTENSION MOMENT LATE IN STANCE PHASE BY RESISTING DORSIFLEXION. (UCLA Functional Long Leg Brace)	No significant function	No significant function	U.S. Mfg.	Aluminum, Stainless steel, Carbon steel
5. Knee joint, polycentric	PROVIDES EXTENSION MOMENT IN EARLY STANCE PHASE. Permits flexion-extension. Prevents hyperextension.	Prevents abduction-adduction	Prevents internal-external rotation	Becker, Otto Bock	Aluminum
6. Knee joint, single axis, free motion	Permits flexion-extension	Prevents abduction-adduction	Prevents internal-external rotation	Becker, Pope, U.S. Mfg., Otto Bock, Malco	Aluminum, Stainless steel, Carbon steel, Chrome Molybdenum

TABLE 2.—*VAPC - ADP Coding System for Artificial Limbs*

Lower-Extremity Prosthetics:		Upper-Extremity Prosthetics:	
Description	Columns required	Description	Columns required
Level	2	Level	2
Socket	2	Socket	2
Suspension	2	Control system	2
Knee	2	Elbow joints (and forearms[a])	2
Shank structure	1	Wrist	1
Foot-ankle	2	Terminal device	2

[a]All forearms plastic laminate.

Examples (prescription and code):

a. Below-knee prosthesis with a hard non-porous PTB socket with a foamed pad, standard cuff suspension, skeletal structure with cosmetic cover, standard SACH foot.
Code: 13–23–01–00–2–12

b. Above-knee prosthesis with a total-contact plastic laminate suction socket with hard end, S–N–S hydraulic unit, wood shank with plastic laminate finish, standard SACH foot.
Code: 15–46–16–72–4–12

c. Hip-disarticulation prosthesis, Canadian type with stride control latch, Bock Safety Knee, wood shank with plastic laminate finish, wood foot with single stem ankle.
Code: 16–56–26–37–4–01

Examples (prescription and code):

a. Below-elbow prosthesis with a thermoplastic socket, unilateral Figure-8 single-control harness, FM disconnect wrist, and Dorrance 555 hook.
Code: 23–11–11–00–2–44

b. Above-elbow prosthesis with a plastic laminate single wall non-porous socket, unilateral Figure-8 single-control harness, elbow with positive lock and forearm, standard friction wrist, APRL hook.
Code: 25–01–11–03–1–41

c. Shoulder-disarticulation prosthesis with plastic laminate socket with shoulder cap and adjustable friction bulkhead, unilateral scapular-abduction dual control w/shoulder elevation elbow lock, standard friction wrist, elbow with positive lock and forearm, APRL VC hand with glove.
Code: 26–51–21–03–1–13

especially those specifying structural or functional defects. These data, now being gathered in the VA Prosthetics Center clinical program, eventually can be accumulated for appropriate correlations by the Prosthetic and Sensory Aids Service of the VA on all patients fitted throughout the VA system.

THE NATURE OF THE MANUFACTURED HARDWARE STANDARD: SPECIFICS ON FUNCTION RATHER THAN DESIGN

The VA Prosthetics Center has been responsible for a long-term program to develop standards for hardware and prefabricated accessories. So far, standards for lift aids, wheelchairs, knee mechanisms (Fig. 6), foot-ankle assemblies (Fig. 7), stump socks, elastic hosiery, crutches, canes, and other related items have been employed. These standards, used for the manufacturers and their distributors, are purposely structured to avoid *channeling designs too rigidly or restricting improvements.* In all cases, standards are reviewed frequently to prevent them from inhibiting progress.

The VA's standards differ significantly from earlier forms in this field. The old ones were based on strength, durability, appearance, and general function, but the specifications defined the dimensions and the materials to be used. Functional requirements were only very broadly specified.

The new standards emphasize functional requirements. The precise materials, fabrication methods, and other mechanical design features are not specified except in isolated instances. Thus, a manufacturer could use any material in any form or size as long as functional (including structural) requirements are accommodated. This type of standard is less inhibiting yet provides adequate controls for patient welfare.

Another Government Laboratory, the Army Medical Biomechanical Research Laboratory (AMBRL) has taken the initiative in the development of a draft of functional standards for externally powered hands. Years ago, under its previous name, APRL, it did a similar job for body-powered mechanical hands and other upper-extremity components. The Veterans Administration is still applying these standards in its clinical program.

