INTRODUCTION

The report for this semiannual period highlights several areas in which VAPC research and development emphasis is now being placed.

The conventional design and the construction of lower-extremity prostheses have been based primarily on the use of wood shanks. Certainly, with the development of patellar-tendon-bearing below-knee and total-contact above-knee sockets, we have seen a national trend to use of plastics in this part of the prosthesis. Now, however, with strong stimuli coming from the hardware needs for temporary prostheses (or simplified prostheses), especially for use immediately after surgery, we are reviewing shank design and construction for permanent prostheses as well.

The pylon-cosmetic cover combinations now being developed and used for temporary prostheses are certainly feasible for permanent prostheses provided these two constituents can be properly designed for that purpose as well. Our focus now is on evaluating items developed by several sources. Progress on a design for a temporary-permanent below-knee pylon has been rapid, but so far, no satisfactory above-knee pylon with multi-functional capability has evolved. Thus the VA Prosthetics Center has elected to try the necessary development effort described in this report.

An area of research and development that has received a great deal of attention in the past has been the design of above-knee prosthetic knee mechanisms. From this research and from private development, many types of swing-control mechanisms have been made available. But stance-control mechanisms have not recently been studied in depth. This, as the report indicates, we are attempting to start now with work on the Regnell Model "A," the several polycentrics, and the mechanical-friction Blatchford Knee. At the same time, the Research and Development Division of the VA's Prosthetic and Sensory Aids Service is planning a clinical application study on the Henschke-Mauch Model "A" system. Hopefully, the results of these several programs will give new insight for aiding the amputee, particularly the geriatric case where stability through a stance control mechanism may be the deciding factor as to whether prosthetic use is feasible or not.

We are also reexamining the matter of "conventional" feet, especially designs featuring four-way controlled motion. The Trautman foot dis-
cussed in this report represents one such design. However, our objective is to refocus design and development on foot-ankle function, and perhaps go beyond the development represented by the SACH foot. Hopefully, Mauch Laboratories, now developing a hydraulic foot-ankle system, will assist enormously in this effort.

And bracing, a seemingly forgotten step-child, needs major emphasis. The CPRD is now encouraging such work. Presented here are our currently relatively minor contributions, attempts to rationalize foot insert design and to provide a simpler, more cosmetic system for “drop-foot.”

External power and its implications in terms of improved performance and prosthetic fitting factors such as controls have been studied in a very limited way in the VA Prosthetics Center. Using the rather highly developed American Institute for Prosthetic Research components, we have studied the problems on one case, but our interest is primarily in hybrid systems, i.e., mixtures of body and externally powered components in each prosthesis. Evolving from these preliminary studies has been a rational plan for evaluation of powered upper-extremity components; this plan has been published in this report.

Dr. Edward Peizer and the staff of our Bioengineering Research Service and others of the VAPC staff made the contributions published in the following report.

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VA Prosthetics Center, New York, N.Y.

I. LOWER-EXTREMITY PROSTHETICS
A. Basic Studies
   None.
B. Components Development
   1. Above-Knee Pylon Designed for Use with Various Knee-Control Mechanisms
   2. Fluid Knee-Control for Through-Knee Prostheses
C. Technique Development
   Transparent Socket
D. Evaluation (Components)
   1. Trautman Foot and Ankle Assembly
   2. Regnell Hydraulic Knee, Model A (Swing and Stance Control)
   3. Northwestern University Polycentric Knee
   4. Laurence Polycentric Knee
   5. Blatchford Stabilized Knee
   6. United States Manufacturing Company Pylon Prostheses
   7. Foort Below-Knee Pylon Prostheses
   8. Mauch Plastic Shank
E. Evaluation (Techniques)
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      2. Plan for Additional Studies of External Power
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      5. Dorrance Hand
      6. Becker Hand
   C. Evaluation (Techniques)
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      2. Single-Bar Brace

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V. TESTING
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      7. Lamiflex Bearing
VI. OPERATIONS REPORT FOR SECOND HALF, FISCAL YEAR 1965
A. The Orthopedic Shoe Service
B. The Prosthetics-Orthotics Service

I. LOWER-EXTREMITY PROSTHETICS

A. Basic Studies
None.

B. Components Development

1. Above-Knee Pylon Designed for Use with Various Knee-Control Mechanisms. The development of an above-knee pylon designed for easy acceptance and exchange of several knee mechanisms has been advanced during this period. A mechanical lock has been designed, an extension stop has been installed, and work continues on the simplification of the adapters.

The basic unit shown in Figure 1 consists of a single-axis pylon-type prosthesis with an adjustable constant friction device, an extension stop, and a manually operated knee lock. Also incorporated in the unit is a torque absorber. The foot attachment ankle plug permits adjustment of the linear alignment of the knee over the foot as shown in Figure 2. The basic unit with SACH foot now weighs 2 lb. 14 oz.

By means of simple adapters, the unit accepts several different knee-control mechanisms. Figure 3 shows the above-knee pylon unit with a Northwestern University Disk Friction System. An internal extension bias mechanism may be installed as shown in Figure 4. In addition, fluid knee-control devices, such as Henschke-Mauch Models A and B, Dupaco, and Hydra-Knee, are easily installed by means of "centered" adapters. Both Mauch units (A and B) may be installed with the same adapter as shown in BPR 10-3 Spring 1965 (Fig. 2, page 111). Since the Hydra-Knee is currently undergoing revision, the developer has offered his cooperation in redesigning the Hydra-Knee to match the geometry of the Dupaco unit so that both may be installed with the same adapter.

Access to the control mechanism has been improved by means of an opening in the cosmetic shank cover. As a result, control system adjustments and the exchange of control units may be more conveniently accomplished.

2. Fluid Knee-Control for Through-Knee Prostheses. As an elective procedure, through-knee amputation offers several advantages over higher level amputations. Surgical trauma is reduced since the major knee flexors and extensors are detached at their distal tendinous attachments and very little soft tissue is damaged. The maximum stump length is preserved without a significant reduction in muscular strength. Moreover, stumps of this type usually tolerate end-bearing.
Due primarily to the lack of an adequate prosthetic device, amputation surgery at this level has not been widely practiced. The long, powerful stump produces high angular shank velocities about the prosthetic knee requiring swing-control mechanisms which provide the necessary resistance to reduce heel rise and terminal impact. However, the long stump also limits the space available for housing appropriate swing-control devices.

Several previous attempts to develop swing controls especially designed for through-knee prostheses were only partially successful. The typical through-knee socket is molded over a replica of the stump and it includes the knee section; therefore, to maintain equal knee height, outside joints and braces are used. Incorporating the required resistance features into joints of this type has been a major problem. The small friction surfaces of conventional outside joints do not provide sufficient resistance to control the vigorous knee action produced by the long through-knee stump. The
high velocities about the knee and uneven wear on the joint friction surfaces cause early breakdown of the system and functional deficiencies.

The residual functional capabilities at this level of amputation require the superior control provided by the more sophisticated fluid knee units which are currently available. We are attempting to meet this need by designing an adapter which will permit any of several fluid units to be installed in the prosthesis. The adapter will consist of an externally placed...
socket attachment strap which is free to pivot around the knee center. The required spatial relationships among the knee center and the two attachment points of the fluid unit will be maintained by means of a yoke connected to the attachment strap at two pivots, and to the piston rod of the fluid unit (Fig. 5).

Several of these devices are being made for patients who will be fitted to provide guidance for further development.

C. Technique Development

Transparent Socket Material. A great deal of interest has been generated in developing a technique for measuring pressure gradients between the stump and the socket as an aid in improving casting techniques, socket designs, and adjunct devices, and as an aid in the clinical evaluation of socket fit. The VA Prosthetics Center, New York University, University of California at San Francisco, and other laboratories have spent time and effort in developing electronic pressure sensors after earlier efforts to photograph stump pressure patterns through transparent sockets were unsuccessful. The two major problems in the photographic method were the limited transparency of sockets and the difficulty of quantifying the observed data. Nevertheless, in the absence of better methods to observe pressure variations between stump and socket, useful data may be obtained photographically if reasonably clear but adequately strong sockets were available.

During a visit to this Center, Brigadier N.A.M. Swettenham of the Ministry of Health, Research Department, Limb Fitting Centre, Queen Mary’s (Roehampton) Hospital, Roehampton, London, S.W. 15, England, suggested the use of textured glass stockinet which, in his experience, resulted in sockets with a considerable degree of transparency. He sent us a sample of 8 in. textured glass stockinet in sufficient quantity to fabricate one test cylinder.

The sample material is a fine-textured, knitted, glass filament resembling Helanca yarn stockinet in appearance and denier. The stockinet is used with polyester resins in the conventional laminating technique. The use of other materials such as Dacron felts or glass mat for reinforcement should be avoided in the lay-up as they seriously reduce transparency.

A test cylinder was fabricated as a three-layer laminate of polyester resin (American Cyanamid 4110) formed over a tapered mandrel. The finished laminate was quite transparent; the visibility of objects placed firmly against the internal surface was comparable to that obtained with clear acrylic (Fig. 6). Figure 7 shows the loss in transparency when both the socket material and the acrylic are held approximately ¼ in. off the typed surface. To a certain extent, high pressure areas could be distinguished from low pressure areas (Fig. 8). Figure 9 shows a certain degree of distortion at the outer edges which may reduce the accuracy of photographs.
FIGURE 6. The section on the left illustrates the transparency of the finished laminate. On the right is a section of clear acrylic of equal thickness, for comparison purposes.

FIGURE 7. The visibility of objects placed approximately ½ in. behind the pocket material is significantly reduced.

FIGURE 8. The light areas over the thenar eminence and the joint of the thumb represent higher pressures than those in the surrounding areas.

FIGURE 9. Objects placed firmly against the internal surface are more clearly visible in the center of the field than at the periphery.

Consisting of three layers of glass cloth and a rigid resin, the test cylinder was rather thin, but it appeared, nevertheless, to be of adequate strength for socket fabrication.

Further investigation of this material is planned to determine: a. the degree of transparency in relation to the number of stockinet layers, b. the effects of stump pressure reliefs on transparency, c. skin reaction to the laminate, d. structural strength, e. size availability, and f. source of supply.
D. Evaluation (Components)

1. Trautman Foot and Ankle Assembly. The Trautman Functional Foot and Ankle Assembly features a four-way functional ankle and permits the adjustment of plantar and dorsiflexion attitude. The foot and ankle assembly consists of a wood ankle section mounted on a molded plastic base, a wood foot with rubber insert ankle fairing, and a rubber ankle block (Fig. 10). Two cables are located along the mid-sagittal line of the foot. The anterior cable connects and secures the entire assembly; the posterior cable permits adjustments of plantar-dorsiflexion attitude of the foot and controls the range of dorsiflexion (Fig. 11).

As there are no applicable specifications for an assembly of this type, the construction design was evaluated and a mechanical analysis was undertaken of the deflection-versus-load characteristics.

The functional characteristics of the unit were evaluated by measuring deflections in the plantar-dorsiflexion range and in the eversion-inversion range under loads corresponding to those imposed by normal non-amputees (1). Deflections in the transverse plane under appropriate torque loads were also measured. Based on normal dynamic ankle loading, moments of up to 80 ft.-lb. were applied in the plantar-flexion range, 80 ft.-lb. in the dorsiflexion range, and 15 ft.-lb. were applied in the eversion-inversion range. Torques of 10 ft.-lb. were applied in the transverse plane.
For these tests, the foot-ankle was assembled with the minimum compression of the rubber ankle block required to maintain the foot at 90 deg. to the shank axis without play between the components.

Reference to Figure 12 shows that the maximum plantar flexion moment about the normal ankle occurs at approximately 12 percent of the gait cycle or just before foot flat, and has a magnitude of about 18 ft.-lb. At this instant, the angular displacement about the ankle is approximately 18 deg. of plantar flexion. Reference to Figure 13 indicates that the Trautman Foot and Ankle plantar flexes an average of 8.5 deg. when a moment of 18 ft.-lb. is applied, or approximately one half the angular displacement of the normal. As the applied load increases, plantar flexion increases to a maximum of approximately 13 deg. under a moment of 50 ft.-lb. A plantar flexion moment of this magnitude is approached in ramp descent by amputees where moments of approximately 40 ft.-lb. and ankle angles of 10 deg. of plantar flexion have been measured. Increasing the load to 80 ft.-lb. does not produce additional angular change in the Trautman Foot and Ankle.

Reference to Figure 12 shows that the maximum dorsiflexion moment of the normal ankle, about 80 ft.-lb., occurs at approximately 50 percent of the gait cycle or just after heel-off when the ankle is in approximately 10 deg. of dorsiflexion. Dorsiflexion angular displacement in the Trautman Foot and Ankle (Fig. 13) is quite linearly related to bending moment. Under a moment of 80 ft.-lb., angular displacement is 4.5 deg. or about one half the normal value.

Reference to Figure 14 indicates that the normal maximum eversion moment of 2 ft.-lb. occurs at approximately 5 percent of the gait cycle (just before foot flat) when the position of the foot is in 7 deg. of inversion. Under the applied moment, the foot moves approximately 5 deg. in the direction of eversion, remaining however in a slightly inverted attitude. As shown in Figure 15, when subjected to an eversion moment of 2 ft.-lb., the Trautman assembly everts 4 deg., a displacement comparable to the normal.

As shown in Figure 14, the maximum normal inversion moment of 15 ft.-lb. occurs at about 14 percent of the gait cycle or just before the period of mid-stance. The foot, having been maintained in a slightly inverted attitude, moves slowly and steadily toward increased inversion rotating approximately 6 deg. just before toe-off. Under a similar moment, however, the Trautman assembly permits 18 deg. of inversion or approximately three times the normal range of motion (Fig. 15).

In the stance phase of level walking, the normal non-amputee applies approximately 6 ft.-lb. of torque in the transverse plane. The torques are generated at heel-contact and rise to a maximum just before heel-off (Fig. 16). Under these circumstances, the tibia rotates approximately 9 deg. inwardly from heel-contact to the beginning of mid-stance. It then begins to rotate in the opposite direction, and just after heel-off it returns to the
position it had at heel-contact. It continues to rotate outwardly for some 8 deg. when toe-off occurs.

The Trautman Foot and Ankle deflects quite linearly under torque loads. As shown in Figures 17 and 18, both internal and external rotation are directly proportional to torque loads up to 10 ft.-lb. Under a torque load of 7 ft.-lb., internal and external rotation averaged 12 deg. or approximately 50 percent more than the normal deflection. In both instances, the characteristic hysteresis can be noted in the failure of the ankle to return to the unloaded position after unloading.

Relating the behavior of the Trautman device under load to that of the normal under the dynamic stresses of walking is intended only to provide certain functional evaluation guideposts. Ignored in these analyses are such factors as the absorption of stresses in the normal joints and the adaptive gait processes in which the muscles controlling the joints respond to external forces first by stretching and permitting joint motion and then by resisting them and preventing motion. Nevertheless, these comparisons serve a useful function in providing a rational context in which to view foot-ankle function.

Since the Trautman assembly is designed to accommodate heel elevation, the same set of tests was accomplished with the foot set in 10 deg. of plantar flexion as it might be, for example, with a 2-in. heel. With the foot in an initial attitude of 10 deg. of plantar flexion additional loading of 20 ft.-lb. produced approximately 7 deg. of deflection, a magnitude similar to that produced with the foot in the neutral attitude (Fig. 19). Unloading to 20 ft.-lb. produced a deflection of 12 deg. with the average approximately 9 deg. However, a substantial increase in hysteresis was observed with the foot retaining an angle of 6 deg. after being unloaded, in contrast to the average of 3 deg. noted in the neutral position (Fig. 15). As shown in Figure 19, after the foot was plantar flexed 10 deg., dorsiflexion angular displacement increased as a linear function of loading over the complete range of 80 ft.-lb. The angular displacement increments were slightly greater than those obtained with the foot in the neutral position. Since the posterior portion of the ankle is compressed to set the joint in plantar flexion, the initial compression on the anterior portion is reduced, permitting somewhat greater displacement under load.

