VAPC Research

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
Edward Peizer, Ph. D.
Chief, Bioengineering Research Service
VA Prosthetics Center, Veterans Administration
New York, N.Y. 10001

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).”
These studies are being continued in an effort to monitor pressures and pulse rates continuously in the hallux by means of a pressure pulsometer and strip chart recorder.

2. Work and Energy in Walking. As previously reported (BPR 10–6), a study has been undertaken to define in objective terms the relationships between energy expenditure and the mechanics of walking. Our initial effort was directed toward improving our understanding of how humans adapt their walking patterns to increases in speed with disproportionately lower increases in energy cost per meter walked, an apparent improvement in efficiency.

Bard et al. (2) have demonstrated that in walking at speeds between 50 and 125 meters per minute (approximately 2 to 4.7 m.p.h.) the curve of energy cost per meter walked is relatively flat. However, these data were expressed in terms of gross energy expenditure and our procedures require the use of net energy cost, that is, the actual energy consumed for the activity over and above the energy consumption at rest. The original studies were replicated employing other data collection methods and, of course, our own subjects.

Despite differences in procedure, gross energy costs per meter walked in a sample of six subjects were quite similar to those previously published (Fig. 2). It may be seen that both curves of gross energy cost indicate a dip or point of least energy consumption per meter walked at approximately 75–80 meters per minute (2.8–3.0 m.p.h.). More significantly, both curves show the relatively low increase in energy cost per meter walked at rates between 55 and 100 meters per minute (2.0–3.7 m.p.h.). Our data are also plotted in terms of net energy cost. The net values, of course, are lower than the gross values and the same
disproportionately low increase in energy cost per meter walked is shown. The resting rates of energy expenditure represent 48 percent of the gross cost in walking at 25 meters per minute (0.85 m.p.h.), 32 percent at 50 meters per minute (1.9 m.p.h.), 20 percent at 75 meters per minute (2.8 m.p.h.), and 26 percent at 100 meters per minute (3.7 m.p.h.).

A significant difference between the net and gross costs is the apparent downward shift in the speed at which walking consumes the minimum energy per meter walked. In terms of gross energy cost, the most efficient speed appeared to be approximately 75 meters per minute.

![Diagram](image)

**Figure 2.**—Comparison of gross energy costs between data published by Bard et al. (A) and VAPC (B). VAPC energy cost data reduced to net values (C) show a dip or point of minimum oxygen consumption per meter walked at a lower speed than the gross values.
in terms of net costs, the most efficient speed would seem to be approximately 53.6 meters per minute (2.0 m.p.h.), a figure more in keeping with that (2.2 m.p.h.) recently published by Elftman (3).

Additional studies are in progress to relate energy expenditure at various walking velocities to a series of physical and physiological variables on an expanded sample of 15 subjects. The number of variables is relatively large since this phase of the study is an attempt to relate gait characteristics at various speeds with "efficiency" as indicated by less-than-proportionate increases in energy consumption with increasing speeds. Depending on the outcome of these studies, a third phase will be undertaken to study the efficiency of walking when limitations are imposed on joint motion.

3. Sources for Control of Prosthetic Function. Conventional prostheses designed for both the upper and lower extremity are controlled by utilizing gross body motions, i.e., musculo-skeletal movement, as the primary source of energy.

The use of gross body motion has become conventionalized principally because simple mechanical devices can be actuated, great forces and relatively large excursions are available, and it is considered desirable to utilize residual joints to the fullest extent. Coupled with this is the still valid principle of drawing required forces and excursion in the case of unilaterals from the amputated side, leaving the unamputated side of the body unhampered by harnesses or other control devices.

These practices have adequately served the unilateral amputee with low level amputations. For higher level amputations and especially with bilaterals, these conventional systems become increasingly inadequate. Proper control of a conventional upper-extremity above-elbow prosthesis, for example, involves a minimum of three separate control motions: terminal device operation, elbow flexion and extension, and elbow locking and unlocking. The control of elbow locking and unlocking by a gross body motion (extension and abduction of the shoulder) creates serious problems with respect to appearance and terminal device displacement. Furthermore, other secondary functions such as wrist rotation, wrist flexion, and humeral rotation are controlled manually by the use of the sound hand or other objects in the immediate environment because the utilization of additional gross body motions would saturate the control capacity of the patient (gadget tolerance) or violate the principle of not involving the sound side.

As a result, other control sources are being sought to actuate these secondary functions in upper-extremity prostheses and to a lesser extent in lower-extremity prostheses. Other control sources under consideration are: fine body motions, "muscle bulges," and EMG signals.

Fine body motions have already been utilized in children's pros-
theses, for example where anomalous digits of phocomelic children are utilized to lock and unlock conventional prosthetic elbows. Other examples are seen in stump-actuated elbow locks and the utilization of extremely small stumps to actuate valves controlling the pneumatically powered Heidelberg Arm, the American Institute of Prosthetic Research (AIPR) system, and others.

Since muscle contraction (concentric) causes the shortening muscle to bulge, resulting in an increase in the diameter of the belly, attempts have been made to harness the relatively smaller motion at the surface of the skin to control prosthetic devices. Although work continues in this field, progress has been slow to date. Current work at New York University on the measurement of pressure between the stump and socket may also have application for control of prosthetic devices.

EMG signals, long studied as a means of controlling prosthetic components, represent perhaps the microscopic end of an energy production spectrum whose other extreme is gross body motion by which we tap the external work done by the limb segment although both muscle bulges and EMG activity are also present. The EMG signal represents the electrical effects of the biochemical changes which are the precursors of muscle bulges and overt limb motion.

A particularly provocative problem in lower-extremity prosthetics for above-knee amputees is the control of knee resistance in stance phase by means of EMG signals. Some work has already been done in this field. For example, at Mauch Laboratories feasibility of tapping the EMG activity of the major muscles to control the resistance of a knee mechanism during the heel contact to mid-stance portion of the gait cycle has been studied.

The Bio-Cybernetics Laboratory of the Philco Corporation has developed a system of "pattern recognition," an attempt to utilize the "pattern" of the electrical output of a group of muscles, which is unique for a specific task.

Professor Reswick at Case Institute is demonstrating the possibility for control purposes of utilizing a single muscle fiber which can be conditioned to produce graded EMG outputs.

The VA Prosthetics Center is developing a system to utilize muscles of the sound leg by means of surface electrodes without conditioning the raw EMG outputs. Several assumptions underlie this approach.

Systems in which the stump surface is the source of EMG control signals must consider the effects of shear, abrasion, and temperature change. Variability of contact at the interface between the stump surface and the inner surface of the socket remains a basic prosthetic fitting problem. Additional difficulties may be encountered in bringing leads out of the socket.

Systems which depend on single fiber EMG activity are limited to the
use of percutaneous or implanted electrodes, a practice of questionable utility.

Systems which depend on precise variability of the differential outputs of several muscles or on precise baseline values of EMG wave propagation velocities through a whole muscle, seem to us to rely too heavily on the inherent stability of the fundamental measures. From the physiological standpoint this is questionable since almost no familiar physiological phenomena particularly those involving muscle chemistry, are stable. Biochemical activity on the cell and on tissue level is in constant flux; metabolism is controlled by a highly sophisticated scheme of feedback loops in which the level of activity at any instant is a response to a homeostatic mechanism. There is no "stability"; there is only continual drift from, 2nd correction toward, optimum conditions.

The first step in the VAPC program is to investigate phase relationships between the electrical activity of muscle groups on the sound limb and the gait "events" on the prosthetic side, that is, heel contact, foot-flat, heel-off, and toe-off. Variations in EMG outputs of the gastrocnemius, quadriceps, hamstrings, and gluteus are being studied to determine if significant changes take place at appropriate times. If so, they might serve as control sources for increasing and decreasing the resistance to knee flexion of any conventional hydraulic knee mechanism such as the Henschke-Mauch HYDRAULIK Swing and Stance Control System, Model A and the Henschke-Mauch HYDRAULIK Swing Phase Control System, Model B or the Dupaco "Hermes" Hydraulic Control System. Control of this nature would be automatic, and since walking is a "bilateral" activity, the principle of non-involvement of the sound side would not be violated. Of course, the effect of unusual situations such as stumbling or walking on uneven terrain would also have to be considered.

This is essentially a "mapping" program to study the patterns of EMG activity of groups of muscles on the sound side which contribute to stance-phase control of knee function (Fig. 3). An underlying assumption is that the muscular activity (and EMG output) of the muscles on one side must be related to the activity of the other side at least with respect to phase. Thus, experimental procedures are in progress in which EMG outputs of gastrocnemius, quadriceps, hamstrings, and gluteus are being monitored on the sound side of an amputee while he walks with an above-knee prosthesis. Simultaneously, the following key gait "events" are also being monitored: 1. the instant of heel contact when the flexion moment at the knee is very low but beginning to increase rapidly; 2. foot-flat, a point when the flexion moment on the knee is approaching maximum; 3. mid-stance, when
the knee flexion moment is diminishing rapidly; and 4. heel-off, when the flexion moment has been reduced to zero and an extension moment is developing. The EMG outputs are being fed directly to an oscillograph to record variations in amplitude on the same time base as the stance-phase "events" are being recorded. The EMG outputs are also fed through the Scott amplifier whose components include two Schmidt triggers, each of which is actuated at different input amplitude thresholds. The instant of activation of each trigger is recorded on the common time base (Fig. 4).