To follow the lead taken by AMBRL, the VA Prosthetics Center has reviewed a number of powered hands either commercially available or under development throughout the world as of the present date. Analyses based on laboratory investigations when possible or on available written material have been published (4). From these analyses, conclusions about the hands available and the developments now underway were formulated. A final standard for this group of items will now be developed by the VA Prosthetics Center in collaboration with the

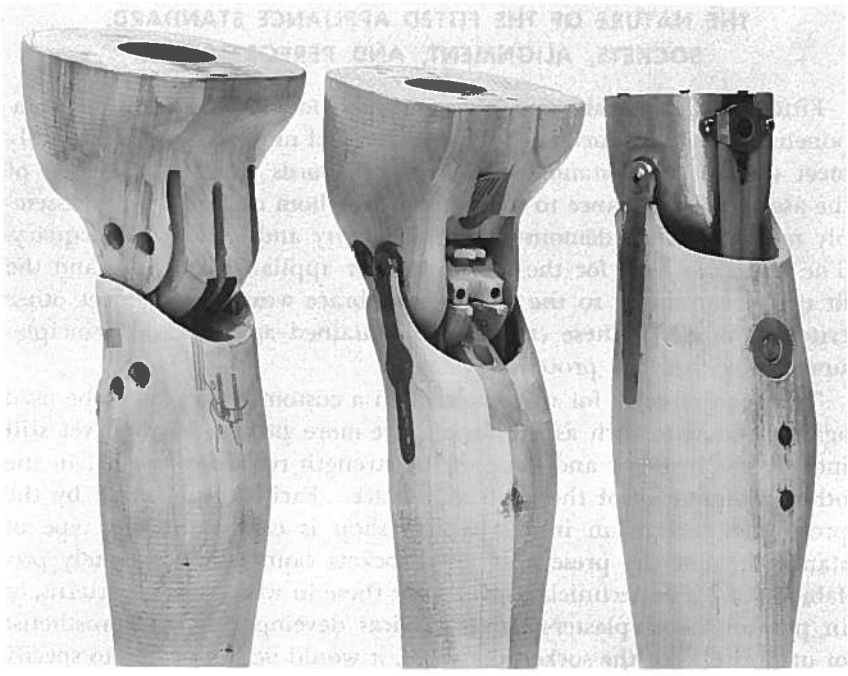


FIGURE 6.—Several prosthetic knee mechanisms of a class which includes joints providing a weight-bearing mechanical friction brake as well as a mechanical friction swing control.

National Research Council's Committee on Prosthetics Research and Development.

Future standards development will encompass orthotics hardware such as brace knee and ankle joints, shoe modifications, and components used for upper-extremity functional braces. The approach will be the same in that these standards will also be based on safety, durability, and function rather than design specifics.

FIGURE 7.—Several variations of prefabricated prosthetic feet on which the Veterans Administration has recently promulgated new standards.

THE NATURE OF THE FITTED APPLIANCE STANDARD: SOCKETS, ALIGNMENT, AND PERFORMANCE

Fitted artificial limbs and braces which include hardware and components already conforming to a VA standard must still as an assembly meet certain other standards. These standards cover relationship of the assembled appliance to the patient for whom designed. The assembly must of course demonstrate high quality and structural adequacy. The materials used for the socket and for appliance finishing and the fit of the appliance to the amputee or brace wearer must meet other criteria. Some of these criteria are contained as the basic principles underlying checkout procedures.

The requirements for the materials in a custom-fitted part to be used against the skin, such as the socket, are more process-oriented yet still include the hygienic and some of the strength requisites needed in the other components of the limb and brace. Facile employment by the prosthetics technician in the typical shop is critical in this type of standard. For the present at least, sockets cannot be completely prefabricated. The technician must form these in wood, using patterns, or in plastics, using plaster-of-paris replicas developed by the prosthetist or orthotist. For the socket, therefore, it would be impossible to specify any one material. Again only the "functional" specification is meaningful.

An example: "The material used for the socket must be easily formed using hand or ordinary power tools or heat. It must be such that it can be reformed with similar ease. It should be hygienic and not produce dermatological reaction. When used for the typical socket, it should be able to absorb the normal amount of loading without excess thickness and weight."