Apart from a mild increase in hysteresis and a well defined change in the eversion-inversion characteristics (Fig. 20), the foot-ankle behaved in substantially similar fashion when set in 10 deg. of initial plantar flexion. A comparison of all the deflection data is shown in Table 1.
Figure 12. Angular change and moment about the normal ankle during stance phase.
Figure 13. Bending moment versus deflection curve in the plantar-dorsiflexion range for Trautman Foot and Ankle Assembly.
Figure 14. Angles and moments in the medio-lateral plane about the normal ankle plotted against percent of stance phase of the walking cycle.
Figure 15. Bending moment versus deflection curve for Trautman Foot and Ankle in the eversion-inversion range.
Figure 16. Normal torques and angles in the transverse plane plotted against percent of stance phase of the walking cycle.
Figure 17. Torque versus deflection curve for Trautman Foot and Ankle in the internal (counterclockwise) direction.
Figure 18. Torque versus deflection curve for Trautman Foot and Ankle in the external (clockwise) direction.
Figure 19. Bending moment versus deflection curve in plantar-dorsiflexion range for the Trautman Foot and Ankle preset in 10 deg. of plantar flexion.
**Figure 20.** Bending moment versus deflection curve in eversion-inversion range for Trautman Foot and Ankle preset in 10 deg. of plantar flexion.

**Table 1.**—Deflection Under Normal Maximum Loadings Applied During Stance Phase

<table>
<thead>
<tr>
<th>Motion</th>
<th>Normal maximum moment or torque in ft.-lb.</th>
<th>Rotation, Deg.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Trautman device at 90°</td>
</tr>
<tr>
<td>Plantar flexion</td>
<td>18.0</td>
<td>18</td>
</tr>
<tr>
<td>Dorsiflexion</td>
<td>80.0</td>
<td>10</td>
</tr>
<tr>
<td>Eversion</td>
<td>2.0</td>
<td>6</td>
</tr>
<tr>
<td>Inversion</td>
<td>15.0</td>
<td>6</td>
</tr>
<tr>
<td>Torsion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal</td>
<td>6.0</td>
<td>9</td>
</tr>
<tr>
<td>External</td>
<td>6.0</td>
<td>8</td>
</tr>
</tbody>
</table>
In general, the Trautman Foot and Ankle Assembly is well shaped and cosmetically adequate. Its best feature in this respect is the rubber insert ankle fairing which gives a reasonably anthropomorphic appearance. Final finishing (laminating) is easily accomplished.

However, adjustment of the assembly is awkward. Adjustments are made by the crossbar on the posterior cable to position the foot in the desired plantar or dorsiflexion attitude. This setting must be made prior to final assembly as the crossbar is located in the shank. Subsequent adjustment of heel height in an above-knee prosthesis requires disassembly of the knee from the shank. In a conventional below-knee prosthesis adjustments can be made with the aid of an extension device for turning the crossbar. In a patellar-tendon-bearing prosthesis adjustments cannot be made after final finishing without making an access hole in the shank or distal end of the socket.

The Trautman assembly is somewhat heavier than any of the currently used SACH feet and the Trautman "U" bolt single axis foot-ankle. As shown in Table 2, the foot alone (without the shank section) weighs approximately 3/4 lb. more than a SACH foot.

The Trautman foot-ankle provides potentially valuable features:

a. It appears cosmetically adequate, particularly as regards the ankle fairing.

b. Adjustability of plantar-dorsiflexion foot attitude permits accommodation of various heel heights.

c. The "universal" motion provided in the ankle is highly functional and may also contribute to increased stability. However, the durability of the ankle blocks and the cables is unknown at present.

d. The 60 (Shore A) durometer block appears to offer adequate resistance to control motion in the plantar flexion, dorsiflexion, and eversion ranges.

e. Controlled motion permitted in the transverse plane may serve the function of torque absorption.
The following are among the potential disadvantages:

a. Adjustment of the foot attitude is awkward.

b. The foot weighs \(\frac{1}{4}\) lb. more than any one of the conventional SACH feet now in use.

c. It permits excessive inversion. However, if this is found to result in instability, the rubber ankle block may be modified by removing a portion of the material on the medial side and filling the void with less compressible material.

The laboratory analysis of the Trautman Foot and Ankle Assembly is being followed with clinical trials and further biomechanical evaluation. Appropriate patients will be fitted and evaluated to determine: (1) durability, (2) patient reaction to function and appearance, and (3) biomechanical analysis of torque absorption and range of motion.

2. Regnell Hydraulic Knee Model A (Swing and Stance Control)

The Regnell Hydraulic Knee, Model A, as shown in BPR 10–3 Spring 1965 (page 121), is supplied as a complete knee-shank-foot assembly. The knee is wood, the shank is a finished plastic laminate, and the foot has a wood base with a semi-rigid foam sole and toe. The unit features an automatic knee lock actuated by weight applied to the foot and a four-way ankle providing motion in two planes—plantar and dorsiflexion as well as inversion-eversion. The ankle mechanism consists of a solid rubber block and universal joint providing some transverse rotation. Ankle motion in the anterior-posterior plane is directly linked with the control of the automatic knee lock. The knee is locked on weight bearing and released when the heel rises in push-off. An additional feature is the manually operated stair valve permitting the knee to yield slowly for stair and hill descent, as described in BPR 10–3 Spring 1965 (page 122).

Swing phase is controlled by a hydraulic system. Extension control is provided internally by the hydraulic mechanism as well as by an external Dacron webbing. Compression of an internal spring furnishes extension bias at approximately 40–65 deg. of flexion when the knee is beginning to extend. Minimum length of the assembly is 16\(\frac{1}{4}\) in. from knee center to floor without shoe. Longer units are available in \(\frac{1}{4}\) in. increments.

Three complete units and two spare systems were obtained for evaluation purposes from Otto Bock Orthopedic Industry, Minneapolis, Minnesota. Resistance characteristics of the swing-control system were determined by means of the VAPC drop tester and the University of California at Berkeley testing machine. Performance data and amputee reactions were obtained from three above-knee amputee subjects who were fitted under the direct supervision of Mr. C. Erik Regnell, the developer.

a. Resistance characteristics. There were discrepancies in the resistance characteristics of the two units tested in the laboratory (Fig. 21). One unit (A191) provided a range of drop-times in flexion adjustable from .34 seconds to .44 seconds while in the second
unit, the range was .30 seconds to .57 seconds. Extension drop-times in unit A191 varied from .29 seconds to .32 seconds while unit A193 varied from .30 seconds to .50 seconds. Nevertheless, the average flexion and extension drop-times fell above the minimum and clustered around the intermediate drop-times for five other hydraulic units.

Although the full adjustment range is approximately 1 to 1½ turns, the first half turn has little or no effect on either flexion or extension resistance. One unit failed to flex at 1½ turns; the other failed to flex and extend at 1½ turns. Due to the narrow range of adjustment, approximately 3/8 of a turn of the adjustment screw differentiates minimum, intermediate, and maximum settings.

Figure 21. VAPC drop test results showing wide variability between two Regnell units.
b. Subjects. Listed below are the ages, heights, and weights of the three subjects:

<table>
<thead>
<tr>
<th>Subject No.</th>
<th>Age (yrs.)</th>
<th>Height (in.)</th>
<th>Weight (lb.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45</td>
<td>71</td>
<td>230</td>
</tr>
<tr>
<td>2</td>
<td>46</td>
<td>68</td>
<td>180</td>
</tr>
<tr>
<td>3</td>
<td>48</td>
<td>72</td>
<td>154</td>
</tr>
</tbody>
</table>

Before being fitted with the Regnell unit, subjects No. 1 and No. 2 wore, respectively, a single-axis mechanical friction knee and a Hydra-Cadence unit. The third subject had not previously worn a prosthesis.

c. Prosthetic Analysis. Detailed below are our experiences to date in obtaining and fitting the unit:

(1) Ordering. Accurate measurement of the knee center to floor length without shoes is critical when ordering this unit. Errors cannot be readily adjusted by the prosthetist, and the unit must be returned. Ordering practice requires that a patient’s shoe be sent to the distributor. This may be a hardship and an unnecessary limitation; perhaps the SACH foot sizing chart could be used to advantage.

The instruction manual describing the function and the fitting procedures is inadequate in its present form. It lacks clarity on many critical points, and it also suffers from awkward language. The manual has been reviewed and annotated to include our suggestions for revision.

To improve appearance, it should be possible to standardize on more cosmetically acceptable knee widths and ankle and calf circumferences.

(2) Fitting and Alignment. Attachment of the socket to the knee shank assembly is achieved by conventional methods. Alignment adjustments are performed by means of a VAPC coupling, and the manual, therefore, should include instructions in the use of the coupling.

The automatic knee lock increases stability independently of knee center location and permits greater latitude in alignment. For difficult cases (flexion contractures, geriatric, and high level bilaterals), increased knee stability may be highly valuable. However, for the average above-knee amputee, gross alignment adjustments may be unnecessary. There was little or no difference in the final alignment of the Regnell and the previously worn prostheses. It was noted that the “soft” heel bumper and the four-way ankle joint contribute to knee stability and flat placement of the foot without affecting overall performance.

The leather ankle fairing, the only one recommended by the manufacturer, is uncosmetic and causes excessive wear of socks. Although the manual gives no finishing instructions, the developer has suggested laminating the foot. As this entails trimming laminate away from the resilient portions of the sole and toes, the result is uncosmetic and awkward.
d. Maintenance. Several deficiencies were noted in units "as received" from the manufacturer: binding of the universal ankle joint limiting plantar and dorsiflexion, excessive play in the universal ankle joint resulting in a clicking noise, and excessive lateral play of the knee block on the bolt.

The most frequent and most serious malfunction occurred in the automatic knee lock. Normal torques on the ankle joint stripped the retainer screw and loosened the entire foot and ankle section. The loose foot rotated, elongating the pilot hole of the lower ankle plate and preventing movement of the automatic knee lock actuating rod, causing the lock to fail. Repeated repair and replacement of parts did not solve the problem. Failure of the foot and ankle assembly and consequent malfunction of the knee lock caused the rejection of two of these units.

A number of other adjustments and repairs were due to stretching of the Dacron strap used as an extension control, stripping of the foot attachment nut, and failure of the ankle plate return spring. Although these maintenance problems did not occur as frequently as failure of the automatic knee lock, the nature of the repair and the time involved indicate a potentially serious maintenance consideration.

e. Extent of Wear. Of the three subjects, two have rejected and are no longer wearing the Regnell unit. In both cases, the primary cause of rejection was recurrent malfunction of the ankle mechanism with consequent malfunction of the automatic knee lock. Subject No. 1 wore the Regnell unit for approximately three months but this period of wear was broken by intermittent malfunction requiring nine visits for adjustment of the ankle mechanism. The longest period of continuous wear did not exceed two weeks. Subject No. 2 wore the leg for approximately two months, a period also broken by repeated maintenance procedures. Due to frequent failure, neither of these subjects used the Regnell unit sufficiently to warrant comparative biomechanical analysis of performance with the Regnell and previously worn units.

The third subject wore the unit for six months until his death. During the period of wear he experienced far fewer maintenance problems than the other two subjects. A less vigorous walker, he was 48 years old, 6 ft. tall, and a recent amputee weighing 154 lb. He had a cardiac condition, phlebitis, a low activity level, and he walked with a cane.

f. Performance. During the relatively short periods in which the unit functioned adequately, the performance of the subjects was observed in level walking, on slopes, and on stairs. Performance was evaluated by a jury of experienced observers using standard gait evaluation procedures. Test procedures to obtain objective measures of gait were scheduled after a minimum period of thirty days of unin-
interrupted wear but, due to the repeated maintenance requirements and the considerably shorter periods of wear, these procedures were not completed.

With the unit functioning adequately, the two subjects who previously wore prostheses (single-axis mechanical friction unit and Hydra-Cadence respectively) performed somewhat better with the Regnell Model A than with their previous device. The automatic knee lock significantly improved the gait of the subject who previously wore a single-axis mechanical knee; there was a reduction in forcible extension of the thigh at heel-contact. Mild improvements noted in swing phase were attributed to the general superiority of hydraulic units over mechanical friction swing-control units.

The slow yielding rate of knee flexion (controlled by the stair valve) was advantageous in descending slopes. With slopes up to 4 deg. there was little apparent difference in performance between the previously worn prostheses and the Regnell units; step length was not appreciably shortened and control during descent was adequate. However, at slopes approaching 8 deg. the subjects descended with shorter step lengths on the prosthetic side when wearing their previous prostheses. With the Regnell, step length and control remained relatively unaffected. On a 12 deg. slope, performance with the previous prostheses was poorly controlled and obviously difficult. With the Regnell, stride length was appreciably shortened but general control seemed superior.

These subjects customarily descended stairs with a “step-to” technique. After fitting with the Regnell, they were given limited training in step-over-step descent techniques. Although they were able to employ this mode during training, they lacked the confidence initially to use it routinely. After a period of wear, one subject became proficient in this technique. These experiences suggest that with adequate training, patients can learn to descend stairs step-over-step with the Regnell unit. However, the manual control of the stair valve may be a potential hazard if users forget to engage it. Without an over-ride feature, attempting to descend with the knee locked in extension may lead to stumbling and falling.

In summary, the swing control afforded by the Regnell unit is similar to many other non-programed hydraulic units. The automatic knee lock is a valuable asset in providing increased knee stability in stance phase on level surfaces. The slow yielding feature controlled by the manually operated stair valve improves performance in descending slopes above 4 deg. It is also a valuable feature in stair descent in permitting a step-over-step mode, but an over-ride feature may reduce the possibility of falling.

g. Patient Reaction. Two of the three subjects rejected the Regnell,
Model A because of repeated malfunction of the foot with consequent failure of the knee lock mechanism.

Subject No. 2, who previously wore a Hydra-Cadence leg, felt that the extension bias was too strong at full knee flexion. (On sitting, the knee tended to extend.)

Subject No. 1, who previously wore a single-axis mechanical knee, thought he could walk faster and better with the Regnell unit—when it functioned properly. However, he expressed a loss of confidence after the knee lock malfunctioned three times. He also disliked the inadvertent extension of the knee when sitting. He commented unfavorably on the uncosmetic gapping at the ankle. Several socks had been torn by the ankle mechanism.

Subject No. 3, a non-previous prosthesis wearer, had noted excessive noise in the foot but had not experienced malfunctioning of the knee lock. In general, he was pleased with the Regnell unit.

h. Summary. The special features of this device—automatic knee lock, slow yielding knee flexion, four-way ankle—provide valuable functions for above-knee amputees. Swing-phase control is of acceptable quality, automatic stance-phase control is desirable, and the slow yielding rate of knee flexion improves performance on slopes above 4 deg. and in stair descent. The unit may be of particular value to elderly patients, cardiacls, or those with muscular weakness.

In its present configuration, this unit is not acceptable for the following reasons:

(1) The most serious deficiency is the failure of the ankle mechanism and the consequent malfunction of the automatic knee lock. The attachment of the ankle mechanism must be redesigned or improved to maintain a secure foot attachment.

(2) The swing-control adjustment mechanism provides an extremely narrow range of adjustability (total range is $\frac{3}{8}$ of a turn). Steps should be taken to increase the excursion of the adjustment valve by use of a finer thread or other appropriate means. In addition, the minimum resistance values provided by this unit are approximately 25 percent higher than those of other hydraulic units. Lowering the minimum resistance would serve a larger group of patients.

(3) The extension bias spring is compressed as the knee approaches maximum flexion and provides a “kicker” action which is dissipated as the knee moves toward extension but while it is still near maximum flexion. Function would be improved if extension bias were available later in the cycle, near full extension; extension would be facilitated even when short steps were taken.

(4) The ankle fairing is not sufficiently anthropomorphic to meet current American standards of cosmesis.

(5) The instruction manual needs clarification.
It should be possible to standardize on more cosmetically acceptable knee widths and calf circumferences.