A second step is being undertaken to develop circuitry and hardware to close and open valves of hydraulic knee mechanisms under the control of the EMG output. The final step will involve an evaluation of the utility of the entire system with respect to cost, functional gain, and reliability.
FIGURE 4.—Phase relationships among quadriceps EMG activity, reaction of Scott amplifier to two EMG thresholds, and stance-phase gait events. The quadriceps electrical activity is shown on the same time base as the key elements of stance phase for the left foot. For the right foot, the electrical activity of the right quadriceps is correlated in time with the gait events and in addition with the time when each Schmidt trigger of the Scott amplifier closed. Although not quantified, an obvious coincidence in time is shown in the activity of the quadriceps and heel contact and push-off.

B. Development (Components)

1. Adjustable Below-Knee Standard Prostheses. The below-knee standard prosthesis (BPR 10–6, pp. 230–232) has been modified to improve the method of socket attachment and detachment. Since a wide variety of socket materials is used, the socket attachment plate should be capable of attachment to plastic, wood, or plaster-of-Paris sockets by both bonding and screwing. In addition, the socket and plate, often laminated together to make a secure attachment, should be readily detachable.

A new socket attachment assembly was designed consisting of a linen base phenolic plate (Fig. 5). The center of the plate is bored and threaded to receive a threaded plug extending upward from the top plate of the alignment device. By means of setscrew holes in the
top plate, the alignment device can be attached to the phenolic socket attachment plate. Metal socket attachment straps may be secured by screws anywhere in the phenolic surface. When the socket attachment is completed, excess material may be contoured into the shape of the distal socket. An adaptation for immediate postsurgical prosthetic fitting has also been designed (Fig. 5).

![Figure 5](image)

**Figure 5.—The Adjustable BK Standard Prosthesis featuring an improved method of attaching and detaching the socket. On the left is the system for attachment of the socket in permanent or definitive prostheses. On the right is the special plate with disconnect used for immediate postsurgical fittings.**

Production drawings including both types of attachment plates have been completed; 100 units with accessories are being made by the PC Foundation, Inc., 197 Southwest Avenue, Kankakee, Illinois. A detailed instruction sheet illustrating functions and methods of application is also being prepared.

2. **Standard Above-Knee (Multiplex) Prostheses.** The design of the standard above-knee prosthesis has been altered to include phenolic socket attachment plates similar to those used on the standard below-knee prosthesis. In addition, a mechanical friction unit has been added which permits adjustment of the range of resistance offered to knee
rotation and variability of resistance during the swing phase (Fig. 6). The device consists of four split-ring segments of Delrin 500, each with an independent adjustment screw. All the friction rings are driven by a single component. To reduce noise, the driver is cushioned with elastic material. The driver rotates about the same center as the piston rod heads of any of the fluid control mechanisms for which this device is also designed. Shown in Figure 7 is the resistance curve produced by this unit. Limited clinical tests on the standard above-knee prosthesis are now being conducted. After production engineering, additional models will be fabricated.

3. Torque Absorber. After having been worn by four below-knee patients, the torque absorber (BPR 10–6, p. 233) is being extensively redesigned. As a result of these experiences, the resistance characteristics have been increased from 2 in.-lb. (2.3 cm. kg.) per degree of rotation to 6 in.-lb. (6.9 cm. kg.) per degree. The new design utilizes the Lamiflex bearing in a cylindrical housing about a vertical tube or pylon base (Fig. 8). The ankle attachment plug fits within the inner bearing. The pylon tube fits over the outer bearing. The new design also incorporates means for adjusting the ranges of rotation. Twelve units are now available for evaluation purposes.

4. Cosmetic Covers. Standard cosmetic covers to be used with pylon prostheses are being produced for field studies in Veterans Administration facilities. The below-knee covers (Fig. 9), fabricated of vinyl, are heavier at the ankle; wall thickness gradually becomes thinner and the cover more elastic at the top. The ankle section of the cover up to the calf area is relatively stiff in order to retain its shape over the pylon. When heated, the material softens and may be stretched over the upper socket to take the contour of the underlying structure. The below-knee covers have a slightly lower-than-normal calf contour to fit over the socket bottom without distortion and to facilitate alignment.
Figure 7.—The knee angular resistance characteristics of the AK Standard Prosthesis mechanical friction unit at one setting and at one velocity.

changes. The upper border of the cosmetic cover is held to the top of the socket by double sided adhesive tape. The covers are fabricated in three sizes—small, medium, and large. Efforts are also being made to standardize the size of all SACH foot-ankle bases and pylon foot-attachment sections.
C. Development (Techniques)

1. Direct Forming of Below-Knee Sockets. The use of Polysar, a rubber-like synthetic, extruded in tubes, to form lower-extremity sockets directly upon amputation stumps, was described in the previous issue of this Bulletin. In the current technique, the heated Polysar tube is formed over the stump by controlled compression applied by a pneumatic sleeve (BPR 10–3, p. 114). Shape retention and creep resistance under wear conditions at room temperatures appear adequate. The results of laboratory tests to date on strength and creep resistance are shown in Figures 10 and 11. Also shown are results of applying a 4-lb. static load to a specimen of Polysar for 10 minutes at constant temperatures ranging from 80 deg. F. to 130 deg. F. Creep appears to be negligible at temperatures up to 120 deg. F. (Fig. 10). The samples deformed upon application of the load but “creep” thereafter was negligible. However, the pattern of elongation was quite different at 130 deg. F. After initial deformation, the samples “crept” steadily during the first eight minutes of the 10-minute period under load and then began to level off. Creep added approximately 30 percent to the initial elongation. Maximum elongation was only .1 in. over the entire
3-in. sample or an elongation of approximately 3 percent. It would seem that the material has minimal creep under these loads at temperatures up to 120 deg. F. Beyond that, higher creep values give it marginal utility. After removal of the load, the material tended to return to its original length. Its memory, however, is such that it does not return to the preloaded length but rather to approximately half of the original length up to 110 deg. F. and to less than half the original length at higher temperatures.

Figure 10.—Elongation of Polysar samples under load at six temperatures for 10 minutes. After the 4-lb. load is applied for 10 minutes, the load is removed.

Figure 11.—Elongation of Polysar 3 in. tubing under a 200-lb. load for 10 minutes and immediately afterwards when the load is removed.

Figure 11 shows the results of a test designed to simulate the worst conditions under which a socket of Polysar rather than a flat sample might be used. At temperatures between 80 deg. F. and 100 deg. F. a 200-lb. static load increased the length of a circumferential section of a Polysar cone (truncated) a maximum of 2 percent. At 100 deg. F.
initial elongation was 1.7 percent; "creep" during a 10-minute period of load bearing was another .3 percent. After removal of the load, no changes took place indicating a lack of memory; i.e., the deformation was permanent.

At 110 deg. F. the material elongated 1.6 percent immediately after the load was applied. In the next 10 minutes it "crept" an additional 2.5 percent with no further effects when the load was removed.

These data seem to cast doubt on the utility of sockets made of Polysar when used in ambient temperatures above 100 deg. F. However, in actual use only intermittent loads are applied and while the exterior surface of the socket may possibly reach 110 deg. F., it would seem impossible for the interior surface of the socket to exceed 100 deg. F. Thus, the behavior of Polysar in actual use may prove more adequate. Of course, tubes with thicker walls may be used or the material may be externally reinforced. Neither procedure is desirable since flexibility may be reduced.

To obtain experience in both below-knee and above-knee applications, four patients have been fitted with sockets made of Polysar. Two below-knee sockets were formed directly on stumps under pneumatic pressure. One of these was fitted with a thigh corset. Two above-knee amputees were fitted with sockets fabricated by molding a heated tube of Polysar over a cast of the stump. One of these was also fitted with a pelvic belt. To date, the fastenings for the hip joints and the knee joints were adequately retained in the Polysar.

In the more highly developed below-knee socket forming techniques, the stump is prepared with the appropriate number of cast socks. A plaster-of-Paris cap is formed over the distal contours of the stump. The cap forms a space in the distal socket for the introduction of foam beneath the stump end in the final socket. It also forms a protective shield over the stump end to prevent the extrusion of tissues distally when forming the socket under pneumatic pressures directly upon the stump. The cap acts as an extension of the tibial crestline distal to the stump end and forms a relief for the cut end of the tibia. A tubular section of Polysar material of a diameter to fit easily over the stump end is immersed in water heated to a temperature of 180 deg. F. When softened, the material is pulled up over the entire stump above the patella. The pneumatic sleeve is applied over the Polysar-covered stump and inflated to a pressure of 2 lb. per sq. in. (.1406 kg./cm.²). No attempts are made to modify the stump shape by deformation or build-ups.