VA contracts have never fully covered all the specifics of complete appliance design. But at present VA is obtaining all information related to the complete limb or brace to specify criteria for fit, alignment, and performance. A new type of standards thus will be formed supporting the VA's artificial limb contract but also providing clinics with a prescription and checkout guide. In the future, standards for orthopedic brace contracts will be developed on this same basis.

The following represents some of the kind of information contained in the draft standard about one type of ischial-gluteal, quadrilateral above-knee socket:

"*Plastic Total-Contact Suction Socket.* This socket embodies all the principles of the UC-BL-type quadrilateral socket. It is constructed with rigid adherence to specific dimensional requirements, including the critical anterior-posterior distance between the apex of the rounded inner surface of the anterior-proximal wall and the inner surface of the

posterior-proximal wall. Intimate fit is essential and particular attention must be paid to reliefs for the hip abductor muscles, the tendons of the gluteus maximus, and for the bulging belly of the quadriceps group.

"The most significant element of this socket is its weight-bearing system in which the ischial tuberosity is positioned accurately to rest on the posterior wall of the socket approximately 1 in. lateral to the inner medial wall. This can only be achieved by maintaining the required anterior-posterior dimension. The socket is designed to distribute the entire body weight among the ischial tuberosity, the proximal inner surface of the socket, and to a lesser extent over the entire surface of the stump, including the distal end.

"The posterior wall is fabricated with a shelf at the level of the ischial tuberosity to provide ischial and gluteal support.

"The lateral wall of the above-knee socket is especially contoured to maintain the stump in approximately 5 to 10 deg. of adduction. This provides partial support of the body weight and stabilizes the pelvis by placing the adducted stump in a physiologically advantageous position (stretch of the abductors) to abduct and to prevent dropping of the pelvis on the opposite side.

"The anterior socket wall is maintained at approximately the same height as the lateral wall. The medial wall is at the level of the ischial tuberosity or level with the posterior wall in order to prevent contact with the ramus of the pubis. It is generally aligned vertically.

"The required close fit for the 'hard end' is produced by laminating the socket over a male cast of a plaster-of-paris wrap of the stump. The 'soft end' is produced by deliberately elongating the stump replica so that the laminated socket will have a void below the distal end of the stump. This void is filled with soft foam under weight-bearing conditions in order to provide the 'soft end' total-contact quadrilateral plastic socket.

"The plastic total-contact socket (hard or soft end) is ideal for suction suspension. Suspension of the prosthesis is achieved by negative pressures developed between stump and socket and also by muscular contraction. In swing phase the force of gravity tends to pull the socket off the stump. Due to the intimate fit, a partial vacuum is created in the distal end of the socket which offers resistance to the withdrawal of the stump. Together with increased pressures due to muscle contraction the socket remains suspended. In stance phase, pressure in excess of the optimum 1 to 1½ lb. per sq. in. may be developed. The 'suction' valve permits the air to escape from the distal end of the socket to prevent excessive pressure. The suction valve is placed in the anteromedial aspect of the socket to permit ready access for pulling the stump into the socket."

COMPLIANCE TESTING

After a standard with its specifics on required attributes and required test procedures has been established, a purchaser or the Government on behalf of all purchasers needs to employ "compliance testing" which not only further tests the standard itself in practice but determines whether products meet the purchaser's requirements.

Most assuredly, the specifics of the "fitted appliance" standard cannot be checked on a sample appliance in one central laboratory. Thus, the quality analysis or "compliance testing" required of artificial limbs and braces requires not only unusual laboratory test methods but daily clinical surveillances.

The evaluation and compliance testing against our type of functional hardware standard requires a sophisticated procedure which cannot normally be handled by manufacturers themselves or by any facility which does not have both the special laboratory equipment and the clinicians responsible for applications of prostheses and braces. Although representative samples of materials and mass-produced hardware can be so checked, atypical testing procedures and equipment (Fig. 8 and 9) are required nevertheless.