In discussions of these findings with the developer, he attributed certain problems to poor control of manufacturing tolerances. In this connection, it is particularly important to prevent binding of the universal joint of the foot attachment assembly and to obtain a closer fit of the piston rod loop in the knee slot. During assembly, care must be exercised to drill parallel holes in the knee block for the knee center and the unit attachment rod head.

He acknowledged inherent design limitations of the ankle fairing. The current ankle fairing is below acceptable cosmetic standards, and the developer proposes to redesign the foot to reduce the space covered by the fairing. A rubber “sleeve” attached to the foot will receive the distal end of the shank.

Also to be considered is the use of a mechanical extension stop among other “positive stops” to replace the Dacron webbing.

He agreed to redesign the resistance control valves to provide a greater range of control motion. The current model provides an adjustment range from minimum to maximum resistance of approximately \( \frac{3}{8} \) of one turn. He will attempt to increase the adjustment range to at least one full turn by modifying the shape of the control valve.

The developer pointed out several critical assembly and adjustment procedures not clearly described in the manual nor mentioned at the time the subjects were fitted:

1. The curved piston rod loop (upper piston rod attachment) must be positioned with the concave side facing forward. The detailed drawings show this component without a curve.

2. The distance from the lowest point of the upper ankle plate to the sole of the foot without shoes should measure 55 mm. This dimension is in the manual but it is unemphasized and difficult to find.

3. The excursion of the automatic knee lock should be approximately 0.5 mm. and in no case should exceed 1.0 mm. We recommend that this adjustment be made at the factory and that a feeler gage be supplied with the unit for use as a check only by the prosthetist in the event of malfunction of the automatic knee lock.

4. The leg should not be aligned in hyperextension. However, with a positive extension stop this precaution may be unnecessary.

5. Adjustment of the extension resistance control by lengthening or shortening the piston rod assembly should be facilitated by marking the cylinder head with directional arrows indicating “increase” (counterclockwise) and “decrease” (clockwise) and with a vertical reference mark to aid in determining the numbers or fractions of turns taken.

Mr. Regnell indicated that the cause of failure in the units worn by two of the subjects, i.e., loosening of the foot assembly and consequent
malfunction of the knee lock, resulted from compression of the wood by the universal joint and the foot attachment unit. Compression reduces the dimension, allows play to develop, and places excessive forces on the single screw designed merely to prevent rotation. As the screw backs out, the excursion of the automatic knee lock guide rod is increased, leading to rotation of the foot and failure of the lock. The developer has designed a more adequate foot and will send drawings. The requirements for an adequate foot are:

(1) The well for the rubber ankle block should be deeper and contoured more closely to the shape of the block.

(2) The nut by which the foot is fastened to the universal joint should include a flange drilled in several places to receive screws.

(3) A core or insert of less compressible material such as hardwood or plastic should be inserted in the section where the foot attachment hole is bored. The diameter of the hole should be reduced to prevent excessive motion of the washer.

(4) Rubber ankle blocks should be available in ranges from 60–70 durometer (Shore A) in addition to those of 45 durometer (Shore A) now available.

Further work on this project will be deferred until new models are available.

3. Northwestern University Polycentric Knee. Three prototypes of this device (Fig. 22) were submitted for evaluation. Each of these models, assembled from handmade aluminum components, consists of a socket mounting plate, a polycentric knee mechanism, a two-piece plastic knee shell, mechanical friction swing-control, a pylon, and a foot attachment. The polycentric knee mechanism consists of a crossed four-bar linkage in which one of the two crossed members is attached to the shank and the other is rigidly attached to the socket section. The developer also submitted a questionnaire designed to provide feedback on clinical fitting experiences and the initial reactions of patients. Our evaluation was designed to include:

a. Design critique.

b. Mechanical analysis of weight distribution and rotational kinematics.

c. Analysis of prosthetic factors relating to installation procedures.

d. Patient reactions.

e. Analysis of performance factors as regards stance-phase stability, swing-phase patterns, and appropriate temporal aspects of gait.

One of the three units was tested in the laboratory and the other two were fitted to patients. This report details our findings with respect to items a. through d. above. Data on item e. are still being analyzed.

a. Design Critique. The knee frame should be redesigned as a casting to provide cross sections with optimal strength-weight ratios and
to reduce machining costs. The strut should also be cast for the same reasons. Redesigning the back links and the back link yoke into one integral casting of a suitable aluminum alloy would eliminate some hardware and improve the appearance of the product. The horsehide washers used as brake material should be replaced by woven asbestos brake material which does not extrude and has a better friction coefficient, as stated in BPR 10–3 Spring 1965 (pages 115–118). The friction adjustment assembly, consisting of a compression spring, washer, and nut, is crude and unreliable. An arrangement with less susceptibility to slippage and reliable adjustment increments is recommended.

b. Mechanical Analysis.

(1) Weight. The knee mechanism alone weighs 2 lb.; adding a cosmetic cover (Hydra-Cadence), SACH foot, and shoe brings the weight of the assembly to 5.8 lb. This is a relatively light device as compared to another recently evaluated polycentric unit, the Laurence Polycentric Knee, which weighs 6.3 lb. in the same condition.

(2) Swing-Phase Characteristics. The four-bar linkage knee mechanism is designed to rotate about a changing axis position. In full extension, the axis of rotation is high and posteriorly located. As the knee traverses the flexion range, the axis of rotation shifts down and anteriorly. As shown in Figure 23, rotation through 65 deg. produces a vertical displacement of 1.031 in. and a horizontal displacement of 0.641 in.

At 20 deg. of flexion or early in the period between heel-off and toe-off when the knee angular velocity is increasing rapidly, the CG of the assembled shank, weighing 5.8 lb., is 12.08 in. from the center of rotation, and its mass moment of inertia is approximately 846.39
COORDINATES OF INSTANTANEOUS CENTER (IN.)

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FIGURE 23. Position of the center of rotation of the Northwestern University Polycentric Knee at various knee flexion angles (θ).

lb.-in.². At 65 deg., or after maximum heel rise, when the knee extension angular velocity is increasing rapidly, the CG of the unit is 11.72 in. from the axis of rotation and the mass moment of inertia is 796.69 lb.-in.². The significance of these displacements and resistances to angular acceleration is difficult to interpret except in relation to another polycentric system. In the Laurence unit, for example, the displacement of the axis of rotation between 20 deg. and 65 deg. is much larger. Whether the order of magnitude of these differences is reflected in metabolic energy cost reductions remains to be determined in additional laboratory studies.

(3) Stance-Phase Characteristics. The potential stance-phase advantages to be derived from the shifting center of rotation lie in the alignment relationships between the instantaneous centers and the weight line in the prosthesis. The single-axis conventional knee is
usually aligned with the axis of rotation approximately ½ in. posterior to the weight line as indicated by the so-called TKA (trochanter-knee-ankle) line. The knee remains stable as long as the resultant of all the forces applied through the prosthesis to the ground remains anterior to the center of rotation. For this reason, amputees maintain the knee in full extension during the period of heel-contact to mid-stance as opposed to the normal gait in which the knee may flex 20 deg. from heel-contact to foot flat. As the resultant passes through or behind the knee center, a moment tending to flex the knee develops, and the amputee can only maintain the stability of the knee by forcible extension of the hip to exert an equal, but opposite, counter moment.

The polycentric knee presumably can be aligned so that the knee remains stable even though it is slightly flexed at heel-contact. Moreover, as opposed to single-axis knees, this stability can be provided without a corresponding increase in the effort required to initiate swing phase. Even if the amputee does not flex the knee in stance phase, appropriate alignment can reduce the effort to stabilize the knee when the resultant passes through or slightly behind the knee center. The added knee stability may also be available at the end of stance phase between heel-off and toe-off when the normal knee may flex more than 30 deg.

However, to achieve these benefits, the polycentric unit should be aligned with the most anterior center of rotation occurring during stance on or slightly posterior to the TKA line. This will provide stability throughout stance and permit an easy transition into swing phase.

In practice, however, aligning the TKA line in relation to an instantaneous center of rotation in space may be difficult. It can be seen from Figure 24 that the axis of rotation at full extension (0 deg. flexion) falls 0.225 in. posterior to point “A,” an easily identifiable landmark also shown in Figure 22. At 65 deg. of flexion, the axis of rotation falls 0.416 in. and at 20 deg., 0.150 in. anterior to point “A.” Therefore, aligning the TKA line 0.150 in. anterior to point “A” will presumably maintain knee stability when the knee is flexed up to 20 deg. since, as shown in Figure 24, the TKA line will fall through the instantaneous center of rotation at 20 deg. A laboratory analysis to test the validity of this theory was undertaken by means of the apparatus shown in Figure 25. The unit was loaded with 200 lb. at a point 0.150 in. anterior to Point A. The knee supported this load without collapsing even though flexed 16.5 deg. The discrepancy between the observed and theoretical points of stability (16.5 deg. versus 20 deg.) can be attributed to measurement errors. It can be said therefore that the test corroborates the theoretical analysis.

(4) Prosthetics Factors. Two subjects were fitted with the Northwestern University Polycentric Knee. However, this was done prior to the development of the theoretical optimal alignment criterium, and
they were fitted with conventional alignment techniques. After approximately 30 days of wear, both rejected it for essentially the same reasons: loss of friction resistance and excessive noise.

The prosthetist's experience in fitting these units indicated that:

(a) Alignment with the VAPC coupling was a routine procedure.

(b) Transfer was simple.

(c) Stability seemed excellent.

(d) Cosmesis was considered adequate.

(e) Friction resistance was inadequate: Although friction adjustment was easy, the initial settings were not maintained; and the unit allowed too long a period when no resistance was available.

(f) The socket mounting plate is inadequate. It failed in one case and the socket became detached.

(g) Maintenance requirements were excessive.
Subject No. 1 noted a strong terminal impact accompanied by a clicking noise. Examination revealed that the rubber extension bumpers were dislodged. They were replaced with $\frac{1}{4}$ in. felt. Friction resistance required readjustment and the assembly showed evidence of wear. Periodic visits were required to adjust or repair the friction unit and to eliminate noise. After several weeks of wear, the socket attachment failed. Subject No. 2 was required to make periodic visits to adjust or repair the friction assembly and to eliminate the noise caused by the rattling of components due to screws backing out.

(5) Patient Reaction. Subject No. 1 reacted favorably to the device initially, commenting on the stability, smoothness, and effortless walking. Later, however, he commented negatively, on the excessive noise and on the initially high friction setting necessary to compensate for the immediate loss of friction after a few steps.

Subject No. 2's initial reactions were similar. Subsequently, he criticized the excessive free motion period of the friction unit.

Appropriate recommendations to eliminate the major shortcomings have been submitted to the developer.

4. Laurence Polycentric Knee. Six production models of the Laurence Polycentric Knee (Fig. 26) were submitted for evaluation. The units are assembled from cast magnesium components including a socket mounting plate, a polycentric knee mechanism, a mechanical friction swing-control, and a pylon with provision for a foot attachment. This unit comes as a complete assembly including a plastic knee shell, cosmetic cover, and SACH foot. The knee mechanism is a four-bar linkage with the fixed link attached to an aluminum tubing upright. It is based on an original design developed by Professor Charles W. Radcliffe of the University of California at San Francisco.

The evaluation procedure included a mechanical analysis of the weight distribution, rotational kinematics, assessments of installation procedures, and amputee performance and reactions. To date, the mechanical analyses have been completed, and several patients are in the process of being fitted with this unit.

The knee mechanism without SACH foot, aluminum upright, or other attachments weighs 2.5 lb. The complete assembly weighs approximately 6.3 lb., making it slightly heavier than the Northwestern University Polycentric Knee.

During the first part of knee flexing, the axis of rotation shifts downward and anteriorly until the knee is flexed 35 deg. whereupon the axis begins to move posteriorly (Fig. 27). At 65 deg. of flexion the axis of rotation displaces 0.625 in. horizontally (same order of magnitude as the Northwestern University Polycentric Knee) and 5.531 in. vertically, which
is approximately five times as great as the vertical displacement of the axis of rotation in the Northwestern University Polycentric Knee (Fig. 23).

At 20 deg. of flexion, the knee axis displaces 1.031 in. vertically and the CG is 12.15 in. from the center of rotation. The mass moment of inertia is 922.63 lb.-in.\(^2\) which is similar to the Northwestern University unit. At 65 deg. of flexion, however, this distance has shortened to 7.64 in. and the mass moment is only 364.81 lb.-in.\(^2\), less than half that of the Northwestern University unit. This decreased resistance to shank acceleration may be reflected in decreased effort and, hence, a lowered metabolic cost.

The unit was loaded with 200 lb. at a point on the knee center displacement curve (Fig. 27) where theoretically, it should remain stable when flexed 20 deg. Under these conditions, the knee actually remained stable when flexed up to 16.5 deg., a relatively minor discrepancy from the theoretically adduced 20 deg.

Prior to clinical testing, a biomechanical analysis of amputee performance will be undertaken to test this theory and to determine the optimal alignment for the unit as was done on the Northwestern University unit.

5. The Blatchford Stabilized Knee. This device, a product of Charles A. Blatchford & Sons Ltd. of Lister Road, Basingstoke, Hants, England, is ingeniously designed to provide stance-phase stability by mechanical rather than by hydraulic resistance (Fig. 28). In the developer's view, mechanical systems are more easily manufactured and require less maintenance than hydraulic systems. Moreover, he believes that a knee mechanism designed for installation close to the knee center provides a more advantageous weight distribution than those whose mass extends down into the shank. Providing stance-phase stability may also permit the use of a softer dorsiflex-
ion foot bumper and require less alignment stability. This, it is pointed out, tends to reduce the "vault" or the magnitude of the vertical elevation of the body center of gravity and to reduce fatigue.

The Blatchford Stabilized Knee relies on the tensions produced in a brake band drawn taut under the influence of the wearer's body weight (Fig. 29). Springs serve the function of releasing the stabilizing effect of the brake band to permit knee flexion in swing phase. The body weight, applied to the limb, is shared between the release springs and the friction activating lever so that knee flexion is possible under very light loads, but as the load
increases the effect of the springs is overcome and the knee becomes increasingly stabilized.\textsuperscript{*}

This interesting device, based on a rather sound mechanical approach to achieve stability, is currently being evaluated as one of a series of stance-control mechanisms.

6. United States Manufacturing Company Pylon Prostheses. With the relatively recent upsurge of interest in early prosthetic fitting, there has been a sharp increase in the development of pylon prosthetic devices for immediate post operative and temporary fitting.

In March of 1965, a prototype model of the United States Manufacturing Company's prosthesis for temporary or immediate post operative fitting of below-knee amputees was evaluated. After several modifications had

\textsuperscript{*} The theoretical considerations as expressed by the developer are available upon request by writing to the Editor, Bulletin of Prosthetics Research.
been effected the unit was resubmitted together with a device designed for the above-knee and another for the through-knee amputee.

a. Below-Knee Pylon. The previous model of this device was evaluated to determine functional adequacy and the suitability of the material and was reported on in BPR 10–3 Spring 1965 (pages 118–121). As a result, several recommendations were made:

1. Index the adjustment plates to permit reorientation to a previous alignment.
2. Reduce the size of adjustment plates.
3. Serrate the foot attachment plug to prevent involuntary rotation.
4. Modify or redesign the quick-disconnect.

The developer submitted a redesigned prototype in which all of the suggested modifications were incorporated (Fig. 30).

The adjustment plates are indexed in ¼-in. increments permitting reorientation of previous alignments. In addition, both anterior-posterior and medial-lateral planes are identified. These features make it possible to measure alignment changes and aid in making trial adjustments. The index marks simplify returning to an original adjustment after trial adjustments. Because the entire alignment mechanism must be loosened, there is a possibility of loss of an alignment through slippage. Reestablishing the original alignment will be facilitated by the index marks.

The diameter of the adjustment plates has been reduced from 3 in. to 2½ in. The decreased bulk improves the appearance of the unit.

The foot attachment plug has been serrated to improve the security of foot attachment and to prevent unwanted rotation. The two-piece foot attachment plug includes a wedge which provides a tight jam fit in the distal end of the pylon.