The socket, so formed, has a minimal patellar tendon contour. However, if a more defined contour is desired later, the area may be heated and remolded. Control of forming pressures results in highly repro-
ducible sockets (Fig. 12). Work with this material continues to evaluate its properties and to improve the direct forming techniques. At the same time, a manual detailing the techniques is being prepared for the Committee on Prosthetics Research and Development. A method for directly forming an above-knee socket utilizing the VAPC casting stand and casting brims is under development.

**FIGURE 12.**—Patellar-tendon-bearing BK socket of Polysar formed directly on the stump of a patient. Minor adjustments in socket and shape are readily made by reheating and reforming. Wrinkling shown occurs only on external socket surface which is covered with a cosmetic cover.

**FIGURE 13.**—UC-BL Pneumatic Swing Control Unit installed in the aluminum shank designed to receive a cosmetic cover.
D. Evaluation (Components)

1. UC-BL Pneumatic AK Swing Control System. Following laboratory testing (BPR 10-6, p. 234), six test subjects were fitted with this device in the clinical portion of the evaluation program. Initial patient reaction has been favorable as regards the functional characteristics of this unit. Among six units presently being worn, one failure has been recorded: the lower attachment of the pneumatic unit pulled out of the wooden shank.

As a result of several similar failures elsewhere, the developer has replaced two of the original wood shanks with cast aluminum shanks which are designed to accept foam covers (Fig. 13).

The piston rod and piston seals have been replaced by hard anodized aluminum rods with Oilite bronze bearings and Quad-Ring piston rod seals. Production drawings have been prepared to permit the procurement of test models for a VA field test.

2. Wagner Above-Knee Assembly (#319). This unit (Fig. 14), a simple mechanical friction device, features a single anterior adjustment screw which forces a hardwood segment against the knee bolt to provide adjustable mechanical friction that is constant throughout the swing phase. It also features a plated steel bar 4½ in. (11.4 cm.) long which serves as the adjustable extension stop for the posterior knee bumper made of felt. The position of this bar, adjusted by means of a screw attached to the anterior wall of the shank, controls the hyperextension attitude of the knee.

No significant deficiencies in the function of this unit were observed during the mechanical test program. It provides relatively low resistance to knee rotation, similar to other mechanical friction devices currently in use.

3. Teufel Protective Nylon Sheath. Evaluation of the Teufel protective nylon sheath indicates that this item may aid in reducing abrasions especially on sensitive stumps. Two subjects who wore the Teufel sheath felt that it minimized skin abrasion which usually occurred during times of high humidity. In other tests a relatively strong preference for the sheath was expressed by six of eight subjects. Shrinkage was negligible.

Since then we have undertaken a broader evaluation of this item through our Prosthetic Representatives in the field.

4. Hosmer Above-Knee Pylon. Ten units were received from the A. J. Hosmer Corporation, Campbell, California, for analysis of design, function, and clinical application.
This device (Fig. 15), a modified version of several previous models which have undergone evaluation, is a pylon with a foot attachment section which permits angular adjustment and a knee mechanism section which permits linear adjustment.

The foot attachment section consists of a steel bolt which connects the distal end of the pylon to the foot. The bolt head is anchored within a slotted section of a flanged fitting. This design permits angular displacements up to 6 deg. in the foot/shank attitude; however, adjustment is limited to a single selected plane. The tubing is constructed of aluminum 1.625 in. (4.13 cm.) O.D. × 1.509 in. (3.83 cm.) I.D., having a .058 in. (1.47 mm.) wall thickness. At the distal end the tube houses a flanged ankle bolt fitting that is expanded and locked against the inner wall of the tubing when the ankle bolt is tightened. The proximal end of the tube is slotted and fastened to the knee bolt housing by a “Hy-Gear” hose clamp. The tubing may be cut to any desired length.

The knee mechanism is a split cast aluminum housing, tightened about the knee bolt by an allen screw. Loosening the allen screw permits 7/2 in. (2.22 cm.) medial-lateral linear displacement of the socket attachment plate from center.

The friction assembly consists of an aluminum cylinder, inside of which is contained the internal friction mechanism. Friction is adjusted...
Figure 15.—Hosmer AK Pylon. This unit permits linear and angular adjustments and features a manual spring-loaded knee lock.

by means of a hex key. Both ends of the cylinder contain sealed ball bearings that are fitted in the center shaft and held in place by “Tru-Arc” rings.

The knee plate and bolt support bracket are constructed of cast aluminum. The lateral and medial sides extend downward and support the knee bolt by means of two 9/8 in. (9.5 mm.) \( \times \) 24 lock screws. The anterior section of the plate incorporates a manually operated spring-loaded lock. The plunger pin engages the forward surface of the knee bolt housing and locks the knee/shank at full extension.

The socket attachment assembly, consisting of an aluminum plate and four socket attachment stops, is attached to the knee plate and support bracket by four machine screws. The perforated steel straps are 3/4 in. (1.9 cm.) wide \( \times \) 12 in. (30.5 cm.) long. The socket is placed within these straps which are easily bent to the required shape.

The device is designed for immediate postsurgical and/or temporary use. It is not recommended as a definitive or permanent prosthesis since it does not permit anterior-posterior linear adjustment which may be required to provide correct alignment of the anatomical and mechanical joints. The foot attachment section permits adjustment in only one plane. It does not permit adjustment of the foot at a composite angle to the sagittal and frontal planes. The direction of the adjustment depends on the position of a slotted spherical component; if foot attitude adjustment is required in another direction, the entire foot attachment section must be loosened and rotated 90 deg.

Several minor deficiencies have been brought to the attention of the manufacturer.
II. UPPER EXTREMITY PROSTHETICS

A. Development

Humeral Rotator. In bilateral applications of above-elbow prostheses access to the midline of the body is limited and horizontal rotation of the terminal device is achieved only by gross body translation. Some of the problem is alleviated by the use of wrist flexion units and elbow turntables both of which are "passive," that is, they must be positioned by pushing against some object. By providing powered humeral rotation it may be possible to achieve greater access to the body midline and convenient horizontal positioning of the terminal device with minimal body motion.

To test the utility of providing humeral rotation in arm prostheses, a laboratory model of a "humeral rotator" was designed (Fig. 16). Rotation is controlled by means of two double-throw shear switches which are built into the wall of the socket and remain in contact with the stump (Fig. 17). The two switches control an "and" circuit, that is, when the stump is rotated axially both switches must be activated in the direction of rotation to activate the elbow. This reduces the chance of accidental activation due to any motion of the stump other than rotation in the transverse plane. Twenty-seven rechargeable double-plate nickel-cadmium batteries provide operating power to a miniature electric motor that rotates the elbow turntable. The unit can also be manually rotated. The rotator is attached to the socket in the standard manner with a knurled laminating ring.

Laboratory tests are in progress to determine the effect of active humeral rotation on the performance of tasks.

B. Evaluation (Components)

AIPR (American Institute for Prosthetic Research) Externally Powered Components. As reported in BPR 10-6, we have completed all of the originally planned experimental steps in this program. We are currently engaged in reestablishing baseline conditions by refitting the test subject bilaterally with the conventional prostheses similar to the ones with which he was initially fitted. At the end of a suitable wear period, the subject will be reevaluated and a complete final report rendered.

Preliminary interpretation of the data indicates that the conventional upper-extremity testing evaluation program, that is, those standardized test procedures that have been used in the past to evaluate conventional, body-powered, upper-extremity components, are not sen-
sitive enough to discriminate certain significant differences between conventional and externally powered systems. For example, the comparative data collected to date on performance with both conventional and AIPR components do not reveal significant differences in the subject’s ability to perform standard prehension and positioning tests. The use of the AIPR system permitted him to perform four additional practical activities which he was unable to perform with the conventional, not a significant numerical increase. Nevertheless, on the basis of other factors, the patient is far better served with the AIPR system than with the conventional.

The superiority of the AIPR system over the conventional lies in:

a. the significance of the four additional activities, not their number; and
b. a sharp reduction in the number of operations required to perform a task (Fig. 18). One of the four tasks the patient was able to perform with the AIPR system which he could not perform with the conventional, was to operate the zipper on his trousers. Being able to urinate without assistance permitted him to travel and use public facilities without an attendant. This capability was directly due to the active elbow extension and the higher pinch force available in the AIPR components.

With the AIPR components he could position a telephone properly with the receiver at the ear, a task he found extremely difficult with
the conventional. This activity opened a new area of communication to him for which he previously required assistance. This capability was attributed to the four-way shoulder joint, powered wrist, and higher pinch force of the AIPR system.

He was also able to drink from any type of cup, a function for which he previously required a special plastic cup with a flat section in the handle. This enabled him to eat in restaurants independently, again widening the extent of travel and the facilities available to him. This capability was attributed principally to the higher pinch force available in the AIPR system.

