The following presents progress during a 6-month period on a number of research, development, and evaluation projects performed by the VA Prosthetics Center:

I. LOWER-EXTREMITY PROSTHETICS
   A. Basic Studies
      Preformed Thermoplastic Above-Knee Sockets
   B. Development (Components)
      1. SACH Foot Modification
      2. VAPC Modular Foot
   C. Development (Techniques)
      Cosmetic Finishing for Skeletal Prostheses
   D. Evaluation (Components)
      1. Blatchford Stabilized Knee (BSK)
      2. Hosmer Pneumatic Swing Control Knee
      3. Regnell Swing and Stance Mechanism
      4. U.S. Manufacturing Hydra-Knee Swing Control
      5. Teufel-Telasto Foot
   E. Evaluation (Techniques)
      Direct Forming of BK Polysar® Sockets

II. UPPER-EXTREMITY PROSTHETICS
   A. Basic Studies
      None
   B. Development (Components)
      VAPC External-Power Program
   C. Evaluation (Components)
      Evaluation of Externally Powered Elbows

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III. LOWER-EXTREMITY ORTHOTICS
A. Development
None
B. Evaluation (Components)
IRM Plastic Spiral Brace

IV. MISCELLANEOUS AIDS FOR DISABLED
A. Development
None
B. Evaluation (Components)
1. Edco Adjustable Walker, Model 1931
2. CMA Stair-Aid Walker
3. Mobil-Aid Convalescent Chair Walker
4. Swail-SFB Folding Cane

V. TESTING
A. Standards Development Program
B. Compliance Testing
1. Upper-Extremity Components
2. SACH Feet

I. LOWER-EXTREMITY PROSTHETICS

A. Basic Studies

Prefabricated Thermoplastic Above-Knee Sockets. These sockets, designed on the model described previously in BPR 10-12, are being tested through routine clinical use. During this evaluation period, only temporary sockets are being made. As predicted, sockets which measure 18, 19, and 20 in. in circumference at the ischial level are used most frequently. The absence of prefabricated sockets with circumferences under 17 in. and above 21 in. has caused no difficulty to date.

Two elements of the adequacy of socket fit are receiving special attention—the predetermined proximal circumferences and the tapers. Fitting experiences to date indicate that the quadrilateral socket shapes, sized in 1 in. circumferential increments and in both anterior-posterior and medial-lateral incremental dimensions, adequately accommodate 90 percent of all above-knee stumps. With slight modifications it has also been possible to accommodate a wide range of stump tapers. Since the preformed sockets are designed with tapers based upon measurements taken from mature stumps, little difficulty is experienced in fitting seasoned stumps with the standard taper of ½-in. decrements in circumference for each inch of socket length measured from the ischial
level. However, "fresh" stumps with redundant tissue such as those frequently encountered in fitting temporary prostheses have little or no taper; the top 4 to 6 in. have almost equal circumferences. In these cases the average of the three top circumferential measurements is used to select the appropriate socket size. As with the socket top, locally applied heat and hand molding are used to fit the lower portion of the socket.

Data collected from this study will be used to launch a broader field program to evaluate the utility of prefabricated sockets. Although Polysar X414 is ideal for forming sockets directly on stumps, its special characteristics are not necessary for above-knee sockets. The need for shaping on the stump is eliminated and final shape modifications are expected to be of a minor nature.

B. Development (Components)

1. SACH Foot Modification. The revised SACH foot specifications, which became effective in January 1970 (BPR 10–12), have been distributed to interested manufacturers. The specifications reflect improved foot shapes with narrower proximal heel widths and with standardized ankle cross sections. The convex plantar foot surface provides better fitting in the shoe. The radius of the arch has been increased. The new configuration is not expected to require significant changes in fitting techniques. However, a problem may occur when a new SACH foot is to be attached to a prosthesis in order to replace an old foot. The new ankle height requires the removal of material from the distal shank. This weakens the ankle attachment area and requires the reinforcement of the shank before the new foot is attached.

A set of foot models reflecting the new shapes and sizes specified has been furnished each manufacturer with the suggestion that it be used for duplicating foot molds. Although current specifications (VAPC–I–6401–1 dated April 1, 1964) will remain in effect until 1972, they will be superseded by the new specifications in January of 1971. For the year 1970 both will be in effect.

2. VAPC Modular Foot. In BPR 10–11 we reported our plans for the development of a modular prosthetic foot. The design concept called for "modularity" with respect to sizing. We proposed a system of three basic sizes—7, 10, and 13—each of which could be adjusted for length to include one smaller and one larger size, thus providing the full range. We also proposed "modularity" with respect to adjustability in the ranges of motion available in three planes. Other design aspects included adjustability of resistance to motion effected by means of a core "ankle module" and by means of a spring-loaded toe section.