The spring loaded, ball-detent, quick-disconnect of the old unit was replaced by a tapered dovetailed connection between the socket attachment plate and a mating plate integral to the adjustment assembly. The socket is disconnected from the shank and foot assembly by means of a captive thumbscrew which jams the tapered dovetailed section together when tightened, but allows very easy separation when loosened. The quick-disconnect system provides extreme stability and a positive connection.

The metal straps by which the unit is attached to the cast are notched to prevent loosening within the cast.

A yoke between the adjustment assembly and the pylon has been eliminated and longer stumps may be accommodated. The new model features a more compact adjustment assembly. In addition, the mating surfaces of the adjustment plate have been sandblasted to improve the resistance to slippage under load.
In general, this unit appears to be a substantial improvement over the previous model in that several problems associated with the quick-disconnect appear to have been overcome. However, laboratory tests comparing the amount of torque applied to stabilize and the amount to release the two mating surfaces, indicate that sandblasting the 2½-in. diameter adjustment assembly plates does not provide as much resistance to slippage under load as the untreated 3-in. diameter adjustment plates of one previous prototype. The need for improving the resistance to slippage will be determined in clinical trials.

b. Above-Knee Pylon. As shown in Figure 31 this unit is constructed on the Hydra-Cadence frame in which is mounted the Hydra-Knee.

This unit also features a tapered dovetailed connection between the socket attachment plate and a mating plate integral with the adjust-

Figure 30. The revised below-knee prosthesis for early ambulation produced by the U.S. Mfg. Co. Shown in the insets are the adjustable alignment devices consisting of wedge-shaped plates, the tapered dove-tailed connection for the socket attachment plate, and the two-piece foot attachment plug.

Figure 31. The above-knee pylon for early ambulation produced by the U.S. Mfg. Co. Shown in the insets are the alignment adjustment assembly and connection for the socket attachment plates. This device features a hydraulic knee-mechanism (Hydra-Knee) and a knee lock. The adjustable foot attachment plug has a spherical section.
ment assembly. However, the diameter of the adjustment plates is greater and the mechanism is therefore bulkier than in the below-knee model. It is also less convenient to disconnect than the below-knee design because an Allen wrench is required to turn the setscrew. The wedge adjustment plates are not indexed and do not permit convenient reorientation of previous alignments.

The foot attachment has a spherical section whose distal surface is serrated to improve the attachment of the foot. However, the ability of the shank section to maintain a setting under relatively high loads is questionable since a previously evaluated unit of similar design rotated after being loaded 13 times with 300 lb.

The knee mechanism features a knee lock. The knee may be locked in full extension by means of a spring-loaded pin which can be engaged in the knee bolt when the knee is in full extension. To unlock the knee, the spring-loaded pin is withdrawn and rotated out of the locking slot. As maintenance of the unlocked position depends upon spring tension, it is possible that vibration and shock when walking may cause the pin to rotate and drop inadvertently into the locking slot. An additional "unlocking" slot position would reduce this possibility.

Several problems previously associated with the installation of the Hydra-Knee unit in wood assemblies were noted: excessive play at the upper attachment, excessive adjustability of the operating rod, and the absence of a positive extension stop. Moreover, previous studies on the function of the Hydra-Knee unit indicated the need for further improvement.

The entire setup, exclusive of cosmetic cover, foot, shoe, and sockets weighs 3.25 lb. The completed prosthesis could weigh in the neighborhood of 13 lb., which may be excessive for even mildly debilitated patients.

C. Through-Knee Pylon. One unit designed for immediate post-operative or temporary application was submitted for evaluation (Fig. 32). The foot attachment mechanism, the provisions for linear adjustment, and the quick-disconnect features are identical with those described for the above-knee prosthesis. This unit does not include a means for angular adjustment at the knee, presumably on the theory that the initial angular adjustment made during the casting procedure would be adequate.

For immediate post operative or temporary use this device should incorporate a positive knee lock feature despite the fact that the relatively long stump of the through-knee patient may provide more control than that of the above-knee. Dependence on force applied by the stump and the resistance offered by the mechanical friction built into the knee joint would seem potentially hazardous during the first few days of wear.
The mechanical friction swing-control mechanism seems inadequate on two counts. It is difficult to maintain a resistance setting due to wear of the bearing surfaces. Moreover, it is extremely difficult to adjust the friction mechanism to provide equal resistances, and as a result one bearing wears more rapidly than the other.

The short sidebars in this unit have too great a cross section to permit convenient forming to the stump shape requirements.

The absence of adjustability for knee width may make it difficult, if not impossible, to fit certain cases. Bulbous distal stump ends are frequently encountered, and prosthetic knee width requirements may be further increased by the plaster cast. Providing adjustability for knee width may also reduce the problem of molding sidebars to conform to stump shapes.

We recommended to the manufacturer that the below-knee prosthesis be given limited trial applications with provision for feedback information.

With respect to the above-knee and through-knee prostheses, we have recommended further development before clinical trials are undertaken.

**Figure 32.** The through-knee pylon for early ambulation produced by the U.S. Mfg. Co. This device features outside knee joints with adjustable mechanical friction.

**Figure 33.** The Foort Below-Knee Pylon Prosthesis with split plastic socket shell which can be fastened over the patient's plaster-of-Paris or plastic socket.
7. Foort Below-Knee Pylon Prostheses. In addition to the devices developed by the A. J. Hosmer and United States Manufacturing Companies, Mr. James Foort of Prosthetics Orthotics Research and Development Unit, Manitoba Rehabilitation Hospital, 800 Sherbrook Street, Winnipeg, 2, Manitoba, Canada has also submitted a model of his temporary prosthesis. It is an adjustable pylon now manufactured by the A. J. Hosmer Corporation (Fig. 33). The device features a split plastic shell which serves as a receptacle for the socket. The socket is secured in the plastic shell by means of an adjustable clamp. The unit is aligned by two adjustment assemblies. One, attached to the distal end of the plastic shell and the upper portion of the pylon, provides adjustment of the socket in the transverse plane and both angular and linear displacement of the shell. The other assembly, attached to the lower end of the pylon, provides control of the foot attitude with respect to the floor.

a. Functional System. Both adjustment assemblies consist of two adjacent wedge-shaped, cylindrical sections placed between two flat plates (Fig. 33). The upper assembly and plastic shell are connected by means of a toggle-type pin. A similar pin is used to connect the lower assembly and foot. The components are maintained in the desired attitude by means of a locknut. Both assemblies are inserted into the pylon by studs and secured in place by clamps.

b. Range of Adjustment. Angular positioning of the socket through 12 deg. is possible by displacing the upper assembly to its maximum in any direction. In a unit measuring 13½ in. from the top of the adjustment plate to the floor, displacing the upper assembly 12 deg. displaces the foot linearly 2 in. The range of compensatory angular adjustment available at the lower assembly is 12 deg. (Fig. 34). By means of a 1-in. hole located in the distal end of the plastic shell, the entire assembly can be displaced 5/16 in. in the transverse plane.

Although the range of adjustment is dependent upon the length of the pylon and its angular deviation from the vertical, no practical limitation is placed on the length of stump which can be accommodated. The limiting factor is the space required for the components.

c. Strength. Under a simulated “worst” condition, the pylon (aluminum tubing) and tube adapter of the foot adjustment assembly failed when a dorsiflexion moment of 204 ft-lb. was applied (Fig. 35). Both components were permanently deformed. The cause of the failure was attributed to excessive tolerance between the aluminum tubing and the tube adapter. The excessive tolerance also caused fractures of the slotted tubing when the securing clamp was tightened.

d. Weight. The entire unit weighs 1.65 lb., a figure comparable to other types of pylons.

e. Maintenance of Setting. Once aligned, this device maintains the original setting under most conditions. The unit, fixed in an attitude
simulating toe-off, was loaded 100 times with 300 lb. or a dorsiflexion moment of approximately 85 ft.-lb. and no changes in the initial setting were evident.

The structural deficiency of the aluminum tubing and adapter revealed in laboratory tests can be eliminated by increasing the outside diameter of the tube adapter from 1.480 to 1.498 in. (the inside diameter of the commercial tubing is 1.500 in.). We recommended to the
developer that the modifications be made before clinical trials are undertaken.

8. Mauch Plastic Shank. In an effort to reduce the overall weight of their prosthetic setup, Mauch Laboratories have designed a polyurethane foam and aluminum shank, a prototype model of which has been submitted for laboratory testing (Fig. 36).

In addition to its lighter weight, the new shank can be produced in smaller sizes than the wood setup improving cosmesis in the fitting of slender amputees. Knee angle adjustability is not affected. The dimensional stability of the rigid polyurethane foam (Nopco BX 2435) RT will not be affected by environmental conditions.

The shank is a sandwich-type design consisting of a tubular aluminum shell which forms the internal surface as well as the cavity for the hydraulic

![Figure 35. The test fixture used to determine strength. The gage reading of 200 p.s.i. equals a 700-lb. load on the pylon. The application of 700 lb. is designed to simulate a condition in which twice the maximum normal dorsiflexion moment (100 ft.-lb.) is applied at the "ankle joint." 700 lb. acting at a point 3.5 in. anterior to the vertical axis of the shank produces a moment of approximately 204 ft.-lb.]

![Figure 36. Prototype model of the Mauch Laboratories' polyurethane foam and aluminum shank.]

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unit. A conventional polyester laminate, applied after final shaping of the foam, forms the external surface. The lower end of the tubular inner shell contains a 2¼-in. wood dowel insert which extends all the way to the lower end of the shank forming a rigid connection between the shank and the foot.

Structural strength and functional adequacy are being evaluated.

E. Evaluation (Techniques)

None.

II. UPPER-EXTREMITY PROSTHETICS

A. Development

None.

B. Evaluation (Components)

1. AIPR Externally Powered Components. Our studies on the application of the external power systems for upper-extremity prostheses developed by the American Institute for Prosthetic Research have proceeded through Step g of the evaluation program described in BPR 10–3 Spring 1965 and outlined below:

   a. Initial fitting of our bilateral amputee with conventional prosthesis on right humeral neck side, shoulder-disarticulation cap on the other side.
   b. Fitting of conventional shoulder-disarticulation prosthesis on left side, with shoulder abduction joint replacing shoulder cap.
   c. Substitution of AIPR CO₂ powered hook and wrist rotation unit for conventional units on the right humeral neck side.
   d. Refitting with Münster-type socket and conventional components on the right humeral neck side.
   e. Substitution of AIPR CO₂ powered hook and wrist rotation unit on right side.
   f. Substitution of a powered elbow for the conventional one on the right humeral neck side.
   g. Substitution on the right side of a passive shoulder joint (humeral abduction-adduction and flexion-extension) with an externally powered lock coupled to the elbow.
   h. Systematic addition of power to the left shoulder-disarticulation prosthesis.

We have previously reported our experiences in Steps a through d and some preliminary findings in Step e. Detailed below are the results of Steps e and f and some preliminary findings on Step g. In Step e, the subject was fitted with the externally powered hook and wrist rotation unit on the right side and conventional components on the left (Fig. 37 and 38).
Step e.—After approximately three months of wear the subject's performance was reevaluated. In general, he expressed satisfaction with the prostheses. However, the number of activities of daily living which he could successfully perform had not increased since the initial evaluation 3 months earlier. At that time, his performance had improved over his performance with conventional components on both arms in that he was capable of completing additional practical activities.

Several problems arose during this wear period. Operation of the additional components increased the control requirements. He found difficulty in separating out the control motions required to operate the externally powered wrist rotator (pronation-supination) and the elbow lock. Inadvertent elbow locking or unlocking occurred when he pronated or supinated his hook.

The addition of the externally powered wrist and terminal device was of no assistance in overcoming the problem of operating the zipper on his
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trousers. This was in contrast to his earlier performance with the conventional terminal device equipped with a passive wrist flexion unit, an arrangement with which he was able to operate the zipper on his trousers.

During this wear period, several minor maintenance problems occurred. The loss of a return spring on the valve controlling the terminal device caused a substantial reduction in the speed of terminal device operation.

At the reevaluation, his performance, as shown in Table 3, on the prehension test was poorer than with conventional body-powered components of Step d. More time was required to perform the test, significantly more errors were made, and overall appearance was poor. Performance on the positioning test was somewhat better, although still below the level achieved with body-powered components.

<table>
<thead>
<tr>
<th>Tests</th>
<th>Total time, min.</th>
<th>No. of errors</th>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prehension</td>
<td>5.3</td>
<td>16</td>
<td>Poor</td>
</tr>
<tr>
<td>Positioning</td>
<td>6.6</td>
<td>4</td>
<td>Average</td>
</tr>
</tbody>
</table>

The performance of practical activities was somewhat improved in that he could now complete six of the seven practical tasks, an improvement over the five performed with conventional components. The net energy cost of performing a second prehension test was slightly lower, 0.905 liters of oxygen as compared to 0.992 liters of oxygen with body-powered components (Step d.) although his performance was slower and he made more errors.

Step f.—The subject’s right prosthesis was completely powered by substituting a powered elbow for the conventional elbow (Fig. 39 and 40). In this configuration, terminal device operation was controlled by shoulder abduction. However, the control system was modified to produce pronation-supination by stump extension (hyperextension) instead of chest expansion. Actuation of elbow flexion-extension was accomplished by shoulder flexion.

After approximately a 5-week wear period, the subject’s performance was reevaluated. During that time, he had been able to do several activities (carry trays, open doors, unlock locks) easier, but not quicker. The time required to flex and extend the powered elbow is considerably longer than that required by a conventional elbow. On the other hand, he did not have to “bother” with the locking and unlocking of the elbow. While writing, constant pressure of the pencil against the table or desk caused the powered elbow to flex slightly, requiring him to extend the elbow periodically to resume the proper forearm attitude. The subject also reported that in
FIGURE 39. Step f.—A powered-elbow actuated by shoulder flexion against a pressure valve has been substituted in the amputee’s right prosthesis. Shoulder abduction still operates the terminal device, but shoulder extension (hyper-extension) actuates wrist rotation. The push valves are illustrated in the inset.

certain activities he inadvertently activated valves. The valves were repositioned to reduce unintentional actuation.

Performance of the prehension test with the powered elbow was slightly better than the performance in Step e (conventional E 400-2 elbow) in terms of taking less time and making fewer errors (Table 4).

Due primarily to the slow rate of elbow flexion-extension, the positioning test required more time than when the conventional elbow was used.

There was no significant improvement in the performance of practical activities, i.e., the same six were completed successfully and one could not be accomplished.

TABLE 4.—Performance with Completely Powered Right Prosthesis (Step f)

<table>
<thead>
<tr>
<th>Tests</th>
<th>Total time, min.</th>
<th>No. of errors</th>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prehension</td>
<td>4.8</td>
<td>14</td>
<td>Poor</td>
</tr>
<tr>
<td>Positioning</td>
<td>7.5</td>
<td>2</td>
<td>Good</td>
</tr>
</tbody>
</table>
The net energy cost for a second prehension test was a total of 0.955 liters of oxygen. This was slightly more costly than his performance with the conventional elbow.

Step g.—The original plan to install powered components in sequence was altered and instead, we completely powered the left shoulder-disarticulation prosthesis in this step. The fenestrated “frame-type” shoulder cap shown in Figure 41 was fitted with a passive shoulder joint featuring an externally powered lock coupled to the elbow and a powered elbow, hook, and wrist rotator. Carbon dioxide for both right- and left-side systems was supplied by a single gas container attached to the posterior side of the left prosthesis. To operate the powered components, the tip of the acromion was harnessed to a “joy stick” valve by which several functions were controlled. Moved in one plane, it produced elbow flexion-extension and in another plane, terminal device operation. A pull valve operated by chest expansion actuated pronation-supination.

After an initial period of controls training, the subject was returned to his home station for additional training with the primary emphasis placed on practical daily activities.