Moreover, proper fit and alignment of prostheses and braces can only be checked on and by each subject with his varying needs. The U.S. Veterans Administration and other agencies in the United States have

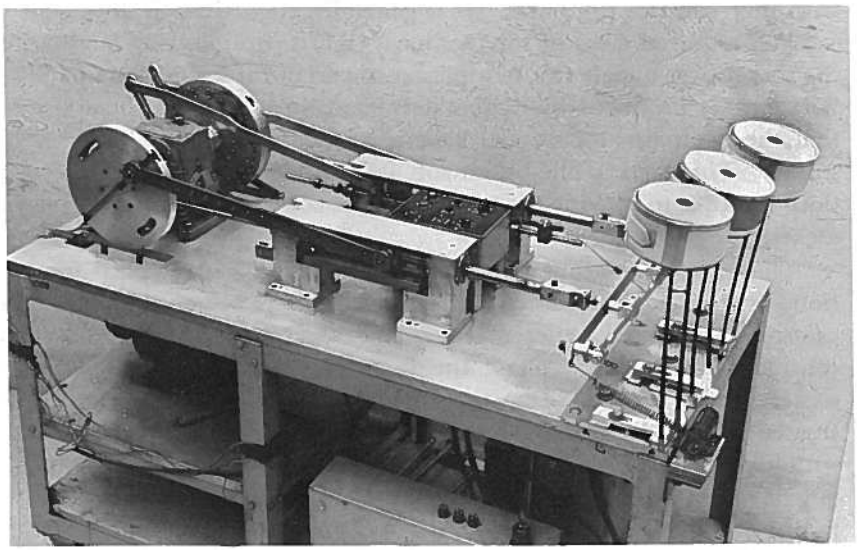


FIGURE 8.—A special cyclic testing machine originally designed by the United States Army Medical Biomechanical Research Laboratory and used by the VA Prosthetics Center for testing of various types of hardware, in this case, plastic braces for plantar-flexion control.

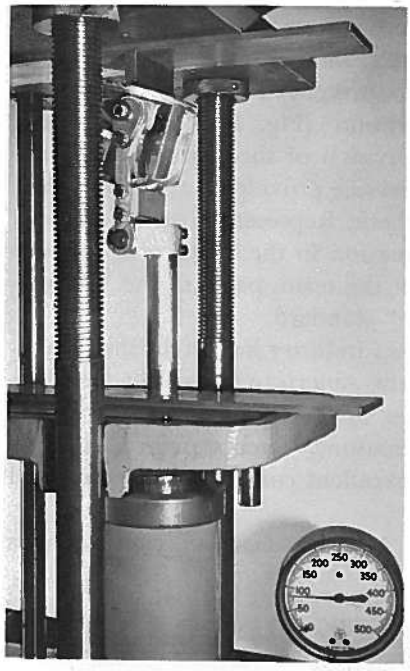


FIGURE 9.—A special test fixture for determining characteristics of mechanical stance-control prosthetic knee mechanisms.

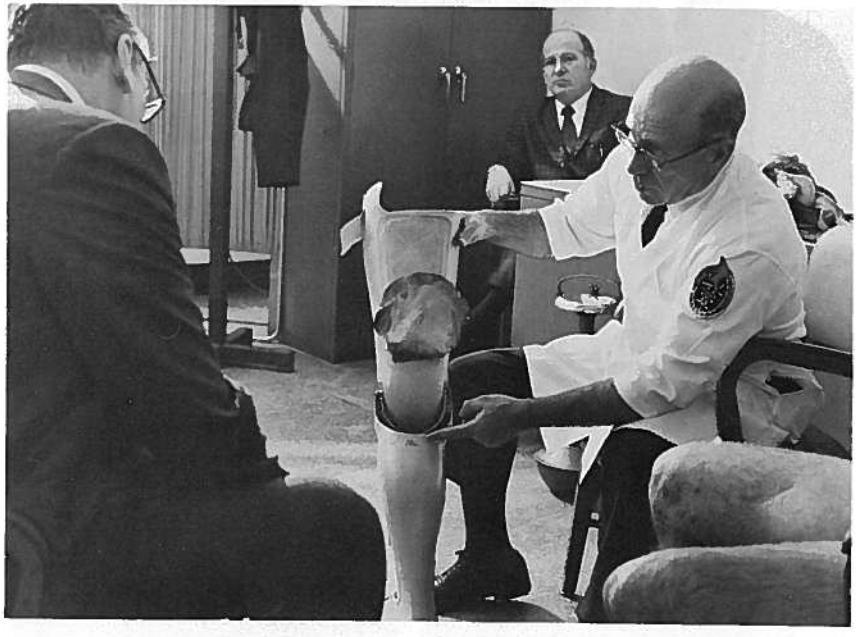


FIGURE 10.—Clinical inspection by a Veterans Administration Prosthetics-Orthotics Clinic Team. The surgeon, the prosthetist, the VA Prosthetic Representative, the physiotherapist, and others on the team evaluate quality, safety, and performance of each case with his own limb or brace.