An additional capability, impossible with the conventional system, was locking and unlocking doors, a function made possible by the powered wrist rotation.

An analysis of the operational sequence required to perform all tasks with the conventional and with the AIPR system demonstrated a dramatic reduction in the number of discrete operations required with the AIPR system. For example, as shown in Figure 18, shaving with the conventional system required twenty-five sequential operations, while the same task with the AIPR system required nine. Thus, the subjectively noted, independently observed, “improved ease of operation” was corroborated by an analysis of the operational sequence required with each system.

It would appear then that the few additional tasks which became possible with the AIPR system were highly significant in broadening the range of independent activity available to the subject.

C. Evaluation (Techniques)

Direct Forming of Below-Elbow Sockets. The development of Polysar for direct forming of below-elbow sockets has advanced to a point where sockets are now being fitted to amputees on a routine basis in the Prosthetics and Orthotics Service of this Center. Preliminary findings indicate that the material is easily reshaped at any time. The sockets maintain their shape (see section I.C.1.) under ordinary wear conditions, and accessories fastened by means of rivets are adequately retained. The program will be accelerated, and if the promise of the Polysar cast material is fulfilled over the next series of fittings, it will be expanded to include other facilities and larger numbers of patients.
OPERATIONAL ANALYSIS (SHAVING WITH ELECTRIC RAZOR)

**FIGURE 18.**—Comparison of the sequential operations necessary for shaving using the AIPR system and the “conventional” system.

### III. LOWER-EXTREMITY ORTHOTICS

#### A. Development

None.

#### B. Evaluation (Components)

*VAPC Single-Bar Ankle Brace.* The developmental model (Fig. 19) of this device consists of a calf band, a lateral spring-loaded round sidebar (permitting axial displacement, slight inversion-eversion, transverse rotation of the foot), and a 90-deg. plantar flexion stop. For evaluation purposes, a 44-year-old, 147-lb. (67 kg.), 5-ft. 3-in. (160 cm.) veteran was fitted bilaterally with these braces. He was also furnishled VAPC orthopedic shoes fitted with sponge innersoles, soft heels, and metatarsal bars.

His bilateral drop-foot condition, resulting from flaccidity of the muscles controlling the ankle, was characterized by inability to dorsiflex the ankle or to invert or evert the foot. The trauma developed as a sequel to a laminectomy in February 1963.

He had previously worn bilateral conventional ankle braces from
FIGURE 19.—A spring-loaded telescoping section of the single-bar ankle brace. This unit prevents the calf band from shifting during locomotion.

June 1963 to December 1966. These braces were fitted with 90 deg. plantar flexion stops, metatarsal bars, and orthopedic shoes with Levy arch support inserts.

He has been wearing the developmental braces 10 to 12 hours daily for a period of approximately 45 days. He is not a highly active person and at the present time attends school.

The patient was interviewed to record his experiences and reactions to the wear of both old and new braces. In addition, his gait was evaluated by standard subjective evaluation procedures and by objective analyses of temporal, kinematic, and kinetic gait factors.

Analysis of the specific comments made by the subject indicated a strong preference for the developmental braces. He preferred them because they felt lighter, were more comfortable and permitted him to walk better. Specifically, comfort was improved by reducing pain in the arch area and on calloused areas of the big toe. The calf bands did not slide up and down in the new ankle braces as the old ones did. In the absence of medial bars, he did not strike one against the other as he did with the old ankle braces.

Subjective gait evaluation procedures indicated two specific improvements in walking with the new braces. Hip abduction was reduced slightly; symmetry was slightly improved in that toe-out was equal
 although excessive (15 deg.) with the new braces as against toe-out of 13 deg. and 10 deg. for right and left feet respectively with the old braces.

Biomechanical analyses indicated improvements in gait factors related to security and stability, reduction of abnormality, and smoother transition from heel contact to toe-off. Forceplate recordings showed a smoother application of body weight through the leg, a factor generally indicative of increased stability, security, or more adequate absorption of loading through the soft heel.

Other improvements noted with the new braces were a reduction in the width of the walking base from an average of 3.6 in. (9.1 cm.) to 2.6 in. (6.6 cm.) and an increase in stride length (heel contact to heel contact on the same leg) from an average of 41 to 46 in. (104 to 117 cm.). In addition, the new braces at 4½ lb. (2.04 kg.) a pair were 1 lb. (.45 kg.) lighter than the conventional pair.

In summary, the results of this analysis indicate improvements in patient comfort due primarily to lighter weight, absence of medial sidebars, and to the axial displacement and transverse rotation inherent in the brace configuration. In addition, the performance with the developmental braces was characterized by a narrower walking base, longer stride length, more normal weight bearing, and smoother weight application.

The subject is being refitted with braces consisting of the developmental sidebar assembly and his previously worn orthopedic shoes to discriminate the differential effects of each major component.

IV. ORTHOPEDIC AIDS

A. Development

Spence-gel Foot Appliance. Spence-gel is a silicone formulation with extremely high capacity for absorbing applied loads. It is a stable, chemically inert gel having the consistency of human fat tissue. It is produced by the Dow Corning Corporation for the Stryker Corporation, Kalamazoo, Michigan, the licensee, under a patent held by Dr. Wayman Spence.

The material is currently being marketed principally in the form of wheelchair cushions but other applications are also being considered by the Stryker Corporation and others. The material was obtained in thin sections, 1/4 in. (6.4 mm.), for use in foot appliances designed to reduce plantar discomfort and callous.

The first foot appliance simply consisted of a full innersole fabricated of Corfam containing a 1/8-in. (3.2 mm.) thick sheet of Spence-gel. In this construction, the Spence-gel was displaced to non-weight-bearing
areas of the foot under load. Subsequently, the innersoles were fabricated with specially designed compartments to contain \( \frac{1}{4} \)-in. (6.4 mm.) thick sheets of Spence-gel in the areas of the heel pad and longitudinal and transverse arches (Fig. 20). Two subjects have been wearing the compartmentalized Spence-gel foot appliances for approximately 3 months with rather dramatic results in one case and clearly positive results in the other.

One subject reported complete relief of uncomfortable pressures under the third metatarsal head. He also reported no discomfort previously experienced at the heel and the longitudinal arch. More significantly, he reported a sharp reduction in the frequency of his visits to his podiatrist to pare callouses under the third metatarsal head, a procedure he underwent every 2 weeks before using the Spence-gel foot appliance.

The second subject previously wore Schaeffer combination arch supports with two longitudinal steel shanks and a high metatarsal elevation. During the 3 months the patient has worn the Spence-gel foot appliance, he has reported a substantial reduction in discomfort on the plantar surface of the foot. During this period, no significant change in the area or growth of the previous callouses was noted.

The material has been in short supply. As it becomes increasingly available, this study will be continued.
B. Evaluation (Components)

Stryker Floatation Pad Field Study. A limited field study has been undertaken to evaluate the utility of the Stryker Floatation Pad, a 16-in. (41 cm.) square, 3/8-in. (1.6 cm.) thick wheelchair pad filled with Spence-gel. It is manufactured by the Stryker Corporation, Kalamazoo, Michigan. Among the claims made for this device are the prevention of decubitus ulcers and relief of pain and discomfort in the buttocks.

Five subjects who participated in this study used the Stryker Floatation Pad for periods of 1 to 4 months. As summarized in Table 1, all of these subjects were unable to sit up as a result of incipient or chronic sores.

All subjects used their respective pads 24 hours a day. One subject, previously unable to tolerate sitting without tissue breakdown, now sits for periods up to four hours. The other four patients were not only able to resume sitting schedules but to sit for longer periods than previously. One of these subjects developed a small ulcer due, in the opinion of the attending physician, to sitting on a wrinkled pajama or cushion-cover. The skin of the other four subjects showed marked signs of improvement.

A number of reports received from other sources generally substantiated these findings. An analysis of all the findings indicates:

a. There is no evidence to indicate that active out-patients need or want the Stryker Floatation Pad. There is some evidence to indicate that patients with clear histories of and high susceptibility to ulceration can benefit from using the pad either as a preventive or an ameliorative procedure.

b. There are clear indications that a high fraction of patients who are confined to beds and unable to sit up because of excessive susceptibility to ulceration may be able to sit up for significantly longer periods on the Stryker Floatation Pad. However, furnishing the Stryker Floatation Pad should be a matter of medical prescription.

Studies of the utility of the Stryker Floatation Pad are being continued in an analysis of the relative merits of several similar devices.