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The development of this concept led to the fabrication of a prototype foot which fulfills all of the requirements listed above and in addition permits limited adjustment of heel height without compromising foot length (Fig. 1).

In its present form the foot provides adjustable plantar flexion, eversion, and inversion by means of small resistance elements incorporated in the ankle section. The position of the “toe break” and the overall length of the foot are adjustable through the use of specially designed mechanical linkages. It may not be necessary to have more than one basic unit whose length is adjustable to all the required sizes. The toe section is hinged to a structure corresponding to the metatarsal line. The toe is fitted with a leaf spring whose resistance to bending can be adjusted to control toe extension and roll-over. The plantar surface of the foot consists of a polypropylene heel and sole section and the entire unit is covered with a flexible cosmetic shell. The unit is easily attached to the VAPC standard above-knee or below-knee pylon or to any conventional shank.

The first prototype model was fitted to one of the prostheses worn by a bilateral below-knee amputee. His subjective reactions to the comfort, stability, and functional aspects of the foot were generally positive. Figure 2 shows a comparison in the pattern of weight application to the ground while the subject is wearing his conventional SACH foot and while wearing the prototype VAPC modular foot. The illustration indicates a longer period of contact between the foot and the ground with the VAPC foot. Weight bearing on the toe is more clearly demarcated. Several other indicators pointed toward a more nearly normal pattern of foot function with the VAPC modular foot.

In its present configuration the device weighs approximately 2 lb. which is somewhat heavier than the smaller size SACH feet and slightly lighter than the largest size.

Six prototypes have been fabricated in order to fit several more patients to provide guidance for further development.
C. Development (Techniques)

Cosmetic Finishing for Skeletal Prostheses. We have developed a finishing process based on the use of polyethylene foam over the metal pylon structure. A prebored block of foam is fitted over the pylon structure and shaped to the desired contours. Both the VAPC Standard Below-Knee prosthesis and the VAPC Above-Knee (Multiplex) Standard prosthesis are finished in this manner. A seamless nylon two-way
stretch hose (full length) is used as a cover for the above-knee prosthesis. A three-quarter length garter hose or stretch sock is used to cover the below-knee prosthesis. Details of the technique are given in the article by Mr. H. Gardner beginning on page 113.

D. Evaluation (Components)

1. Blatchford Stabilized Knee (BSK). This device, designed by Blatchford & Sons, Ltd. of Hants, England, and available in this country from the U.S. Manufacturing Company of Glendale, California, provides both stance-phase stability and swing control by mechanical friction (BPR 10–12). Stance-phase stability is achieved by the tension produced in a brake band drawn taut under the influence of the wearer's body weight (Fig. 3). Laboratory tests indicated that the unit was capable of resisting significant loads tending to flex the knee. Although this device has been accepted for VA purchase, clinical testing continues to provide more information about the specific types of patients for whom the unit is most suitable.

Five amputees ranging from 22–50 years of age, with relatively short above-knee stumps, have been fitted to date. Three were previous wearers of the Otto Bock Knee, one wore the Mauch Model "A," and one wore the Mauch "S-N-S" unit. The BSK has been worn by these patients for periods ranging from 3 months to 1.3 years. In all cases reactions to the use of the BSK were positive with patients reporting that they "felt more secure" and that it was "easy to walk with" the Blatchford unit. All five patients have elected to continue wearing the device.

No significant problems were noted in fitting, aligning, or adjusting the device. Additional laboratory tests are underway to determine the
stance-phase characteristics of this unit in both downhill and downstair walking.

2. Hosmer Pneumatic Swing Control Knee. Described in detail in BPR 10–12, this unit is similar in design concept and functional characteristics to both the UC-BL and the Blatchford pneumatic units. One Hosmer pneumatic knee has been installed in the prosthesis of a right above-knee amputee. This subject had previously worn a UC-BL pneumatic unit (since August 1966), and he is in a position to furnish useful comparative information. Fitting, aligning, and adjusting the device were accomplished without difficulty. The patient’s initial reactions after fitting were generally positive. More information will be obtained after longer periods of wear.

3. Regnell Swing and Stance Mechanism. An earlier model of this hydraulic swing- and stance-control unit was evaluated and found to produce erratic and excessively high resistance values in the extension portion of the knee rotation cycle (BPR 10–4). Redesigned by the developer, the unit was found to be significantly improved in that the range of adjustment was increased from ⅜ of a turn to approximately two full turns. This permits a wider range of adjustments and a more gradual increase in resistance to knee flexion and extension. The resistance patterns developed during swing phase at various speeds (Fig. 4) are similar to those produced by other acceptable hydraulic knee mechanisms. This unit was returned to the developer who has not, to our knowledge, made the unit commercially available in this country.