2. Plan for Additional Studies of Externally Powered Arm Prostheses. The development of externally powered arm prostheses during the past several years has become an object of great interest to prosthetics research centers in this country and abroad. As a result, the development of pneumatic and electrically powered artificial arm components has been accelerated and, at the present time, several different types of externally powered components and complete systems are being applied in the treatment of upper-extremity amputees. One of the earliest developments was the German “Heidelberg” arm, a reliably operating system powered by compressed carbon dioxide. De
developments in this and the related field of devices providing various forms of feedback control, have included the French "Vaduz" hand, the Russian electric hand, the Yugoslav "Tomovic" hand, several units developed by the British, and a family of Swedish components. In this country, the AIPR under the direction of Dr. Edward Kiessling has developed the original principle of the "Heidelberg" arm to a highly advanced state in which powered terminal devices, wrist rotators, elbow flexors, and partially powered shoulder units are available. Also under development in this country are the Sierra and the Northwestern University systems and the AMBRL and the Gilmatic electric elbows.

Among the American systems, the AIPR components are the most highly developed, and they represent an extremely high order of engineering design and technology. These devices have been used in the treatment of 52 upper-extremity amputees during the past 7 years at New York's Institute for Crippled and Disabled (ICD); a few systems have been used elsewhere in limited trials.

Although a great deal of time, energy, money, and inventive genius have been expended in development, only sporadic and incomplete efforts have been applied in the evaluation of these or any other externally powered components. More information of an objective nature is needed on the specific type of upper-extremity amputees for whom completely powered systems are indicated and on those who can profit most from hybrid systems employing one or more externally powered components in an otherwise conventional or body-powered prosthesis. We have proposed a broad evaluation program to achieve these aims. As the AIPR system is the most advanced American development, the program initially calls for a comprehensive study of this system to be followed by comparable studies on other systems.

Apart from case histories and internal evaluation studies conducted at ICD, previous efforts to evaluate the AIPR components include the work done at New York University, the University of California at Los Angeles, and the VA Prosthetics Center. As reported in April 1964 (2), the evaluation conducted at NYU was an ex post facto survey of 22 patients previously fitted with AIPR components. The study found the individual components to be reliable and well designed, but some doubt was registered about the utility of the available elbow torque and of the three-function pull valve. As the sample for this study was a group of previously fitted severely handicapped patients, comparisons were not drawn on performance achievement with conventional and powered systems, nor were prescriptive indications validated and prosthetic fitting techniques examined with respect to socket fitting, alignment, and control systems.

The work at the University of California at Los Angeles has not been published but the results communicated to the Director, AIPR in an
exchange of letters did not provide needed information on the application of these devices.

Since July 7, 1965, the VA Prosthetics Center has been engaged in a study of the effectiveness of externally powered upper-extremity prostheses as reported in BPR 10–2 Fall 1964, BPR 10–3 Spring 1965, and this issue. The study was initiated with the systematic application of the AIPR CO2 powered components to one bilateral amputee. The experiences gained during this investigation indicate that the AIPR components operate reliably and require very little maintenance. There are also indications that the severely handicapped upper-extremity patient found it easier to use the AIPR components than conventional devices, and that potential functional achievement may be higher.

The expansion of this program to a larger, more representative sample of upper-extremity amputees will provide useful information on the prescription indications for these devices among all amputees. As a bilateral shoulder-disarticulation/above-elbow, the single subject of the VAPC investigation represents the most severely disabled type of patient for whom any degree of meaningful functional regain is possible with currently available prosthetic treatment. The real potential of the AIPR system can best be studied by application to patients with amputations at other levels. We, therefore, have proposed an investigation of the effectiveness of the AIPR components on a sample of 12 to 15 patients with various types of bilateral and unilateral amputations. This study is conceived as a two-part effort:

A Clinical Study, to develop guidelines for the prescription and application of AIPR components for clinical use; and a Biomechanical Study, to obtain objective data on various aspects of performance with externally powered and conventional components.

The specific purposes of the Clinical Study program are:

a. Compare the relative effectiveness of externally powered and conventional components on the performance of selected high-level bilateral amputees.

b. Determine the reliability and durability of the AIPR components in a wide range of use activities.

c. Determine appropriate socket and harness designs to employ the AIPR components to their fullest advantage.

d. Identify efficient control sites and determine appropriate control elements (valves) for each site.

e. Develop effective training techniques.

f. Develop prescription criteria for the selection of specific externally powered components and/or completely powered prostheses.

The major purpose of the Biomechanical Study program is to evaluate the forces, velocities, ranges of motion, and areas of accessibility provided...
by the AIPR components. The results may indicate needs for additional components, or for the redesign of currently available units.

To achieve the purposes of the Clinical Study, at least six bilateral amputees with selected combinations of amputations will be fitted with appropriate AIPR components. After a suitable period of training and practice, the amputees' status will be evaluated by comparison with conventional prostheses in terms of the degree of comfort and function provided. In the Biomechanical Study, three additional unilateral subjects will be fitted with selected AIPR components. After appropriate training and practice, they will undergo a series of biomechanical test procedures to compare temporal, kinematic, and kinetic factors of performance with the AIPR and the conventional components.

SUBJECTS

Nine to twelve amputees who have not previously used externally powered prostheses will participate in this study. They will be divided into two groups. The Clinical Study group will consist of 6-9 bilateral amputees including one or two patients in each of the following categories:

Shoulder-disarticulation/shoulder-disarticulation
above-elbow/above-elbow
below-elbow/below-below
below-elbow/above-below
above-elbow/shoulder-disarticulation
below-elbow/shoulder-disarticulation

Bilateral amputees who have previously been fitted with conventional prostheses are preferred; however, several non-previous wearers may be selected.

The Biomechanical Study group will consist of three unilateral amputees including one each of the following: shoulder-disarticulation, above-elbow, and below-elbow. This group will be selected from a class of patients who have previously worn conventional prostheses and who are considered highly adept.

CLINICAL STUDY

After careful selection of the most suitable subjects, the following steps will be undertaken:

Step 1.—Evaluate performance with optimally fitted “conventional” prostheses.

Selected patients will be examined thoroughly, with particular attention to residual forces, ranges of motion, control sites, and adequacy of conventional prostheses. All deficiencies noted in fit, alignment, and function of prostheses will be corrected before initiating the performance evaluation.
Step 2.—Prescribe and fit subjects with externally powered prostheses. Based on level of amputation and functional status, the most appropriate prescription recommended by the developer will be determined. This prescription will be considered the initial or trial prescription. If subsequent fitting procedures and evaluation indicate the need for change, the trial prescription will be modified accordingly. As a result of this step, prescription guidelines for use in the field will be validated for each amputee category.

Step 3.—Intensive training including controls and use training.

A program of controls training will be applied to develop maximum facility in the operation of specific components and in the integration of all functions provided. The use of special equipment and the extensive use of drill are aimed at reducing the neuromuscular activity pattern required to operate the components to an “unconscious” level.

As control develops, use training will be initiated to include the most significant activities of daily living. During the training period, performance will be evaluated to describe the achievement curves.

Step 4.—Performance evaluations after 1-month, 3-month, and 6-month wear periods.

Apart from the testing of performance during the training period, evaluations will be undertaken at the prescribed intervals in order to compare the relative effectiveness of AIPR components with conventional components. The procedures are described below under Tests.

Step 5.—Reevaluation of prosthetic prescription with subsequent refitting, and if indicated, the repetition of Steps 2, 3, and 4.

Step 5 will actually be undertaken during each of the procedures after Step 2. As the subject’s proficiency and range of activities increase, new needs may be identified necessitating modification of the prostheses. If no modifications are indicated at the termination of Step 4, the prescription will be validated for the type of patient involved.

TESTS

The following series of tests will be administered to the Clinical Study group for purposes of comparison with conventional systems:

a. Abstract Function Tests
   (1) Two-dimensional prehension test.
   (2) Two-dimensional positioning test.
   (3) Three-dimensional prehension and positioning test.

b. Practical Activity Tests
   (1) Self-care including eating, dressing, and toilet activities.
   (2) Performance in household and office activities.
   (3) Performance of travel activities.
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c. Energy Cost of Two-Dimensional Prehension Test
All performances will be scored employing a combination of systems previously established at New York University, the University of California at Los Angeles, and the VA Prosthetics Center (3, 4, 5, 6, 7). Overall evaluation of the prosthetic systems will be based on: a. objectively scored abstract tests and energy requirements, b. subjective evaluation of proficiency in performance, c. number and significance of activities of daily living performed, and d. patient preference.

BIOMECHANICAL STUDY
The three unilateral amputee subjects, one each below-elbow, above-elbow, and shoulder-disarticulation will participate in biomechanical analyses of:

Step 1.—Performance with conventional prosthesis.
Terminal devices, wrists, elbows, and shoulder units will be instrumented to measure displacements, velocities, and forces during the performance of standard tasks. Performance patterns will be determined by means of three-dimensional photometric techniques and by electronic instrumentation to record joint motions.

Step 2.—Performance with the sound limb.
Performance with the sound limb of a unilateral amputee is a more meaningful standard of performance than the performance of non-amputees. In effect, the remaining intact limb becomes functionally, if not neurologically, dominant and therefore represents the maximum achievement potential providing a reasonable basis for comparison with prosthetic performance utilizing different devices.

Step 3.—Performance with AIPR systems.
The performance achieved with AIPR components, conventional prostheses, and with sound limbs will be compared. The influences of biomechanical factors on performance will provide redesign guidance.

Step 4.—Performance with hybridized systems.
Based on all the preceding analyses, conventional components will be substituted for powered units to study the effects of mixed systems.

The program has not yet been initiated due to current limitations in the number of professional personnel available. With the required personnel, approximately 18 to 24 months will be required to carry out the complete program. However, useful information will be obtained within 3 or 4 months and reported, as available, for each case type. The availability of amputee subjects will determine both the order in which cases are studied and the duration of the entire program.

3. Gilmatic Wrist Rotator. A prototype of this device, designed to permit amputees to pronate and supinate their terminal devices, has been developed under VA contract by Mr. Gilbert Motis.
Shown in Figure 42, the unit is 4 3/4 in. in length with a wrist diameter of 2 1/2 in. The laminating ring is approximately 2 in. in diameter and the complete device weighs 5.2 oz. It provides “pronation” and “supination” by means of an alternating mechanism consisting of a lock and rider assembly mounted directly behind the laminating ring.

The device has two internal cable-pulley systems and a locking mechanism directly linked to the control cable.

Pulling on the control cable moves the alternating lock which engages one of these internal systems. As the lock moves proximally, it drags one of the two internal cables causing the terminal device in the wrist to rotate in one direction. Upon releasing the control cable, the spring-loaded lock moves distally cocking the alternator so that it disengages from the first operating cable and moves laterally into a position to engage the other internal cable in the next cycle. Pulling the control cable again rotates the terminal device but in the opposite direction.

The control cable requires an excursion of 1 3/16 in. providing a maximum of 140 deg. of rotation. Approximately 6.0 lb. of force are required to operate the mechanism.

The unit was installed in the forearm of an above-elbow prosthesis to evaluate functional utility and to identify possible control sites. The test subject was an experienced and active wearer of a standard above-elbow prosthesis including a modified “figure 8” harness, manual friction wrist, and double-transmission triple-function control system.

Installation was relatively simple, but the selection of the most appropriate control motion and site is a significant problem. Several control sites were selected for trial use, and the following harness modifications were made:

<table>
<thead>
<tr>
<th>Control Site and Motion</th>
<th>Harness Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>opposite shoulder anchor and shoulder flexion on stump side</td>
<td>single axilla loop</td>
</tr>
<tr>
<td>scapular excursion</td>
<td>auxiliary strap</td>
</tr>
<tr>
<td>shoulder elevation</td>
<td>lateral suspension strap</td>
</tr>
<tr>
<td>stump abduction</td>
<td>chest strap</td>
</tr>
</tbody>
</table>

Although the subject had sufficient force and excursion to activate the unit at the selected control sites, he had difficulty in separating the control motions from those required to operate the other two components. Inadvertent activation of one or more of the other components (elbow and terminal device) occurred with all of these harness configurations.

Initial laboratory evaluation indicates that the individual subject’s ability to separate the various control motions may be a determining factor in the utility of the device. Standard harness configurations may not be applicable with the control motions presently used to operate the terminal device, to flex the elbow, and to lock the elbow; unusual control sites may be required.
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The value of wrist rotation to the above-elbow amputee is unquestionable, but perhaps not at the risk of over-harnessing or restricting motion of the sound side. We are continuing our studies to identify the most effective control sites. In this connection, we are exploring the possibilities of utilizing the wrist rotator in hybrid systems consisting of both externally and body-powered components.

4. Child Amputee Prosthetics Project (CAPP) Terminal Device. Prototypes of this device, also known as the Sumida hook, are currently being examined in several laboratories around the country (BPR 10–3 Spring 1965). It is designed to be utilized with external power actuating the push-pull operating rod. In the absence of a suitable system, it was necessary to modify the unit and power it with springs in a voluntary opening mode. Of particular interest were the finger and the “palm” section and the utility of the angle of approach. The limited area of the contact surface between the finger and palm makes it difficult to grasp small objects such as a pencil since there is essentially only one “point” of contact. The medial angulation of

Figure 42. Prototype of Gilmatic Wrist Rotator. A pull on the operating cable rotates the terminal device in one direction. Relaxing allows the mechanism to recycle so that a subsequent pull causes the terminal device to rotate in the opposite direction.

Figure 43. CAPP terminal device deviates 15 deg. medially with respect to the forearm.
the fingers (Fig. 43) requires considerable humeral shoulder-abduction in
grasping objects on a table or desk. This attitude, however, may be advan-
tageous in reaching the mid-line of the body or the mouth.

The resilient palmar surface and finger configuration are excellent for
grasping round smooth objects such as glasses and cups and irregularly
shaped objects.

The device is being redesigned for more effective body power actuation, in
order to continue the evaluation of its prehension capabilities.

5. Dorrance Hand. Three Dorrance Model No. 4 Voluntary Opening
Hands (Fig. 44) were submitted to this laboratory for evaluation. One
unit was checked against “Tentative Specifications, Hand, Adult Size, Me-
canical, Voluntary Opening for Upper Extremity Amputees,” APRL
Technical Report 223-902, and the other two are being fitted to patients
in an effort to obtain clinical data.

The hand is adequately anthropomorphic and operates smoothly and
without undue noise. In general, it is mechanically sound and potentially
acceptable. However, several apparent deficiencies were noted:

a. The force to initiate finger movement is rather high. The hand
required 10.5 lb. or approximately twice as much as the recommended
4.5–5.0 lb. Whether this is excessive for normal utilization by ampu-
tees remains to be seen.

b. The force required to open the hand fully with glove on is ex-
cessive. Without the glove, opening the hand required 16.0 lb., a
figure well within the acceptable limit of 13.0–18.0 lb. With glove,
however, full opening required 25.0 lb.

c. Moving the active fingers through the full range of motion re-
quired an excursion of 1¼ in. or approximately ¼ in. over the rec-
ommended amount of travel.

d. The grasping surface of the thumb was not equipped with a
resilient pad. This may cause excessive glove wear, a matter to be
determined by patient use.

To date, neither durability test data (300,000 cycles) nor adequate
clinical data are available. The cited deficiencies were brought to the
attention of the developer who modified the unit appropriately. Clinical
and durability tests now in progress are being performed on this modified
hand.

Opening Hand was submitted for evaluation (Fig. 45). The hand features
a plastic hand shell and coil spring fingers with resilient plastic finger tips.
The four fingers and thumb are movable with prehension provided between
the index finger and thumb. The pinch force is adjustable to the individual
patient requirements. The fingers move independently permitting a four
finger grasp of irregularly shaped objects. The device can be covered
with any of the commercially available cosmetic gloves.
To date, neither the durability tests data nor adequate clinical data are available. However, laboratory analyses indicated the hand is generally mechanically sound, adequately anthropomorphic, and lighter in weight than previous models and, therefore, potentially acceptable.

We suggested to the developer that the finger coils be coated with a flexible plastic to prolong the life of the cosmetic glove. Clinical and durability tests are continuing to complete the evaluation program.