C. Evaluation (Techniques)

None.
TABLE 1.—Description of Subjects Participating in Clinical Evaluation of Stryker Floatation Pad

<table>
<thead>
<tr>
<th>Subject</th>
<th>Disability</th>
<th>Initial status</th>
<th>30 day followup</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Quadriparietic</td>
<td>No ulcers—history of sores</td>
<td>Sore developed—sits 4 hours daily</td>
</tr>
<tr>
<td>(2)</td>
<td>Paraplegic (T-8)</td>
<td>No ulcers—history of sores</td>
<td>Skin improved—sitting increased 3 1/2 hours daily</td>
</tr>
<tr>
<td>(3)</td>
<td>Paraplegic (T-10)</td>
<td>Sacral ulcer—unhealed since 1965</td>
<td>Surgical closure and healing—sits 15 hours daily</td>
</tr>
<tr>
<td>(4)</td>
<td>Paraplegic (T-8)</td>
<td>Slow healing ulcer since 1966</td>
<td>Healing and resumed sitting 15 hours daily</td>
</tr>
<tr>
<td>(5)</td>
<td>Generalized weakness (MS)</td>
<td>Two severely discolored areas</td>
<td>One spot healed, other improved—increased length of sitting intervals 3–5 hours daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On Gurney full time</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>On Gurney 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>On Gurney 1–2 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>On Gurney 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bedrest—1 week</td>
<td></td>
</tr>
</tbody>
</table>
V. TESTING

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

As one of the largest consumers of manufactured goods in this country, the United States government annually disburses billions of dollars through its many agencies. Procurement of this vast array of products is governed by official standards and specifications established to control the quality of these products. Setting standards too low, or too loosely specifying requirements, can lead to staggering fiscal wastes or chaotic conditions at the point of final consumption. The system for establishing standards and specifying requirements is a vital function whose benefits in the field of prosthetics and orthotics have been described at length by the late Otto Rothman (4). Standards refer to a quality or a value which represents a desired goal or condition; specifications relate to the attributes required to attain a standard. A test procedure 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 knee mechanism is that it provide a normal range of knee rotation. The related specification would require that the knee rotate through a minimum of 120 deg.

Charged with these responsibilities, the VA Prosthetics Center has been engaged in a long term program to develop standards and specifications for SACH feet, lift aids, wheelchairs, knee mechanisms, foot-ankle assemblies, stump socks, elastic hosiery, crutches and canes, and other related items. The outcomes expected of this program are: 1. economies in spending; 2. minimum standards of patient treatment; and 3. valid guidelines for prescription of devices, and training and evaluation of patients. Since its inception, the program has produced standards for the SACH foot and for lift aids which are currently in use by Supply Service. More recently, standards for wheelchairs are currently being evaluated.

These standards differ significantly from earlier forms in this field. The old ones were also based on strength, durability, appearance, and general function. But the specifications used in these standards primarily defined the strength and dimensional requirements of materials. Functional requirements were very broadly specified.

In the development of new standards, functional requirements are emphasized. Materials, fabrication methods, and other mechanical design features are not specified except in very few instances. An example of this change may be seen by comparing the following two excerpts from the old and the new lift aid specifications.
The development of functional standards for knees and feet has proved to be an even more complex task than the rather difficult one encountered in lift aids and wheelchairs. Knee mechanisms are not only more complex, but more critical for patient functioning than are wheelchairs. Prosthetic and orthotic devices are attempts to replace body segments, while lift aids and wheelchairs are machines which act on, or are acted upon, by the patient without becoming part of his structure. Consequently, the specific properties of knee mechanisms and/or feet are apt to have far greater influence over patient performance than those of wheelchairs. Another difficulty is the profusion of knee mechanisms and feet available today and worn by large numbers of patients. The quality of these devices and the functions they provide vary extensively, yet they apparently perform useful service since patients continue to wear the whole array.

The problem thus posed is one of establishing standards related to ideal function while recognizing the realities of present practice. This outline of the proposed functional standards for knee mechanisms and foot-ankle assemblies is presented to familiarize the field with them since in the near future they will be included in VA procurement contracts.

**Knee Mechanisms.**

The scope of the standard for above-knee knee-shank assemblies may be stated simply: it should relate to prosthetic knee mechanisms for use by adult, above-knee amputees. The knee-shank assembly, a component of above-knee artificial limbs, provides motion simulating the function of a normal human knee. Before the functions derived from human performance can be meaningfully specified as requirements for prosthetic knee mechanisms, descriptive and functional terms must be standardized. The following definitions were devised for this purpose.

1. **Knee Rotation.** The angular motion about the knee joint or relative motion between knee block and shank. That portion of knee rotation in which the angle inside the joint formed by the knee block and the shank is diminishing, is termed positive rotation or flexion. Motion in which the angle is increasing is called negative rotation or extension.

2. **Swing Phase.** The portion of the gait cycle in which the reference leg is not in contact with the ground.
3. **Swing-Phase Controls.** Devices which provide resistance in order to control angular velocity and/or acceleration of knee rotation. Included are mechanical and fluid resistance mechanisms.

4. **Extension Bias Controls.** Devices which provide a force to facilitate active negative rotation of the knee (extension). They may be internal, that is, integral components of the knee mechanism, or externally applied devices.

5. **Adjustable Resistance.** The capacity for presetting the magnitude of resistance to knee rotation at any of several prescribed levels.

6. **Constant Resistance.** The characteristic resistance pattern provided by a swing-control mechanism in which its magnitude remains relatively constant throughout the swing phase independently of angular velocity or time.

7. **Variable Resistance.** Variation at any preset level of the resistance to knee rotation as a function of angular position of knee rotation.

8. **Cadence Response.** Variation in resistance to knee rotation at any preset resistance level as a function of angular velocity.

9. **Independent Adjustment of Resistance to Flexion/Extension.** The capacity for altering the ratio of the resistances to positive and negative rotation.

10. **Stance Phase.** The portion of the gait cycle in which any part of the reference leg is in contact with the ground.

11. **Knee Moment.** The product of the force tending to produce knee rotation, and the perpendicular distance from the line of action of that force to the center of knee rotation.

12. **Knee Lock.** A mechanism which prevents rotation at the knee joint in stance phase. Automatic knee locks operate cyclically under the control of applied loads, inertia, or other forces to prevent positive knee rotation. Manual knee locks are non-cyclical in that, once engaged, they prevent knee rotation until disengaged manually.

13. **Yielding Resistance in Stance Phase.** A higher degree of resistance to positive knee rotation than normally available designed to reduce the rate of knee rotation under load.

14. **Polycentric Joint.** A mechanism whose instantaneous center of rotation displaces posteriorly to decrease positive knee moment during stance phase.

15. **Correlated Knee and Ankle.** A mechanism in which knee and ankle motion are coupled; motion of one is accompanied by motion of the other.

The work on knee standards has progressed to the point where a rational system has been devised under which may be classified the large number of knee mechanisms currently on VA contract and several which are now being evaluated and may soon be on contract. There are at the present time 17 knee mechanisms on contract and 7 others cur-
rently undergoing evaluation. They range from the simple to the complex: some permit a range of motion about the knee to meet the requirements of swing phase, sitting, and kneeling but furnish no other functions or controls. Others are sophisticated hydraulic mechanisms which control the character and timing of swing, and the degree of stance phase stability. Despite the variety of functions and features afforded by this array of mechanisms, it was possible to classify them on the basis of certain primary functions. We may consider as primary functions: 1. knee rotation, 2. resistance to knee rotation in swing phase and/or in stance phase, and 3. extension bias. All other functions are considered accessory features including those which relate to the character of the primary functions. On this basis, three major classes and several subclasses (types) include all the knee mechanisms in accordance with their primary functions and other special features they provide.

Class I includes knee mechanisms which provide "free knee rotation." In these units, knee rotation is resisted solely by the friction inherent in the bolt and bushing assembly. They do not permit adjustment of the magnitude or phase (time pattern) of resistance (Fig. 21). Accessory features include, or permit inclusion, of an extension bias control whose tension or compression is adjustable. Other accessories such as stability controls consisting of manual knee locks or polycentric joints may be included. Two units fall into this category: the Otto Bock 3P4 Knee and the Polymatic which features a polycentric knee joint, a stance control feature.

Class II includes knee mechanisms whose rotation is controlled by special mechanical or fluid resistance mechanisms which permit adjustment of resistance to knee rotation. All such units include extension bias control features which are adjustable. They may include other accessory features. This class consists of four types of knee mechanisms:

Type 1000 units permit adjustment of the magnitude of resistance to knee rotation. They provide constant resistance (Fig. 22) at any setting. They do not provide variable resistance nor cadence response, that is, variability of resistance at any given resistance setting in relation to either angular position of the knee or to walking cadence. The units falling into this category include the Standard Wood and Standard Metal, Vari-Gait Economy, Vari-Gait Modified, and Wagner 98.

Type 2000 units permit adjustment of the magnitude of resistance to knee rotation. These units also provide variable resistance: the magnitude of resistance varies with angular position of knee rotation at any given resistance setting (Fig. 23). They do not provide cadence response. Units in this category are: Northwestern Uni-
CLASS I
"FREE KNEE" CONSTANT RESISTANCE

PERCENT OF KNEE FLEXION—EXTENSION CYCLE

FIGURE 21.—The typical constant resistance curve characteristic of simple mechanical friction knee mechanisms showing the initial rise in knee resistance during stance as the knee flexion moment increases. The resistance level remains relatively constant through the first half of swing phase reaching zero at maximum heel rise and producing a relatively constant resistance to negative rotation during extension.

versity Disk Friction Unit, Vari-Gait Deluxe, Navy Variable Cadence Knee Unit, Otto Bock 3P25 Knee, and the VAPC Multiplex Mechanical Friction Knee described earlier in this report.