a mechanism for doing this through clinic teams using established standards of quality developed by the University Prosthetics Education Program and the Veterans Administration (Fig. 10). Several years ago, the Research and Development Division of the Veterans Administration's Prosthetic and Sensory Aids Service provided a training course on checkout procedures for VA Prosthetic Representatives throughout the country. This in effect put information in the hands of those who would, with the patient and the rest of the team, perform the VA compliance testing of the "fitted appliance" standard.

The United States prosthetics-orthotics industry has established standards of quality for its fitters through the American Board for Certification (ABC) which qualifies candidates on the basis of both practical (Fig. 11) and written (Fig. 12) examinations. Such standards, applied to people and not devices, constitute excellent controls over fitting and alignment quality.

VA recognizes the substance of the ABC certification criteria and is

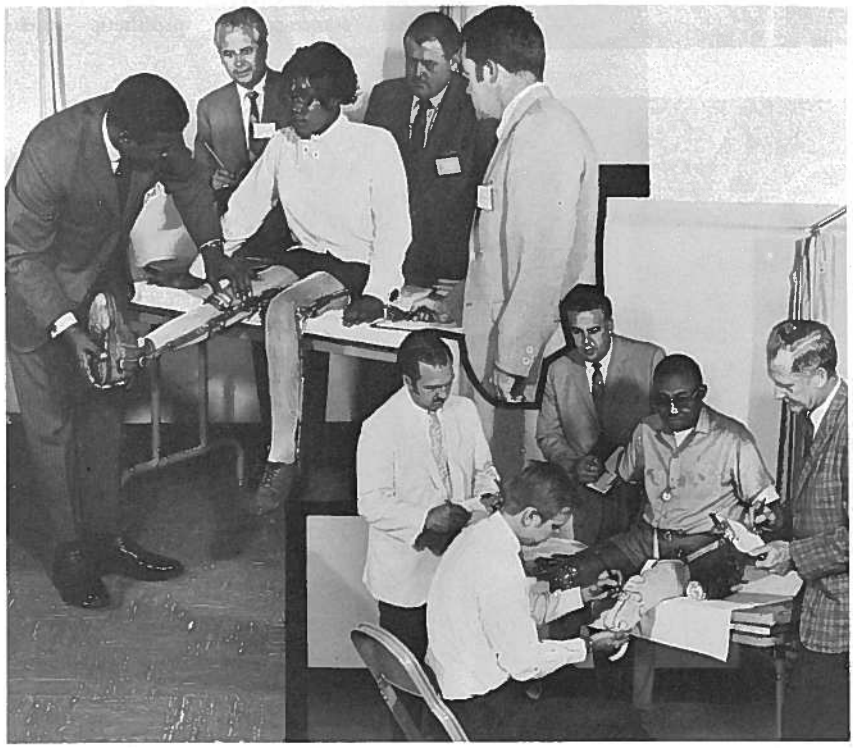


FIGURE 11.—Practical evaluations of candidate certifees during recent American Board for Certification examination.

FIGURE 12.—The application of written tests to ABC candidate certifees.

very dependent on them for quality of fitted appliances. Moreover, VA's contracts require education and training in the fitting and fabrication of certain appliances. This is an excellent form of standard. Certification alone is satisfactory, but there is need for upgrading standards since certification is temporarily based; that is, a certifee has met a standard at one particular time. But new things happen, situations change, and progress is made. Thus, there is need for a continual upgrading of a standard covering an individual. For this, VA employs requirements based on University Educational Programs.

CONCLUSION

We look on our VA standards development and application programs and the 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, the American Board for Certification, 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 and thus to the disabled of our country and of other nations. Manufacturers

cannot easily duplicate the unusual facilities available to us; nevertheless, they are free to submit all devices to us prior to mass production and sale. We should like the prosthetics-orthotics industry and the agencies which procure appliances to recognize this VA program . . . a service to all.

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