C. Evaluation (Techniques)

None.

III. LOWER-EXTREMITY ORTHOTICS

A. Development

Friction Ankle for “Drop-Foot” Brace. A typical “drop-foot” condition resulting from disease or trauma frequently involves more than one muscle group; as for example, injury of the common peroneal nerve may affect both the tibialis anterior and the peroneal muscles. Spring-loaded braces with rigid sidebars are usually prescribed for these cases—the spring action substituting for the function of the disabled muscles. However, spring-
loaded devices often cause discomfort and perhaps contribute to increased spasticity.

We have designed a "drop-foot" brace employing friction ankle joints instead of spring-loaded joints (Fig. 46). Under dynamic conditions, the weight of the patient is sufficient to overcome the frictional resistance at the ankle, thereby permitting a full range of ankle motion controlled only by the application of body weight. When the patient's foot is lifted from the floor after toe-off, the frictional resistance of the ankle brace holds the foot in the last weight-bearing attitude established. The friction resistance at the ankle prevents the foot from dropping during the swing phase of walking. At heel-contact or at the beginning of stance phase, the joint friction prevents foot-slap by resisting the plantar flexion movement developed about the ankle.

The friction mechanism, essentially a lap joint, is constructed of two thin steel disks. The friction "drop-foot" brace is a thin plastic laminated shell molded around the ankle and under the sole of the foot. Consisting of a molded arch support section, an ankle section, and a calf band, it is designed for wear inside the sock and shoe. Mild inversion-eversion imbalance of the foot can be controlled by judicious casting of the arch and ankle section. Additional development of this device, now in progress, may permit the independent adjustment of plantar flexion and dorsiflexion resistances.

B. Evaluation

1. Foot Supports. During the past year, two techniques for molding arch supports under dynamic conditions have been evaluated. Both the Army Medical Biomechanical Research Laboratory Dynamic Arch Support and the VAPC Neoprene Foot Support are molded to the plantar surface of the foot by inserting the molding material into the shoe and relying upon
the pressure of the body to form the support while the patient walks with the shoe. The specific functions performed by these supports and by several other conventional types have not been general agreed upon by orthotists, podiatrists, and other clinicians. While it seems fairly clear that supports molded to the plantar surface of the foot can provide relief for painful areas by reducing surface pressures, it is not at all clear just how and to what degree they affect foot balance, a purpose for which they are frequently prescribed. In an effort to clarify these matters, we have undertaken a program to study the effects on both comfort and foot balance of various types of arch and foot supports.

This program involves the fitting of patients with several types of supports presumably designed for the same purpose. The results will be evaluated in terms of: a. patient reaction to comfort, b. objective measures of posture and gait, and c. fabrication complexity and time.

Both patient reactions and time/convenience/cost data are relatively simple to obtain. It is far more difficult to collect objective data on such matters as “foot balance,” pressure distribution, and weight transition during stance phase.

The portion of this study dealing with the collection of objective data is being held up for want of an adequate instrument. Reduced force plate data can provide measures of the transition of the instantaneous center of pressure across the sole of the foot or shoe during the period of heel-contact to toe-off. Based on the vectorial sums of all the forces interacting between the foot and the ground, these data provide in effect only “averages” to describe the path of the instantaneous center of pressure from heel-contact to toe-off. The barograph, on the other hand, permits the pressure distribution pattern over the entire surface between the foot or shoe and the ground to be photographed. Developed initially by Elftman (8) and refined by University of California at Berkeley (1) it relies on the regulation of light transmission through a Plexiglas plate by pressure of the foot on a dimpled mat.

We have not yet been able to calibrate the barograph in terms of load versus light transmission. Nevertheless, it seems sufficiently sensitive to relative pressures and to alterations in pressure distributions. Although we are continuing our effort to refine the barograph to the point where we can quantify the data, we are employing it to demonstrate alterations in foot balance resulting from the use of foot supports.

Shown in Figures 47 through 53 are barograms illustrating the pressure patterns between the floor and the plantar surface of a patient’s foot and between the floor and the sole of his shoe.

The subject was a temporary staff member for whom his personal physician had prescribed Whitman plates, medial heel and sole wedges, and a Thomas heel. The series of barograms (Figs. 47, 48, 49, 50, 51, 52 and 53)
were made to determine whether the instrument was of sufficient sensitivity to indicate the effect on foot balance of each element of the prescription. Shown in Figures 47 and 48, for comparative purposes, are barograms of a normal individual with and without shoes. Figures 49 and 50 are barograms of the subject with foot pathology, barefooted and wearing conventional uncorrected shoes. The absence of the normally sharp pressure gradient from the lateral to the medial border of the bare foot can be noted. Although the shoes appear to mask the tendency toward excessive medial weight bearing, closer inspection reveals higher pressures on the lateral border of heel particularly in the normal, a feature not apparent in the patient's barogram.

Seen in Figure 51 is the foot pressure pattern of the patient wearing conventional, uncorrected shoes with the prescribed Whitman plate. In general, the apparent effect was a slight shift of the patient's weight posteriorly to a somewhat greater extent on the left than on the right. The Whitman plates in the conventional shoes do not appear to have influenced the medio-lateral distribution of weight; the effect was primarily a shift of weight in the anterior-posterior direction which may be related to the subject's feelings of comfort. Figure 52 shows the effect of wearing the orthopedic shoes corrected with a Thomas heel and medial and sole wedges. It is apparent that a substantial shift of weight to the lateral borders of the shoes had been effected, indicating an alteration

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**Figure 47.** Barogram of normal feet without shoes with individual standing erect with weight equally distributed on the two feet.

**Figure 48.** Barogram of same normal individual as in Figure 47 but with shoes.

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FIGURE 49. Pressure distribution of subject with foot pathology, not wearing shoes.

FIGURE 50. Pressure distribution patterns of subject wearing conventional, uncorrected shoes.

FIGURE 51. Barogram of subject wearing conventional, uncorrected shoes with Whitman plates.

FIGURE 52. Pressure distribution of subject wearing orthopedic shoes with Thomas heels, and medial heel and sole wedges.
in the medio-lateral balance of the foot. Figure 53 is a barogram of the patient wearing the orthopedic shoes in which the Whitman plates have been inserted as originally prescribed. Although there are slight indications of additional shifting of weight toward the area of the fifth metatarsal head, no appreciable change seems to have taken place.

Taken at face value, this series of barograms would seem to indicate that the Whitman plate is effective in redistributing the weight in the anterior-posterior plane but has no effect on medio-lateral balance of the foot. The Thomas heel and the wedges, however, shift body weight to the lateral borders of the feet. Improvement of the sensitivity and reliability of the barograph may improve the objectivity of these data.

2. Single-Bar Brace. In the latter part of 1962, the VA Prosthetics Center began to develop single-bar braces designed for both leg and leg-thigh applications. The first patient fitted was a 42-year-old female with bilateral flail lower extremities as a result of multiple sclerosis. She complained that her braces (double-bar aluminum braces with ring locks at the knee and stirrups) were too bulky, heavy, and taxed her strength excessively. In an attempt to reduce weight and bulk, a pair of single-bar braces was fabricated for this patient. Made from commercially available aluminum components, these braces included pelvic bands, ring locks at the hips and knees, conventional thigh and calf bands, and conventional stirrups. The ring locks at the hips were used only while standing, but not while walking. The single-bar braces were approximately 25 percent lighter than the double-bar braces she had previously worn. There was a marked improvement in the patient's balance and gait and she could walk for much longer periods before becoming fatigued. Encouraged, we continued to experiment with different up-
right and brace band designs in an effort to develop an adequate single-bar brace for general use. It has been difficult to formulate an adequate strength-weight ratio for the sidebars. Our previous studies on the materials and sidebar cross sections for use in the single-bar brace was reported in BPR 10-3 Spring 1965.

Single-bar construction provides advantages for both patients and orthotists. The patient benefits from reduced weight and less bulk. Comfort and mobility are increased due to the elimination of the medial bars. Concerned with the alignment of only one mechanical ankle joint, the orthotist finds it easier to align the mechanical ankle joint more precisely with the anatomical one. Toe-in and toe-out adjustments are easily accomplished, as are corrections for varus and valgus. The single-bar upright requires less shaping and bending than the two lateral uprights on conventional braces.

During the past two years we have fitted eight bilateral and nine unilateral patients with single-bar braces. We have also continually altered the brace bar material and cross section in an effort to determine the optimal combination.

The single-bar leg brace, whether unilaterally or bilaterally fitted, was routinely worn full time. However, the four patients fitted unilaterally with leg-thigh braces wore them only part of the time. These patients indicated that they wore their conventional braces for “strenuous activity” because the “functional knee,” with which all of the single-bar leg-thick braces were equipped, did not provide a positive knee lock.

We have also attempted to improve the calf and thigh band configuration. At the present time, we are using only two bands and cuffs (one above the knee and one below the knee) as opposed to the three bands used on conventional leg-thigh braces. Both bands are designed to encircle two-thirds of the extremity and to provide sufficient anterior opening for the patient to enter the brace.

The thigh band is fitted just distal to the greater trochanter and it extends anteriorly beyond the upright on the thigh. Posteriorly, it spirals downward following the gluteal fold and the medial aspect of the thigh and terminates antero-medially at approximately 4 in. above the knee (Fig. 54). The calf band extends anterior to the upright on the leg and is located posteriorly at mid-calf level. The upper medial portion of the band borders on the flare of the tibia.

This calf and thigh band configuration is designed to provide maximum stability by increasing the rigidity of the coupling between the single external lateral bar and the internal tibia and femur. In effect, we are attempting to substitute the tibia and the femur for the medial bar by means of the bands.
In continuation of these studies, we are analyzing the causes for part-time use of the leg-thigh braces. The preliminary indications are that increasing the resistance of the sidebars to deformation is necessary even at the risk of some increase in the weight of the single bar. Even a substantial weight increase would be offset by the use of one bar instead of two because of the potential advantages of single-bar construction for both patients and orthotists.

**Figure 54.** Anterior view of a VAPC single-bar leg-thigh brace. The thigh and calf bands have been designed to provide maximum lateral stability by increasing the rigidity of the coupling between the single lateral bar and the femur and tibia.
IV. ORTHOPEDIC AIDS

A. Development

None.

B. Evaluation (Components)

1. Vagabond–28 Lightweight Stainless Steel Wheelchair. Three models of the Vagabond–28 wheelchair (Fig. 55) were submitted for evaluation by the Stainless Specialties Company of Bell Gardens, California. These devices are primarily of stainless steel construction and feature pneumatic tires on the drive wheels. Weighing from 31.00 to 31.25 lb., depending on whether a light or heavy caster tire is used, they are 4 to 5 lb. heavier than other “lightweight” chairs, and approximately 10 to 15 lb. lighter than conventional chairs. The hand rims, 21 in. in diameter, are constructed of 3/8-in. outside diameter stainless steel tubing. An accessory pouch is provided on the nylon back support. A 2-in. wide plastic heel strap is provided on each footrest which is of the swinging, detachable type.

Figure 55. Vagabond–28. Lightweight Stainless Steel Wheelchair featuring pneumatic tires on the drive wheels.
The evaluation procedure included mechanical, biomechanical, and clinical analyses:

a. Mechanical. The chairs were checked against “VA Specification 7043400b, April 22, 1958, Wheelchairs, Folding, Universal, Modified.” Strength and durability were assessed by means of a destructive test.

b. Biomechanical. The relative stability of the chairs was determined, and the force required to set them in motion was measured. Also evaluated were safety, ease of operation, maneuverability, and comfort. The chairs were used in the laboratory and at home by two wheelchair users.

c. Clinical. An independent evaluation was conducted at the Bronx, N.Y. VA Hospital where several patients used the chairs for a period of 1 month.

In general, the Vagabond-28 Stainless Specialties Wheelchair appears to be a comfortable device with relatively high resistance to impact. Whether impact resistance is due to the pneumatic tire feature or the strength of the stainless steel members is unknown and essentially irrelevant, since both features are standard in this unit. The chair is very easy to propel, quite maneuverable, and relatively stable. This initial evaluation, however, revealed several shortcomings which have been brought to the attention of the manufacturer who has taken the necessary steps to eliminate them.

2. Hydro-Crutch Model FP 2000-1. An earlier model of the Hydro-Crutch (FP 2000) was evaluated in January 1965 and reported in BPR 10-3 Spring 1965. Considered a second generation prototype, the new model incorporates several modifications recommended in our evaluation of the original model.

The appearance of the FP 2000-1 (Fig. 56) is quite similar to the earlier model, consisting of a telescoping steel tube acting as a piston inside a second tube acting as a cylinder, a bi-valved sacroiliac axillary support, a D.C. motor driven by nickel-cadmium batteries, and a hydraulic lift system. The crutch has been modified to permit controlled retraction under load without power, and to eliminate inadvertent retraction under no-power conditions. The axillary support has been modified to provide relief for the axillary nerve and pectoralis tendon. Each unit, including oil and batteries, weighs approximately 7.7 lb. The telescoping portion of the fully extended crutch displaces a maximum of 16.0 in. Overall height of the fully extended crutch is 58.5 in.; fully retracted the crutch is 42.5 in. in length. A limiting switch has been installed to facilitate automatic adjustment of the extension range at any point within these limits. The available range of extension will probably serve 99 percent of the normal adult male population since floor-to-axilla heights for adult males average 52.5 in. (9).
The test program devised to evaluate the modified crutches included analyses of:

a. Design. A detailed analysis of the electrical and hydraulic systems was undertaken. The method of fabrication and construction with respect to materials, connections, and seals was evaluated, and the safety factors associated with use of the crutches were assessed. The electrical circuitry was found adequate for the intended purpose. However, the conductors, the connectors, and the switches are undersized for the most efficient operation of the motor. The hydraulic masterslave system controlling the retraction valve does not operate reliably. Operation of the main hydraulic piston-cylinder lift assembly demonstrated a slow but continuous leakage of hydraulic fluid. The rate of fluid loss is very low and would not cause the system to fail more frequently than perhaps every six months without refilling. The Hydro-Crutch incorporates features which permit its operation without undue hazard. Due to the action of check valves, power failure for any reason does not result in uncontrolled retraction of the crutch.
A power failure during a lift does not prevent subsequent retraction.

b. Performance. The operation of the crutches was tested in a specially designed fixture which was programmed to simulate expected usage under rigorous but realistic conditions. The crutches were cycled under load to determine battery charge life, power requirements, extension-retraction times, and endurance of the hydraulic systems. By means of the fixture shown in Figure 57, axial loads were applied to the crutches while they were maintained in a vertical position. An electronic programming unit controlled the sequence and duration of each of the test operations and switched the recording oscillographs on and off.

As no reference data were available on the weights typically borne by crutches designed for lifting, appropriate loads were empirically derived. In the initial test series, the crutch was loaded with 100 lb. to simulate a "worst condition." The underlying assumption was that a 250-lb. man employing a 3-point base to raise himself from a chair, would apply a maximum of 100 lb. to each crutch and 50 lb. to both feet. To simulate a somewhat more typical heavy use condition, it was loaded with 75 lb. in the second test series.

To simulate anticipated conditions of normal use, a single complete cycle was defined to include: one full extension from the fully retracted position, a pause in the extended position, and a return to the retracted position. All of these operations were performed under load. Failure to reach full extension, or retraction within 20 seconds was considered indicative of the end of useful battery charge life. As there are no reference data on the expected frequency of crutch lifts in daily use, the fixture was programmed to cycle the crutch as frequently as possible without generating thermal effects that might interfere with operation.

The following phasic pattern was automatically and repetitively programmed by the electronic segment section of the test fixture:

1. Switch on transistorized recorder for 5-second warmup to initiate recording of voltage, current, and crutch length.
2. Close extension electrical circuit and continue recording.
3. Actuate malfunction signal if crutch does not reach full extension within 20 seconds. Open extension circuit at 20 seconds.
4. Pause 20 seconds in extended position.
5. Actuate retraction control and continue recording.
6. Actuate malfunction signal if crutch fails to retract fully within 20 seconds. Release retraction control and shut down recording system for 10 minutes.