Type 3000 units: 1. permit adjustment of the magnitude of resistance; 2. provide variable resistance, that is, resistance varies with angular position of the knee; 3. are cadence responsive, that is, resistance at preset levels varies with walking cadence (knee angular velocity) (Fig. 24). Examples are the Henschke-Mauch HYDRAULIK Swing Phase Control System, Model B; the Dupaco "Hermes" Hydraulic Control System; the U.S. Manufacturing Co. Hydra-Cadence; and the US-BL Pneumatic System.

Class III units include knee mechanisms whose rotation is controlled by special mechanical or fluid devices during both swing phase and stance phase. Four specific types are identified:

In Type 1000 units, the swing phase control permits: 1. adjustment of the magnitude of resistance to knee rotation, and 2. they do not provide variable resistance or cadence response.

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VAPC Research

CLASS II TYPE 1000
ADJUSTABLE RESISTANCE (CONSTANT)
THREE SETTINGS

FIGURE 22.—Three distinct levels of resistance to knee rotation are distinguishable. Each resistance level is separate from the other by a maximum of 25 in.-lb. of resistance and each curve demonstrates a more variable resistance pattern than Type I units in this class.

Stance phase is controlled by friction generated under weight bearing. The following items would fall into this type: Bock 3P24, Bock 3P23, Wagner 200, Wagner 205, and Secura Knee.

In Type 2000 units, the swing-phase control provides: 1. adjustment of the magnitude of resistance to knee rotation, and 2. they may provide variable resistance but they do not provide cadence response.

Stance phase is controlled by means of a changing locus of the knee center of rotation which increases stability by reducing the positive knee moment in stance phase. These units shall include, or permit inclusion, of an adjustable extension bias control. Examples of this type are the Laurence Polycentric Knee and the Northwestern University Polycentric Knee.

In Type 3000 units, the swing-phase control: 1. permits adjustment of the magnitude of resistance to knee rotation, 2. it provides variable resistance, and 3. it is cadence responsive.
Stance phase is controlled by means of an automatic “positive” lock which prevents positive knee rotation but permits negative knee rotation. An example of this type is the Regnell Hydraulic Knee Model A.

Type 4000 units: 1. permit adjustment of the resistance to knee rotation, 2. provide variable resistance, and 3. they are cadence responsive.

Stance-phase control is effected by means of yielding resistance. The single example of such a unit is the Henschke-Mauch HYDRAULIK Swing and Stance Control System Model A.

All functions of the knee mechanisms are summarized in Table 2. As a general requirement, prosthetic knee mechanisms should simulate the normal human knee in function and appearance. But it should be understood that these standards establish minimum levels of function, durability, and the physical dimensions required for proper sizing and appearance.

The knee-shank assembly should readily be attached to above-knee sockets and should receive prosthetic feet conveniently. It must be durable, safe, relatively lightweight, and of good workmanship. Re-
Figure 24.—Adjusted to any resistance setting, this unit shows marked variability of resistance to knee rotation during each cycle. Resistance also varies with angular velocity of the knee or walking cadence.

Requirements for materials, appearance, weight, structure, and size are also specified.

The prosthetic knee-shank assembly should be fabricated of such rugged and substantial materials that it will retain its functional characteristics without failure under normal amputee usage. Both the knee and shank should be anatomically contoured. The knee may be neuter but the shank must be contoured for right and left legs. Shanks of the pylon design and their cosmetic covers should conform to these requirements.

The weight of each unit should be proportional to the functions provided. However, it has proven quite difficult to find an equitable way of assessing relative weights of the various units. Questions still remain about the components to be included in weighing them.

The strength and durability of the materials and the bonding of various components should be adequate to withstand without failure the forces applied during a minimum of one year of normal use by an amputee. Average amputee use is considered to be approximately one million cycles per year. Durability is checked by a cycling test of one
### Table 2—Classification of Knee Mechanisms According to Primary Functions and Special Features

<table>
<thead>
<tr>
<th>Swing control</th>
<th>Stance control</th>
<th>[1000 \text{ (Free knee rotation)}]</th>
<th>[1000, 2000, 3000 \text{ (Swing phase control)}]</th>
<th>[1000, 2000, 3000, 4000 \text{ (Swing and stance control)}]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
<td>Type</td>
<td>Adjustable variable braking</td>
<td>Positive lock back</td>
<td>Yielding lock</td>
</tr>
<tr>
<td>I</td>
<td>1000</td>
<td>(X)</td>
<td>(X)</td>
<td>(X)</td>
</tr>
<tr>
<td>II</td>
<td>1000, 2000, 3000</td>
<td>(X)</td>
<td>(X)</td>
<td>(X)</td>
</tr>
<tr>
<td>III</td>
<td>1000, 2000, 3000, 4000</td>
<td>(X)</td>
<td>(X)</td>
<td>(X)</td>
</tr>
</tbody>
</table>
million cycles. At scheduled intervals resistance characteristics are recorded. Structural strength is checked by a static vertical load of 350 lb. (159 kg.) applied to the complete assembly at approximately 3 in. (7.60 cm.) anterior to the knee axis (approximately 1000 in.-lb. or 1152 cm. kg.).

The complete knee-shank assembly, as delivered by the manufacturer, should reflect first-class workmanship. The unit should be clean and free from any blemishes or defects which affect the appearance or which may impair the serviceability of the device.

Qualified knee-shank units should be available in a series of sizes and dimensions so that with minor modifications, they may be contoured to simulate the normal in appearance and dimensions.

In addition, all knee units should substantially meet the following performance requirements:

Range of Motion. All knee mechanisms should provide smooth rotation through a range of not less than 120 deg. measured from a position in which the long axes of the knee block and shank are aligned vertically through the knee center (180 deg.).

Extension Bias Control. Each component should provide a force of sufficient magnitude to measurably decrease the resistance to negative knee rotation. The peak moment should occur within the last 20 deg. of negative knee rotation. The magnitude of the extension moment should be readily adjustable.

Range of Resistance Adjustment. Resistance to knee rotation should not be less than 25 in.-lb. (28.8 cm. kg.) of moment at a given point (peak) during swing phase. Class II and Class III knee mechanisms should provide swing phase resistance to rotation which is adjustable through a range of not less than 30 percent above the minimum setting for each unit.

Cadence Response. In Class II, Types 3000 and in Class III units magnitude of resistance to knee rotation should vary with angular knee velocity or cadence.

Resistance characteristics must be established for each unit to determine minimum-to-maximum resistance magnitudes and cadence responsiveness.

Foot-Ankle Assemblies.

The work on foot-ankle assembly standards has progressed to approximately the same point as the work on knee mechanisms. We have developed a system to classify all the foot-ankle assemblies currently acceptable on VA contract. The basis of classification is the function provided by each unit; three major classes were defined in terms of the types of motion provided. Thus, one class is represented by the “single-
axis,” another by the “dual-axis,” and a third class by the “multi-axis” foot-ankle assembly. In addition, proposed requirements and performance specifications have been developed on the basis of desirable standards of function, durability, and comfort.

In scope these standards relate to all prosthetic feet for use by adult, male amputees. The foot-ankle assembly refers to an anthropomorphic foot with an associated section whose deflections simulate the functions of the normal foot and ankle. They should provide the types of motion, if not the full ranges, provided by the normal foot-ankle complex. We believe these to be minimal requirements irrespective of the structure of the foot, that is, regardless of whether the foot provides motion about a single metal axis or about some undefined or shifting point as in the SACH foot. The standards are in no way intended to guide the design of foot-ankle assemblies toward the duplication of either the structure or the function of the human foot-ankle; they are intended to guide designers toward replication of the shape and simulation of the functions of the human foot-ankle complex. All the feet covered by these standards fall into three classes:

Class I includes foot-ankle assemblies which provide motion in the sagittal plane in simulation of plantar flexion-dorsiflexion of the ankle (one directional). Conventional Wood Feet with standard 2-way ankle joint or with a U-bolt or ball bearing ankle joint fall in this category. Included are at least twelve commercial products.

Class II includes foot-ankle assemblies which provide motions simulating plantar flexion-dorsiflexion and inversion-eversion (two directional).

Class III includes foot-ankle assemblies which provide motion simulating plantar flexion-dorsiflexion, inversion-eversion, and transverse rotation of the ankle (multi- or three-directional). At the present time, four foot-ankle assemblies fall into this category: the Trautman Rubber Foot-Ankle Assembly, the Teufel Telasto Foot and Ankle Assembly, the SACH Foot, and the Mauch Hydraulic Unit now under development.