4. U.S. Manufacturing Hydra-Knee Swing Control. This device was initially evaluated several years ago and found to provide insufficient resistance through the first half of the resistance control range (BPR 10–3). In addition, the full range of resistance was achieved abruptly, i.e., with less than one full turn of the valve. The unit also featured an adjustable extension bias system which operates throughout the flexion-extension cycle, a feature thought to be particularly useful for patients with short stumps. The difficulties in achieving a useful range and precise adjustment of resistance were attributed to the fact that the unit was originally designed with a single orifice fluid metering system. To overcome these problems it was redesigned with multiple orifices as shown in Figure 5.

As shown in Figure 6, a comparison between the old and the modified versions indicates that a substantial improvement has been achieved in the resistance pattern. The useful range of adjustment has been increased from approximately one full turn to two and one half turns. Altering the metering technique permits this unit to furnish eminently satisfactory cadence control, comparing favorably with other acceptable hydraulic knee mechanisms.
5. Teufel-Telasto Foot. Mr. Adolf Wolfer of Stuttgart, Germany, submitted a revised model of a similar unit tested in 1966 (BPR 10-6) for evaluation. The unit (Fig. 7) has been significantly improved. Toe flexure resistance has been reduced to meet current standards, and the flexion-under-load characteristics of the foot in plantar flexion were similar to other acceptable units. Minor discrepancies were noted in the point at which toe break occurs and in the overall length for the size specified. Two additional models will be fitted to patients to obtain clinical data.
E. Evaluation (Techniques)

Direct Forming of BK Polysar Sockets. Early clinical trials of below-knee sockets fabricated of Polysar X-414 indicated potentially valuable applications for both temporary and definitive prostheses (BPR 10-12). To date, 75 directly formed Polysar prostheses have been fitted and delivered to patients. The first 50 prostheses included 41 temporary PTB and nine permanent PTB types. All 50 were made from Polysar tubes (with wall thicknesses of approximately \( \frac{3}{16} \) in.) by means of the pneumatic pressure sleeve technique employing a casting of 1.5 p.s.i.

During the casting procedure, it was noted that the wall thickness diminished to approximately \( \frac{1}{8} \) in. in some areas. The resultant reduction in strength led to three failures among the nine patients fitted with permanent PTB-type prostheses. Cracks appeared in the proximal-anterior areas of the sockets. Our experience in fitting the first 50 cases also indicated the limitations of the pressure sleeve pneumatic casting technique as regards "fresh" stumps with some degree of redundant tissue.

A second series was fitted consisting of 25 temporary PTB-type prostheses. Two basic changes in the fitting procedure were made. The wall thickness of the Polysar tubes was increased from \( \frac{3}{16} \) to \( \frac{1}{4} \) in.; the

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HYDRA-KNEE HYDRAULIC UNIT
US MFG CO. NO. 3-9-70
UC-BL TESTING MACHINE

PERCENT OF KNEE FLEXION-EXTENSION CYCLE

Figure 6.—Comparison of resistance curves (old vs. new).

Figure 7.—The Teufel-Telasto foot.
pneumatic pressure casting technique was discontinued in favor of casting by means of pressure sensitive tape, a procedure described in detail in BPR 10–12, beginning on page 34. No failures have been noted in the last group of 25 temporary sockets. Prosthetists find the technique for using this material simple and generally agree that, at least for temporary use, it is the method of choice.

II. UPPER-EXTREMITY PROSTHETICS

A. Basic Studies

None.

B. Development (Components)

*VAPC External-Power Program.* The VAPC electric elbow described in BPR 10–12 has been redesigned for limited commercial production. Five of six models, fabricated in our Model Development Laboratory, have been fitted to patients, including one bilateral, very short above-elbow amputee, who are currently wearing them. The sixth unit has been cycled 100,000 times and inspected to determine areas of wear. Negotiations are underway with the Union Carbide Company to arrange for fabrication of our Power Pack A (Fig. 8), designed for installation within the humeral section of the prosthesis. Arrangements are also being made with the United Shoe Machine Co., Inc., of Fairfield, New Jersey, for the injection molding of several hundred elbow shells in a plastic material. One mold is used for both halves of the elbow shell with the rigid spline section of the harmonic drive molded integrally. The second part, the flexible portion of the harmonic drive, is molded separately. When these arrangements have been consummated, bids from manufacturers will be invited to fabricate and assemble a sufficient number of elbows, power packs, and control switches. These units will be used in the program (described in this issue on page 25) for fitting Vietnam-era veteran upper-extremity amputees throughout the country.

The VAPC electric hand, a substantially modified, switch-controlled version of the Viennatone myoelectrically controlled hand, is being carefully reviewed. Minor design changes are being considered prior to arranging for the procurement of a number of these devices for fitting in the same program.

Work on the VAPC wrist and convertible electric hand/hook continues.