Two series of tests were performed. In the first, the crutch was powered by the supplied nickel-cadmium batteries and the number of complete cycles provided by charged batteries was determined. Ex-
FIGURE 57. The test fixture showing the crutch in the extended position during a lifting cycle. The program control unit turns on the recorder, actuates the lifting and lowering mechanism, and shuts off the recorder at the end of a cycle. It controls the sequence and duration of the operations and signals the occurrence of malfunction or interference with the programmed cycle.
tension-retraction time was monitored throughout the series to determine the effect of repeated cycling. During the first series, the crutch was initially loaded with 100 lb. and subsequently with 75 lb.

The second series was performed without the supplied batteries. Utilizing external power, the crutch was cycled to determine life and reliability of the electrical, mechanical, and hydraulic systems.

The results of these tests are shown below:

1. Number of Cycles per Battery Charge. Under a load of 100 lb., freshly charged batteries provided an average of 11.6 complete cycles. As shown in Figure 58, fully charged batteries in one instance failed to extend the crutch completely within 20 seconds after 8 cycles; in the second and third tests, failure to attain maximum extension within 20 seconds occurred after 10 and 16 cycles respectively. Retraction time was completely independent of battery life, occupying a period of approximately 2.9 seconds during all the tests.

Under a more realistic condition of "hard use" (a load of 75 lb.), freshly charged batteries provided more than twice the number of useful cycles available under 100 lb. of load. As shown in Figure 59, an average of 23.0 cycles was completed before the gradual rise in extension time exceeded 20 seconds. In three separate series of tests, battery charge life ranged from 20 to 27 cycles. Retraction time was

---

![Figure 58. Time versus Number of Cycles, 100-lb. load.](image-url)
slightly higher under the 75-lb. load consistently requiring 3.6 seconds, or approximately 0.7 seconds longer than under the 100-lb. load.

Due to the apparently nonlinear character of the weight-versus-number of cycles relationship, lighter individuals can expect a slightly longer battery charge life. For example, a 150-lb. man might distribute his weight during a lift to carry 40 lb. on his legs and 55 lb. on each crutch. In these circumstances, he might expect the crutches to provide approximately 27 complete cycles with one battery charge.

(2) Time Required to Attain Full Extension. Under a load of 100 lb. the average rise time was approximately 16.4 seconds over a series of 35 cycles in which three sets of freshly charged batteries were depleted. Reference to Figure 58 reveals that, in general, a mild rise time increment occurred with each cycle. After the rise time approached 20 seconds, it began to increase rapidly.

Under the 75-lb. load (Fig. 59), rise time averaged approximately 14.0 seconds, being 2.4 seconds faster than under the 100-lb. load. Rise time remained fairly constant for approximately 22 cycles before rapid increases with each cycle occurred.
(3) Power Degradation with Repeated Cycling. To extend the crutch through the full range within 20 seconds under a 100-lb. load required an average of slightly less than 17.0 amperes at approximately 7.5 volts (Fig. 60 and 61). Current and voltage dropped rapidly after approximately 11 cycles, a point corresponding to the time when rise time exceeded 20 seconds. When the voltage available under motor load fell below 7 volts, the crutch failed to extend within 20 seconds. Full extension under the 75-lb. load consumed an average of 18.0 amperes at approximately 7.8 volts (Fig. 62 and 63). Due to the shorter rise time under the lighter load, more power was available as indicated by the higher current and voltage values.

(4) Life Cycling by Means of Externally Supplied Power. With the batteries removed, the crutches were cycled in the test fixture (which provided operating power equivalent to fresh batteries) to determine life expectancy of the subsystems. Under a 75-lb. load, 2500 cycles have been completed without failure of structural members, the hydraulic systems, or the electrical system. The life cycling program was discontinued pending redesign of the Hydro-Crutch. Oil leakage around the main cylinder was slight, but continuous throughout the program. The total amount of leakage did not cause malfunction nor require refilling of the reservoir.
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VOLTAGE VS NUMBER OF CYCLES
100-lb LOAD

LEGEND
- FIRST BATTERY CHARGE
- SECOND BATTERY CHARGE
- THIRD BATTERY CHARGE

NUMBER OF CYCLES

FIGURE 61

AMPERAGE VS NUMBER OF CYCLES
75-lb LOAD

LEGEND
- FIRST BATTERY CHARGE
- SECOND BATTERY CHARGE
- THIRD BATTERY CHARGE

NUMBER OF CYCLES

FIGURE 62
A summary of these performance data is shown in Table 5.

c. Clinical Use. Patient performance with the Hydro-Crutches was observed in several clinics and hospitals under “normal” conditions for periods up to two weeks. These limited clinical studies were designed solely to provide a small volume of data on the performance of the crutches in actual use by patients. The primary purpose was to clarify and amplify specific laboratory findings. These observations are not considered clinical trials of adequate scope.

<table>
<thead>
<tr>
<th>Table 5.—Summary of Performance Data</th>
</tr>
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<tbody>
<tr>
<td>Crutch load in pounds</td>
</tr>
<tr>
<td>Typical number of cycles available per battery charge</td>
</tr>
<tr>
<td>Average crutch retraction time in seconds</td>
</tr>
<tr>
<td>Average crutch extension time in seconds</td>
</tr>
</tbody>
</table>

The performance of one patient was observed in the Physical Medicine and Rehabilitation Service, Veterans Administration Outpatient Clinic in New York, and of two additional patients who used the crutches at home. A pair of Hydro-Crutches were also loaned to the
PM&R Services of the Bronx VA Hospital and to the East Orange VA Hospital for an independent evaluation in their clinics on selected patients. The results of these evaluations are summarized below:

The experiences in the Bronx and East Orange clinics were quite similar; very few patients found that the Hydro-Crutch provided functions that their conventional wood, adjustable crutches did not also provide. Nearly all the patients thought the crutches too heavy and the axillary support too bulky. Patients with multiple sclerosis lacked the coordination required to maintain their balance while using the lifting feature. Another subject, a bilateral below-knee amputee, complained of considerable discomfort in the axillary area during the lifting procedure when his entire body weight was supported under the arms. An arthritic patient, however, was able to stand more erect with the aid of the crutches.

Observation of patients in our own laboratory and reports from home use indicate that:

One patient, an arthritic, found that the crutches were extremely helpful in getting in and out of chairs, primarily because they reduced the amount of pain as a result of bearing less weight on the lower-extremity joints. He reasoned that they would prove equally helpful in getting in and out of the bathtub, a prescribed daily home treatment. He reacted negatively to their weight and to the bulkiness of the axillary support. He also stated that the location of the hand grip forced him to keep his hand dorsiflexed while bearing weight. This proved fatiguing and painful, limiting his use of the crutches.

A quadriparietic subject was unable to prevent his arms from abducting during the lift. The vertical force under the axilla pushed his arms away from the body and his very weak hands could not maintain their grip on the crutch handles.

A poliomyelitis patient who used crutches routinely found that the Hydro-Crutch was extremely helpful in going up and down curbs. By lengthening the crutches and placing them on the curb he could swing his lower extremities up onto the walk. Although he found the lifting feature useful to get into chairs, he did not use it to get out of them, preferring a conventional technique.

The results of these limited clinical experiences indicate that, although the Hydro-Crutch functions reliably as a crutch and as a lift aid, the band of patients for whom it might be prescribed seems to be narrow. Patients who, due to weakness or pain, cannot get up from a sitting position will find the Hydro-Crutch most valuable particularly in rising from beds, chairs, and, in some cases, commode seats.

This device may also have applications for activities other than those intended by the developer. For example, with adequate training patients may use it to climb steps or curbs. In addition, with an appro-
appropriately placed hand-hold in the wall over a bathtub, a patient may be able to rise by using one crutch outside the tub.

In short, the clinical data indicate that the utility of the crutch may be greater as a specialized portable lift aid than as a crutch for ambulation. Its utility as a crutch could be enhanced by reducing the weight, improving the configuration of the axillary support, and repositioning the hand grip.

d. Summary. The telescoping, self-powered Hydro-Crutch represents a feasible design concept and may be a valuable addition to the armamentarium of orthopedic aids. The basic design of the subsystems, including the mechanical, electrical, and hydraulic sections, is adequate. However, the design of specific details in the present configuration is deficient in several respects, and appropriate recommendations have been to the manufacturer.

A definitive clinical evaluation may be required to identify the specific types of patients who can benefit the most from this device.

3. Home Galvanic Muscle Stimulator. Two units of the Home Galvanic Muscle Stimulator Model MS–12, manufactured by the Waters Corporation, Rochester, Minnesota, were evaluated (Fig. 64). This study supplemented a relatively large scale clinical evaluation conducted at the VA Hospital, Dallas, Texas. Since the use of galvanic current for muscle stimulation is an accepted and commonly used therapeutic modality, our
evaluation was primarily concerned with the specific utility and safety of the Home Galvanic Muscle Stimulator.

*a. Operational Characteristics.* The Waters Muscle Stimulator (Model MS-12) measures $2\frac{7}{16}$ in. in width, $2\frac{7}{8}$ in. in length, and $2\frac{7}{16}$ in. in depth.

Two electrodes, each one in. in diameter, are attached to the electrode lead wires with spring clips. The color-coded electrode leads are 36 in. long.

The circuit includes a 67½-volt battery, a 5,000-ohm potentiometer, and a single-pole, single-throw pushbutton (Fig. 65).

*b. Patient Application.* Treatment with galvanic current usually is prescribed in doses of 1 to 15 milliamperes $\times 10$ depending upon the desired modality and/or the stimulation threshold of a muscle being treated. To determine the applicability of this device for various normally prescribed treatment programs, it was necessary to estimate the full range of current which the device delivers. Current delivery depends on the available voltage and on the resistance of the human body. The battery provides a maximum of 67½ volts. As there were no data available on the range of skin resistances, measurements were obtained on eight normal subjects. A known voltage supplied from a regulated source was applied to the skin by means of the stimulator's electrodes. The current, measured by means of a milliammeter, was used to derive the resistance of the skin. Body resistances were found to range from 12,000 to 48,000 ohms (12 K ohms to 48 K ohms respectively). By means of an ammeter and a voltmeter, the output current of the Muscle Stimulator was measured within 10-
volt increments for the minimum (12 K ohms) and for the maximum (48 K ohms) skin resistances. The results are plotted in Figure 66.

At the maximum output voltage of this device, the maximum range of current flow through normal skin resistances ranges from 16.5 to 18.0 milliamperes. Thus, the Home Galvanic Muscle Stimulator provides the full, normally prescribed treatment currents of 1 to 15 milliamperes and can be usefully employed in all treatment modalities for which galvanic current is used, e.g., muscle stimulation, iontophoresis, muscle reeducation, negative galvanic massage, softening of scar tissue, etc.

c. Safety. When used according to directions to stimulate muscles of an extremity or the body periphery, the Muscle Stimulator seems to be safe and reliable. The maximum current which can be delivered to the human body in these circumstances is less than 20 milliamperes (at a minimum skin resistance of 12 K ohms), a figure well below the level of dangerous shock as reference to Table 6 (11) indicates. Currents are given in overlapping steps.

<table>
<thead>
<tr>
<th>Current, Milliamperes</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>Perception</td>
</tr>
<tr>
<td>1-4</td>
<td>Surprise</td>
</tr>
<tr>
<td>4-21</td>
<td>Reflex action</td>
</tr>
<tr>
<td>21-40</td>
<td>Muscular inhibition</td>
</tr>
<tr>
<td>40-Up</td>
<td>Respiratory block</td>
</tr>
</tbody>
</table>

However, normally nonlethal currents may be hazardous for patients with abnormally low skin resistance, cardials, or when applied to the brain area or cardiac region (10). Severe injury is also possible as an indirect result of electrical shock by reflex action and consequent body impact with nearby objects (11).

Burning the patient's skin is also possible if the unprotected metal electrodes inadvertently come in contact with the skin during a treatment, or when the skin surface has not been thoroughly cleaned. Patients with normal sensation will usually terminate the treatment before sustaining injury, but in a subject with sensory loss, the possibility of burns is increased.

Use of paper facial tissue as substitutes for wet pads, as suggested by the manufacturer, is not adequate. During the treatment, the tissue is apt to tear and allow the metal electrode to touch the skin directly, resulting in irritation and burns.
d. Design Critique and Recommendations for Improvement.

(1) Current Control. The Home Galvanic Muscle Stimulator has no provision for accurately monitoring the current being applied to a muscle. Without a read-out meter, the dosage must be subjectively determined or measured with appropriate equipment in the clinic by a qualified person. The intensity of stimulation is affected by the life of the battery and by normal fluctuations in skin resistances. The current applied, therefore, may require frequent readjustment to main-
tain the prescribed dosage. The addition of a milliammeter would be a substantial improvement.

(2) Electrodes. Although color-coded, the polarity of each lead should also be plainly marked so that patients using the device will not confuse the electrodes. The leads should be lengthened to give more freedom for electrode placement. Both electrodes should be covered with chamois and adequately padded with moistened gauze or cotton, which remains well moistened throughout the treatment. The conducting surface of the dispersive electrode should be enlarged to approximately 4 sq. in. to provide better contact and insure adequate moisture retention during the treatment.

(3) Attachments. The use of EKG-type rubber straps to attach the electrodes to the body may constrict blood vessels and force electrolytic fluid out of the pad. Use of an oversized dispersive electrode which can be conveniently placed anywhere on the skin surface would eliminate the need for attachment. Velcro, as suggested by the Dallas VAH, is an acceptable alternative.

e. Caution for Home Use. The whole concept of unsupervised home therapy is questionable. With only a superficial understanding of this modality, patients left to themselves may alter the prescription and overdose themselves, either in duration or intensity, and risk possible injury to weakened muscles. In the hands of a patient with a sensory loss, improper use of this device could result in severe skin burns if the metal electrodes touch the flesh.

However, a survey among eight experienced, registered physical therapists in private practice, hospital service, and university faculties reveals that this device has been successfully used in the home without direct supervision in selected cases. In these instances, the treatment was prescribed for Bell's palsy or similar conditions involving small facial muscles and requiring currents in the lower range.

The Home Galvanic Muscle Stimulator provides an adequate range of controlled current for use in all the commonly prescribed galvanic treatment programs. It is inexpensive, portable, and easily applied, and battery replacement is simple. These features make it potentially useful in ward programs where portability and cost permit several devices to be used, in out-patient clinics, and in home visitation treatment.

The following minor and inexpensive modifications would enhance safety and utility: larger dispersive electrode, ammeter, lead marking.

Home use by the patient should be prescribed with caution. The patient should be instructed in its use and potential hazards, e.g., use near eyes, chest, brain. Cardiacs and patients with sensory loss should not be given the device for home use.
4. Lincoln Carriage. Two prototype models (Fig. 67) of this novel and versatile device have been submitted for evaluation by the Lincoln Carriage Corporation of Tempe, Arizona. Combined in this single folding apparatus are several functions which are designed to replace such individual aids as a wheelchair, a patient lift, and a commode seat. It is capable of lifting and conveying patients to and from a bed, an automobile, and a toilet. Two special features of this device are a turntable, which makes possible the conversion of the seat and back to a horizontal position, and movable main wheels which allow the horizontal supporting area to be positioned over a bed or treatment table (Fig. 68).

Figure 67. Prototype of Lincoln Carriage Patient Handling Aid (Model C) combines the functions of patient lift, wheelchair, and commode seat in a single folding apparatus.
A design analysis and a mechanical testing program have been completed, and the unit is now undergoing biomechanical and clinical trials.

5. *Stand-O-Matic Wheelchair*. A prototype model (Fig. 69) of a device to assist a seated patient to stand has been submitted for evaluation by the Kelhoffer Development Corporation of Elizabeth, New Jersey. Standing is achieved by means of a hand-pumped hydraulic lifting mechanism which lifts the wheelchair seat through an arc from the horizontal to approximately 90 deg., pushing the patient into the erect position. It also features an adjustable knee support and a retractable standing frame mounted on the chair.