The following performance and general design requirements are intended to establish minimum levels of function, durability, and the physical dimensions required for proper sizing.

Each prosthetic foot-ankle assembly should be fabricated of such rugged and substantial materials that it will: a. retain its original functional characteristics and shape for 3 months of normal amputee usage without major repair, major adjustment, or replacement of components; and b. have a shelf life (indoors) of one year without affecting any of the functional characteristics specified for its class.
Each prosthetic foot-ankle assembly should be shaped to conform to the general appearance of a normal foot and it should be available in rights and lefts.

Qualified foot-ankle assemblies should be available in the nine sets of sizes and dimensions shown in Table 3 so that they may be fitted into standard shoes in sizes 5½ through 14. Shoe size is indicated in the system currently in use in the specifications for SACH feet. The lengths indicated for each size are also derived from the same source. Width and circumference measurements are derived from anthropomorphic tables for each of the sizes and lengths shown. Table 3, drawn to these dimensions, matches current empirical standards rather closely.

In general, feet should be as light as possible while providing the full range of function for which they are designed. It must be recognized, however, increased function may be obtained only at the cost of increased weight. Therefore, the weights specified for feet should be proportional to the functions they provide. In a reasonable standard, the weights should not exceed the following: for Class I—1½ lb. (.62 kg.); for Class II—1¾ lb. (.74 kg.); and for Class III—2¼ lb. (.96 kg.).

Each class of foot-ankle assembly should provide the types and ranges of motion under specified loads in tests of deflection, flexure resistance, toe-break, and meet the requirements for structural strength.

Functional characteristics of foot-ankle assemblies should be evaluated by measuring deflections in those ranges of motion provided by each class of foot under loads corresponding to those imposed by normal non-amputees in walking. The deflections measured in degrees of rotation should not be exceeded under the loads indicated; nor should rotation under increments of load up to the maxima given in Table 4 fall outside the limits specified. No foot-ankle assembly should provide motion in any other direction, or in excess of those ranges specified for its class. The construction or design of the foot-ankle assembly should permit the adjustment to reduce any of the motions below maximum limits.

Except for Class I feet where no toe-break is provided, all foot-ankle assemblies should meet the specifications for toe flexion (No. 7 in Table 4). However, feet designed to provide a range of dorsiflexion could meet the specifications if the sum of the dorsiflexion (No. 2) and toe flexion (No. 7) displacement does not exceed 40 deg. In addition, Class I feet must meet the specifications for plantar flexion and dorsiflexion (Nos. 1 and 2); Class II feet must meet the specifications for plantar flexion, dorsiflexion, eversion, and inversion (Nos. 1 through 4); Class III feet must meet the specifications for plantar flexion, dorsiflexion, inversion, internal rotation, and external rotation (Nos. 1 through 6).
<table>
<thead>
<tr>
<th>Shoe size</th>
<th>Length</th>
<th>Heel width</th>
<th>Ankle width</th>
<th>Width at MTP joint</th>
<th>Foot circumference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
<td>in.</td>
<td>in.</td>
<td>in.</td>
<td>in.</td>
</tr>
<tr>
<td>5½-6</td>
<td>9.12</td>
<td>2.34</td>
<td>2.70</td>
<td>3.37</td>
<td>8.12</td>
</tr>
<tr>
<td>6½-7</td>
<td>9.50</td>
<td>2.41</td>
<td>2.76</td>
<td>3.48</td>
<td>8.37</td>
</tr>
<tr>
<td>7½-8</td>
<td>9.87</td>
<td>2.47</td>
<td>2.83</td>
<td>3.59</td>
<td>8.62</td>
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<td>8½-9</td>
<td>10.25</td>
<td>2.53</td>
<td>2.89</td>
<td>3.70</td>
<td>8.87</td>
</tr>
<tr>
<td>9½-10</td>
<td>10.62</td>
<td>2.59</td>
<td>2.96</td>
<td>3.81</td>
<td>9.12</td>
</tr>
<tr>
<td>10½-11</td>
<td>11.00</td>
<td>2.66</td>
<td>3.02</td>
<td>3.92</td>
<td>9.37</td>
</tr>
<tr>
<td>11½-12</td>
<td>11.37</td>
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<td>3.09</td>
<td>4.03</td>
<td>9.57</td>
</tr>
<tr>
<td>12½-13</td>
<td>11.75</td>
<td>2.88</td>
<td>3.15</td>
<td>4.15</td>
<td>9.62</td>
</tr>
<tr>
<td>13½-14</td>
<td>12.12</td>
<td>2.94</td>
<td>3.22</td>
<td>4.26</td>
<td>9.67</td>
</tr>
</tbody>
</table>

* Measured heel to tip along plantar surface.
* Maximum width of heel plantar surface posterior to vertical projection through malleoli.
* Through spines of malleoli.
* Measured across toe-break on plantar surface.
* Around plantar and dorsal surface of the toe-break.
The ability of the prosthetic toe to recover from flexural deformation (toe-curl) should be tested before and after cycling for all classes of foot-ankle assemblies. (This specification would not apply to those Class I foot-ankle assemblies where no toe-break is provided.) After being subjected to a load of 60 lb. (27.2 kg.) for 2 hours, the residual deflection of the toe, 10 minutes after removal of the load, should not exceed 0.06 in. (.152 mm.).

The toe-break of each foot should be measured on the medial side of the foot. It should measure no more than 70 percent, nor less than 65 percent, of the overall length of the foot-ankle assembly.

The strength and durability of the materials and the bonding of the adhesives should be tested by means of a cycling machine. Based on normal amputee use requirements, it should withstand 500,000 cycles (approximately 6 months of wear) without failure of any kind. After cycling, a thorough visual and X-ray examination should reveal no tears, breaks, cracks, or delaminations that would impair function, safety, or appearance.

In addition to meeting dimensional and structural requirements, each foot-ankle assembly should also meet the specifications set forth below governing the comfort and ease of installation and workmanship.

The foot-ankle assembly should provide a means for absorbing the initial shock as the foot is applied to the ground during walking. Some means of adjusting the ankle attitude should be provided.

The foot-ankle assembly should be capable of being easily shaped and finished so that it presents a smooth appearance which can be faired to blend into the shank of the prosthesis to resemble as nearly as possible a normal human foot.

Each foot-ankle assembly should remain positively locked in the correct attitude in all directions. The foot section should be detachable for repairs or replacement by access from the bottom and external to the shank.

Materials should be water resistant, non-toxic, and exude no offensive odor. There should be no loud or objectionable noises during use. No moving parts should be exposed. All metallic parts should be of standard quality as to length, size, and number of thread, and should be corrosion resistant.

The shaped foot-ankle assembly as delivered by the manufacturer should reflect first-class workmanship. It should be clean and free from any blemishes or defects which affect the appearance, or which may impair the serviceability.
### Table 4.—Foot Motion Under Normal Walking Loads

<table>
<thead>
<tr>
<th>Class</th>
<th>Direction and magnitude of applied moment</th>
<th>Maximum deflection (in degrees)</th>
<th>Slope of loading curve (ft.-lb. per deg. rot.) ± 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I, II, III</td>
<td>1. Plantar flexion 18 ft.-lb. 2.8 m. kg.</td>
<td>18</td>
<td>1/1</td>
</tr>
<tr>
<td>I, II, III</td>
<td>2. Dorsiflexion 80 ft.-lb. 11.1 m. kg.</td>
<td>10</td>
<td>8/1</td>
</tr>
<tr>
<td>II, III</td>
<td>3. Eversion 2 ft.-lb. 27 m. kg.</td>
<td>6</td>
<td>1/3</td>
</tr>
<tr>
<td>II, III</td>
<td>4. Inversion 15 ft.-lb. 2.07 m. kg.</td>
<td>6</td>
<td>2.5/1</td>
</tr>
<tr>
<td>III</td>
<td>5. Internal rotation 6 ft.-lb. 33 m. kg.</td>
<td>8</td>
<td>3/4</td>
</tr>
<tr>
<td>III</td>
<td>6. External rotation 6 ft.-lb. 33 m. kg.</td>
<td>8</td>
<td>3/4</td>
</tr>
<tr>
<td>I*, II, III</td>
<td>7. Toe flexion 6 ft.-lb. 33 m. kg.</td>
<td>30</td>
<td>1/5</td>
</tr>
</tbody>
</table>

*This specification does not apply to a foot without a functional toe-break, i.e., a foot for which the prosthetist must fabricate a toe-break.*
B. Compliance Testing

1. SACH Feet. During this period, four manufacturers submitted samples of SACH feet for annual compliance testing. The results of the tests indicated that only one manufacturer’s product was in substantial compliance with the requirements. The other samples could not be rated as acceptable in view of three significant deviations from the specification requirements:
   a. Toe-break too short.
   b. Toe-curl in excess of allowable limits.
   c. Heel durometer below requirements.