Primary emphasis in the evaluation of this prototype has been placed upon assessment of the mechanical design and the biomechanical adequacy of the ranges of motion and stability features.

6. *American Wheelchair*. Three wheelchairs (Fig. 70) have been submitted for evaluation by the American Wheelchair Company. Although the chairs themselves are conventional models covered by VA Contract No. V7018P-7646(a), several special features have been incorporated in an effort to improve them. The evaluation program, currently in progress, is aimed at determining the relative merits of a Lexan polycarbonate 8-in. caster wheel, a plastic skirtguard designed for high resistance to impact, plastic leg rest panels, and a novel type of padded upholstery which is readily detachable by the patient for cleaning or replacement.

7. *Gendron Lightweight Wheelchair (Model 8515–15)*. An adult sized folding wheelchair (Fig. 71) of lightweight design (28 lb.) has been resubmitted for evaluation. The new model, presumably improved on the basis
of previous testing, is constructed of lightweight nickel-plated steel and aluminum. It features swing-away detachable and adjustable foot rests and nylon seat and back upholstery.

8. E. and J. Mono-Drive Wheelchair. The Everest and Jennings Co. of Los Angeles, California has submitted for evaluation an improved model (Fig. 72) of their Mono-Drive, a power-driven wheelchair. The drive unit is powered by a 12-volt battery. It has two forward speeds and a reverse speed controlled by rotation of the hand grip. The new model is 3 to 4 in. narrower, has removable arms for entry and the steering mechanism is side mounted.

Figure 69. Stand-O-Matic with standing frame attached and seat in position to support standing patient.
FIGURE 70. American Wheelchair featuring Lexan polycarbonate caster wheels (see arrow), plastic skirt guard, leg rest panels, and black padded upholstery.

The evaluation of this chair includes analyses of both mechanical and electrical adequacy and an assessment of the biomechanical aspects of use.

C. Evaluation (Techniques)

None.

V. TESTING

A. Specifications Compliance

1. Lumbo-Sacral Corset Material. Five manufacturers submitted samples of lumbo-sacral corset material for compliance testing in accordance with Federal Specification CCC T-191b, Part 5550.2 (DOD), September 17, 1963 “Shrinkage in Laundering, Cotton, Linen, and Mixed Cotton and Linen Cloth.” The test results, in Table 7 show that three samples submitted by Company IV and three samples submitted by Company V shrank excessively. Excessive shrinkage was noted in both warp and fill.

2. Stump Socks. Five samples of wool leg stump socks, cotton leg stump socks, and wool arm stump socks were tested for compliance with specifica-
tions. The testing procedures described in Invitation No. 66-1, April 14, 1965 were applied.

Test results obtained on the five samples of wool leg stump socks are detailed in Table 8.

In general, the samples submitted by each of the five manufacturers complied with specifications. The product of Company C was, however, only marginally satisfactory as it slightly exceeded the maximum allowable shrinkage in length.

As shown in Table 9, all five samples of cotton stump socks met the specifications requirements.

With two exceptions, the samples of wool arm stump socks complied with specifications (Table 10).

The products of Company B and Company D were knitted with 16.5 stitches per in., a minor deviation from the specification calling for a minimum 17.0 stitches per in.

FIGURE 71. Gendron Lightweight Wheelchair (Model 8515–15) with nylon seat and back upholstery.
B. Materials

The properties and potential use of various materials are being investigated in a continuing program aimed at improving currently used appliances. Evaluation of the products listed below has been undertaken during this period.

1. Cohesive Neoprene. A Du Pont product, this easily molded neoprene polymer, has been processed into sheets by Ortho-Shoe Products. It can be provided in any size or thickness. Softened over low heat (250 deg. F.) or immersed in boiling water, the material becomes quite pliable and it can be easily molded over the skin, provided that the body part is protected by a single layer of stockinet. The properties of the material do not vary and it can be resoftened, reshaped, and reapplied as often as is necessary.
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#### Table 7.—Maximum Shrinkage in Percent After 5 Wash-Dry Cycles

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Manufacturer</th>
<th>-Warp</th>
<th>Filling</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>I</td>
<td>2.3</td>
<td>2.9</td>
</tr>
<tr>
<td>B</td>
<td>II</td>
<td>1.8</td>
<td>2.3</td>
</tr>
<tr>
<td>C</td>
<td>III</td>
<td>2.2</td>
<td>2.7</td>
</tr>
<tr>
<td>*D</td>
<td>IV</td>
<td>3.8</td>
<td>3.0</td>
</tr>
<tr>
<td>*E</td>
<td>V</td>
<td>4.6</td>
<td>9.3</td>
</tr>
<tr>
<td>F</td>
<td>III</td>
<td>2.4</td>
<td>2.3</td>
</tr>
<tr>
<td>*G</td>
<td>IV</td>
<td>3.7</td>
<td>3.1</td>
</tr>
<tr>
<td>H</td>
<td>I</td>
<td>2.6</td>
<td>3.0</td>
</tr>
<tr>
<td>I</td>
<td>III</td>
<td>2.4</td>
<td>2.5</td>
</tr>
<tr>
<td>*J</td>
<td>V</td>
<td>4.9</td>
<td>9.5</td>
</tr>
<tr>
<td>K</td>
<td>II</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>*L</td>
<td>IV</td>
<td>4.3</td>
<td>3.1</td>
</tr>
<tr>
<td>*M</td>
<td>V</td>
<td>4.9</td>
<td>9.7</td>
</tr>
<tr>
<td>N</td>
<td>II</td>
<td>2.0</td>
<td>2.1</td>
</tr>
<tr>
<td>O</td>
<td>I</td>
<td>2.0</td>
<td>1.8</td>
</tr>
<tr>
<td>P</td>
<td>IV</td>
<td>2.0</td>
<td>.9</td>
</tr>
<tr>
<td>R</td>
<td>IV</td>
<td>2.1</td>
<td>.8</td>
</tr>
<tr>
<td>S</td>
<td>IV</td>
<td>2.1</td>
<td>1.1</td>
</tr>
</tbody>
</table>

*In excess of 3 percent shrinkage.

#### Table 8.—Compliance Test Data on Fine Wool Leg Stump Socks

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yarn size</td>
<td>16-18.5</td>
</tr>
<tr>
<td>Ply</td>
<td>3, 4, 5, 6, 7</td>
</tr>
<tr>
<td>Stitches/in.</td>
<td>18 ± 2</td>
</tr>
<tr>
<td>Wales/in.</td>
<td>12 ± 1</td>
</tr>
<tr>
<td>Maximum Shrinkage in Percent of Initial Length and Width After 5 Wash-Dry Cycles</td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>12</td>
</tr>
<tr>
<td>Width at 2 in. from toe</td>
<td>10</td>
</tr>
<tr>
<td>Width at 5 in. from toe</td>
<td>10</td>
</tr>
</tbody>
</table>
Our experience to date indicates that the material lacks the necessary rigidity for splints and protective shields. We are having some success, however, using it in conjunction with foam as a method for producing a dynamic molded arch support.

2. Thermoplastic Vinyl. Produced by Union Carbide, this vinyl may be procured from Johnson and Johnson in sheets of any size or thickness. It can be easily softened by immersion in boiling water or in an oven at 250 deg. F. As it becomes quite brittle upon cooling, it should be cut or shaped while it is still warm. This material has been successfully used for fabricating splints and protective shields.

3. Cordopreg (Pre-impregnated Fibreglas). Developed by Ferro Corporation primarily for "dry lay-ups," this semicured, polyester resin-impregnated Fibreglas molds easily over irregular shapes. Curing is completed by either exposure to ultraviolet light or in an oven. Laminated between layers of stockinet, it has been found useful for accurate control of a reinforcement to provide rigidity in specific areas. It has been used with some success in the fabrication of an experimental leg brace.

4. Polyhinge. Made of polypropylene, this lightweight, color-fast material is fabricated by Stokes Molded Products in a continuous roll. This low cost material is highly resistant to grease, acids, and corrosion. As it is extremely resistant to bending fatigue, we are currently experimenting with it as a substitute for metal brace joints.

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5. Polypropylene Filament. This product of the Vectra Corporation, processed into tubular stockinet, is being evaluated as a substitute for conventional reinforcing materials used in laminating procedures. It is stronger, more flexible, less expensive and approximately one-third the weight of glass filament.

6. Curulite. This transparent Plexiglas material is a product of the Master Craft Medical and Industrial Corporation. Softened by immersion in boiling water, it can be shaped or directly molded over a part of the patient which needs only to be protected by gauze. Once hardened, these plastics are strong and remain rigid at body temperatures. Cylinders are currently being fabricated over VAPC molds for applying this material in the direct forming of below-knee sockets as described in BPR 10-2 Fall 1964.

7. Lamiflex Bearing. A product of Marlin-Rockwell, the Lamiflex Bearing is made of alternate layers of very thin metal and rubber (or elastomer), which may be built up, layer by layer, to any desired thickness. When lateral or twisting forces are applied to the Lamiflex Bearing, each rubber layer stretches permitting some motion; when the force is removed, each layer returns to its original position. The maximum movement within the bearing is dependent upon the total of the individual movements possible within each of the rubber layers. We are investigating this product for possible application in torque and impact absorbers.

VI. OPERATIONS REPORT FOR SECOND HALF, FISCAL YEAR 1965

The data in this section reflect the prosthetic and orthotic services provided for veteran beneficiaries during the second half of Fiscal Year (FY) 1965 by the VAPC's Orthopedic Shoe Service and Prosthetics-Orthotics Service.

A. The Orthopedic Shoe Service

As shown in Table 11 and Figure 73, the workload of the Orthopedic Shoe Service has not increased appreciably despite the additional three hundred beneficiaries added to the roles in F.Y. 1965. The issuance of protective footwear (rubbers or overshoes) continues at a steady pace. During the reporting period, 11 pairs of custom-made rubbers and 39 pairs of custom-made overshoes were issued. The total cost for these items was $1,380.

In the second half of F.Y. 1965 it was necessary to duplicate 194 worn clinic lasts at a cost of $2,164.

B. The Prosthetics-Orthotics Service

The Orthotic Components Unit of the Prefabricated Appliances Section, Prosthetics-Orthotics Service has the responsibility for the distribution of surgical supports and elastic hosiery. The issuance of these items seems to be leveling off as shown in Tables 12 and 13 and Figure 74.
### Table 1. Numbers and Costs of Shoes in VAPC National Orthopedic Shoe Program

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Benef. on roles</td>
<td>9,017</td>
<td>9,344</td>
<td>9,681</td>
<td>10,021</td>
<td>10,322</td>
</tr>
<tr>
<td>New shoes, prs.</td>
<td>7,154</td>
<td>7,465</td>
<td>7,249</td>
<td>7,317</td>
<td>7,336</td>
</tr>
<tr>
<td>Prs. of new shoes issued per benef. on roles per yr.</td>
<td>.80</td>
<td>.80</td>
<td>.75</td>
<td>.73</td>
<td>.71</td>
</tr>
<tr>
<td>Cost, $</td>
<td>372,798</td>
<td>394,222</td>
<td>387,757</td>
<td>*440,536</td>
<td>442,641</td>
</tr>
<tr>
<td>Repaired shoes, prs.</td>
<td>8,390</td>
<td>8,660</td>
<td>9,716</td>
<td>9,487</td>
<td>9,422</td>
</tr>
<tr>
<td>Prs. of shoes repaired per benef. on roles per yr.</td>
<td>.93</td>
<td>.93</td>
<td>1.00</td>
<td>.95</td>
<td>.91</td>
</tr>
<tr>
<td>Cost, $</td>
<td>91,760</td>
<td>92,514</td>
<td>97,778</td>
<td>93,520</td>
<td>130,916</td>
</tr>
<tr>
<td>Total Cost, $</td>
<td>464,558</td>
<td>486,736</td>
<td>485,535</td>
<td>534,056</td>
<td>573,557</td>
</tr>
</tbody>
</table>

* Revised cost; supersedes figure that appeared in Table 9, BPR 10-3.

### Table 2. Numbers and Costs in the VAPC Elastic Hosiery Distribution Program

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Cost ($)</td>
<td>No.</td>
</tr>
<tr>
<td>Individuals</td>
<td>5,806</td>
<td>33,385</td>
<td>9,989</td>
</tr>
<tr>
<td>VA Orthopedic shops</td>
<td>6,598</td>
<td>37,938</td>
<td>12,258</td>
</tr>
<tr>
<td>Total</td>
<td>12,404</td>
<td>71,323</td>
<td>22,247</td>
</tr>
<tr>
<td>Average cost, $</td>
<td>5.75</td>
<td>5.75</td>
<td>4.61</td>
</tr>
</tbody>
</table>

As reported in BPR 10-3 Spring 1965, the average cost fluctuation is due to changes in the internal accounting procedures.

During the second half of F.Y. 1965, the Prosthetics Components Unit of the Prefabricated Appliances Section distributed 71 additional Hydra-Cadence Above-Knee Systems. The number of beneficiaries wearing this unit is 1,255.

During the report period, 454 Hydra-Cadence (H-C) units were replaced. In addition, 484 H-C cosmetic covers and 76 H-C feet were replaced. The manufacturer repaired 15 units at no cost and 180 units were repaired and converted at a cost of $27,000. One hundred and seventy-four units were repaired by VAPC technicians at a cost of $1,635.
TABLE 13.—Numbers and Costs in the VAPC Surgical Support Distribution Program

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Cost ($)</td>
<td>No.</td>
</tr>
<tr>
<td>Individuals</td>
<td>2,162</td>
<td>11,568</td>
<td>2,434</td>
</tr>
<tr>
<td>VA orthopedic</td>
<td>3,098</td>
<td>14,239</td>
<td>3,995</td>
</tr>
<tr>
<td>shops</td>
<td>5,260</td>
<td>25,807</td>
<td>6,429</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average cost, $</td>
<td></td>
<td>5.60</td>
<td></td>
</tr>
</tbody>
</table>

* Revised cost; supersedes figure that appeared in Table 11, BPR 10–3.
* Revised costs; supersedes figures that appeared in Table 10, BPR 10–2 and Table 11, BPR 10–3.

Figure 73. As shown, number of new shoes issued and number of repairs for each beneficiary are decreasing, while the number of beneficiaries are increasing.
Figure 74. As shown, distribution of elastic hosiery for FY 1965 has fallen off, while distribution of surgical supports has remained relatively constant.

Late in the report period, two additional fluid-controlled knee mechanisms were authorized for distribution. These were the Henschke-Mauch HYDRAULIK swing-control unit, Model-B, and the Dupaco "Hermes" unit. Both units had been evaluated in a nationwide clinical application study. Twenty-eight Mauch Model "B" units were issued. Including the study wearers we now have 84 amputees using this unit. The Dupaco unit was issued to 54 wearers bringing the total of users to 106. Three Mauch and 5 Dupaco units had to be replaced during the report period; these went to wearers who had been in the clinical application study.

VA Orthopedic Shops received 10 above-knee and 21 below-knee temporary prosthesis units. Nine above-knee and 5 below-knee temporary prosthesis units were sent to commercial limb facilities, 48 SACH feet were issued to VA Orthopedic Shops and 13 to commercial limb facilities.
Figure 75. Total output of lower-extremity prosthetic and orthotic devices and appliances produced during the second half of FY 1965.

Figure 75 shows the total output of lower-extremity prosthetic devices and lower-extremity orthotic appliances produced by the Limb and Brace Section during the second half of F.Y. 1965. In the same period, 27 spinal braces and 787 arch supports were furnished to beneficiaries.

The VAPC Clinic Team held 31 meetings during the second half of F.Y. 1965. Seventy-one beneficiaries coming from 7 different states were seen.

REFERENCES


Bulletin of Prosthetics Research – Fall 1965


9. SAHLEY, FLOYD W.: Dimensions of the Human Figure. Cleveland Designers and Consultants, Inc., Cleveland, Ohio, 1957.