2. Teufel Lower-Extremity Wool Stump Socks-Leg. Four sample stump socks, bearing style numbers 3300, 3303, 3304, and 3318 were tested in accordance with specification requirements as outlined in Invitation No. 67-2. These socks are of German manufacture and their dimensions differed to some extent from the domestic socks that are periodically checked. Normally, three samples of each style are submitted for testing to permit averaging of test results. The single sample per style used in this test may therefore have affected these findings.

   All four samples were considered below the minimum standards for yarn size. Three of the samples were adequate with respect to ply number, stitches/inch, and wales/inch.

   All the samples complied with the requirements for shrinkage after washing.

   Three of the samples (#3300, #3303, and #3318) are in substantial compliance with the specifications except for yarn size. The fourth sample #3304 does not comply with respect to yarn size, ply, stitches/inch, and wales/inch.

C. Materials Testing

Polypropylene Reinforcing Fabric for Lamination. Polypropylene fiber, a thermoplastic polymerization of propylene gas, is produced by the Vectra Company, Odenton, Maryland. In sheet form, it is currently being used as a reinforcing material in the fabrication of molded boats. A report in The Skipper, January 1966, indicated that as part of a laminate it was superior in strength to Fiberglas, nylon, and other reinforcing materials.

As reported in BPR 10-5, this material is being investigated for possible application in prosthetics and orthotics. Samples of polypropylene stockinet and polypropylene sheeting of various yarn sizes and weights were impregnated with polyester and epoxy resins and
compared with samples using common prosthetic and orthotic reinforcing materials (nylon and Fiberglas). The results of this test appear in Figure 25.

In general, polypropylene stockinet offers no advantage over nylon stockinet. In sheet form it is far stronger than nylon although not stronger than Fiberglas. In sheet form of sufficient weight, 10.5 oz. (297.68 gm.), it may have some application for local reinforcement because it is less dense than the more commonly used Fiberglas and easier to handle.

VI. OTHER PROJECTS

A. Wheelchair Field Study

A clinical evaluation study of wheelchairs is being undertaken by R&D, PSAS, to validate the tentative set of functional standards for wheelchairs and to determine the relative merits of various wheelchairs, their durability, patient and clinician preferences, and prescription criteria.
B. Cetrone Contoured Support Belt

Three samples of the Cetrone Belt were submitted by the U.S. Manufacturing Company for evaluation prior to production of 50 samples for a forthcoming field study. The three samples included one each of a small, medium, and large size designed to accommodate a range of hip sizes from 28 in. (72 cm.) through 48 in. (122 cm.). Examination of these samples revealed the following:

a. The small size belt, 39¼ in. (100.33 cm.) in length was actually too long to permit adequate cinching at the lower end of the range by approximately 4 in. (10 cm.).

b. There was a gap in the hip sizes which could be accommodated between the medium and the large size belt.

c. When the male portion of the Velcro fastener is attached to the female portion at the low end of the hip size range which each belt accommodates, the end flaps freely. Worn under the clothing, it may become unfastened by the movement of clothing.

These matters, brought to the attention of the manufacturer, have been rectified and a field study of this device is being planned by the Research and Development Division of PSAS.

VII. OPERATIONS REPORT FOR FIRST HALF, FISCAL YEAR 1967

The data in this section reflect the prosthetic and orthotic services provided for veteran beneficiaries during the first half of Fiscal Year (F.Y.) 1967 by the VA Prosthetics Center's Orthopedic Shoe Service and the Prosthetics-Orthotics Service. Fiscal year comparisons are also included where available and meaningful.

A. The Orthopedic Shoe Service

Table 5 reflects full fiscal year comparisons of our national Orthopedic Shoe Program from 1963 through 1966, plus the first half of F.Y. 1967. An increase of 162 beneficiaries for the first half of F.Y. 1967 was experienced.

Issuance of protective footwear during the first half of the fiscal year totals as follows: 57 pairs of overshoes and 36 pairs of rubbers. Also, 371 clinic lasts were duplicated or modified.

B. The Prosthetics-Orthotics Service

The Orthotics Components Unit of the Prefabricated Appliances Section is responsible for the distribution of surgical supports and
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Table 5.—The VAPC National Orthopedic Shoe Program

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>1963</th>
<th>1964</th>
<th>1965</th>
<th>1966</th>
<th>First half 1967</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiaries on rolls</td>
<td>9,681</td>
<td>10,021</td>
<td>10,322</td>
<td>10,587</td>
<td>10,749</td>
</tr>
<tr>
<td>New shoes, prs.</td>
<td>7,249</td>
<td>7,317</td>
<td>7,536</td>
<td>7,688</td>
<td>3,206</td>
</tr>
<tr>
<td>Prs. of new shoes issued</td>
<td>0.75</td>
<td>0.73</td>
<td>0.71</td>
<td>0.73</td>
<td>*0.60</td>
</tr>
<tr>
<td>per benef. on rolls per yr.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repaired shoes, prs.</td>
<td>9,716</td>
<td>9,487</td>
<td>9,422</td>
<td>10,482</td>
<td>5,152</td>
</tr>
<tr>
<td>Prs. of shoes repaired</td>
<td>1.00+</td>
<td>0.95</td>
<td>0.91</td>
<td>0.99</td>
<td>*0.96</td>
</tr>
<tr>
<td>per benef. on rolls per yr.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Projected for full fiscal year.

elastic hosiery. Table 6 reflects the activity from F.Y. 1963 through F.Y. 1966, plus the first half of F.Y. 1967.

The Prosthetic Components Unit of the Prefabricated Appliances Section is responsible for the distribution of prosthetic and orthotic devices. Table 7 summarizes the distribution for the first half of F.Y. 1967.

Table 7.—Distribution of Prosthetic Components by the VAPC, First Half F.Y. 1967

<table>
<thead>
<tr>
<th>Issuance channel</th>
<th>Temporary prostheses</th>
<th>SACH feet</th>
<th>Hydraulic systems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AK</td>
<td>BK</td>
<td>Initial issue</td>
</tr>
<tr>
<td>For specific beneficiaries</td>
<td>32</td>
<td>33</td>
<td>56</td>
</tr>
<tr>
<td>VA orthopedic shops</td>
<td>54</td>
<td>61</td>
<td>184</td>
</tr>
<tr>
<td>Totals</td>
<td>86</td>
<td>94</td>
<td>240</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>Directly to veterans</td>
<td>2,162</td>
<td>5,806</td>
<td>2,434</td>
</tr>
<tr>
<td>VA orthopedic shops</td>
<td>3,098</td>
<td>6,598</td>
<td>3,995</td>
</tr>
<tr>
<td>Total</td>
<td>5,260</td>
<td>12,404</td>
<td>6,429</td>
</tr>
</tbody>
</table>
The Limb and Brace Section of the Prosthetics-Orthotics Service fabricated and delivered lower-extremity prostheses as indicated in Tables 8 and 9. In addition the following items were fabricated and delivered: 780 arch supports, 90 spinal braces, 70 leg braces, 47 leg-thigh braces, 35 miscellaneous braces, and 15 artificial arms.

The VAPC Clinic Team held 26 meetings during the first half of F.Y. 1967. The 59 beneficiaries seen were referred by 13 field stations.

**TABLE 8.—Complete Below-Knee Artificial Limbs Fitted by VAPC, First Half F.Y. 1967**

<table>
<thead>
<tr>
<th>Type</th>
<th>Permanent</th>
<th>Temporary</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molded socket</td>
<td>33</td>
<td>7</td>
<td>40</td>
</tr>
<tr>
<td>Non-PTB</td>
<td>4</td>
<td>—</td>
<td>4</td>
</tr>
<tr>
<td>Syme</td>
<td>8</td>
<td>—</td>
<td>5</td>
</tr>
<tr>
<td>Chopart</td>
<td>63</td>
<td>19</td>
<td>82</td>
</tr>
</tbody>
</table>

**TABLE 9.—Complete Above-Knee Artificial Limbs Fitted by VAPC, First Half F.Y. 1967**

<table>
<thead>
<tr>
<th>Type</th>
<th>Permanent</th>
<th>Temporary</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molded socket,</td>
<td>15</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td>non-total contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip disarticulation</td>
<td>2</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Knee bearing</td>
<td>51</td>
<td>26</td>
<td>77</td>
</tr>
</tbody>
</table>

**C. Special Service for Vietnamese Wounded**

In the two immediately preceding issues of the Bulletin it was reported that the VAPC was providing orthotic services to Vietnamese veterans since late 1965. In the 6-month period ending December 31, 1966, six patients were fitted with braces, making a total of 50 Vietnamese veterans fitted. The braces fitted were similar to the typical braces previously reported.

Of the 56 patients originally sent to the VA Hospital, Castle Point,
20 have since returned to Viet-Nam. The remaining 36 are still undergoing rehabilitative techniques and will most likely be returned to Viet-Nam by the end of June 1967. The forthcoming issue of the Bulletin will contain a final report highlighting those aspects of special interest and exploring various problems encountered.

REFERENCES