C. Evaluation (Components)

*Evaluation of Externally Powered Elbows.* In cooperation with a nationwide program initiated and conducted under the guidance of the Committee on Prosthetics Research and Development, we have fitted the Boston, AMBRL, and Rancho electric elbows to several patients.
We are participating in this program as one of eight facilities throughout the nation for the purpose of obtaining valid information on the fitting requirements for externally powered elbows. In addition, patient reactions to these experiences will provide valuable prescription, training, and maintenance information.

III. LOWER-EXTREMITY ORTHOTICS

A. Development

None.

B. Evaluation (Components)

*IRM Plastic Spiral Brace.* Developed by Mr. Richard Lehnes of IRM, this uniquely designed plastic ankle brace (Fig. 9) is formed around the leg of the patient. In stance phase the helical spiral construction tends to “unwind” permitting plantar flexion. As it is unloaded during swing phase it tends to “wind up” and assist dorsiflexion. Due to the spiral construction, transverse rotation and controlled eversion and inversion are also facilitated.

Shown in Figure 10 is the cycling machine used to simulate the plantar flexion and dorsiflexion stresses that might be applied during normal use. Failures were induced in several samples (Fig. 11) fabricated in different thicknesses (4 mm. and 5 mm.). Some were heat treated and others were soft tempered models; samples with both full and partial heels were also included. Testing consisted of cycling the units through a range of 20 deg. of plantar flexion and 10 deg. of dorsiflexion at a rate of 40 cycles per minute until failure. The fracture
sites and areas of crazing were analyzed by means of a circular polariscope constructed of two quarter wave plate filters and two conventional polaroid filters. This technique (Fig. 12) resulted in a qualitative analysis of the magnitude of internal stresses both residual, i.e., under "no load" conditions, and those induced by the cycling program. Test results have been made available to Mr. Lehneis who is considering further design modifications.

**Figure 10.—The VAPC cycling machine.**

**Figure 11.—Failures of IRM plastic brace.**
IV. MISCELLANEOUS AIDS FOR DISABLED

A. Development

None.

B. Evaluation (Components)

1. Edco Adjustable Walker, Model 1931. In response to complaints of structural failures in invalid walkers currently on the Decentralized Procurement Schedule, Mr. W. D. Monts, VA Marketing Center, Hines, Ill., requested the Director, Prosthetic and Sensory Aids Service, Central Office, to consider revising current specifications for these devices. A general upgrading of the existing minimum specification may lead to superior products.

Two units of the Edco Adjustable Physio-Therapy Walker, Model 1931 and, for comparative purposes, two units of the Edco Standard Adjustment Economy Walker, Model 180 currently on contract, were evaluated (Fig. 13 and 14). Both models were checked for compliance with the current VA Specifications for Invalid Walkers No. X–1490 (Nov. 27, 1967).

Except for the center brace which does not permit the Edco Physio-Therapy Walker to be used over-the-toilet, it complied essentially with
the current VA Specifications for Invalid Walkers. The Edco Economy Walker, however, deflected excessively during strength testing due to the use of a single upper crossbar. This could lead to permanent deformation under heavy patient use. Both the Edco Economy and the Edco Physio-Therapy models were found to be quite satisfactory for level walking during limited field testing. No negative comments were elicited from a variety of patients. A recommendation for improving stability by the use of bolts has been made to the manufacturer.

Standards and specifications currently in effect are being studied with a view toward revision in order to reflect functional requirements more reliably.

2. **CMA Stair-Aid Walker.** One unit of the Stair-Aid Walker (Fig. 15) was submitted for evaluation by California Medical Aids, Montrose, California. In addition to being adjustable in height, it is designed to aid persons in going up and down stairs. It fits over any standard toilet and it aids disabled persons in getting on and off the commode. This unit was checked for compliance with current VA Specifications for Invalid Walkers, Type II, No. X-1490 (Nov. 27, 1967). In addition, a bioengineering analysis of patient function, comfort, ease of operation, safety, and a limited clinical test were conducted.

The principal deviations from the Specifications were that the plastic hand grips were too small (3¾ in. in length; specifications call for 5 in.) and there was a tendency for the frame to sway under load (specification is 400-lb. load). During clinical testing, several elderly patients complained that the CMA Walker was "slightly shaky." This was attributed to the absence of a structural reinforcing member at the upper
junction between the side rails and the front horizontal rail. The stair-climbing feature was found to be quite useful provided the patient had been instructed in the proper hand placement and that the stair treads were approximately 8 in. wide.

In general the CMA Stair-Aid Walker complied with a functional interpretation of the current VA Specifications for Invalid Walker Stair Climbing Type. Recommendations for improving stability were transmitted to the manufacturer.

3. **Mobil-Aid Convalescent Chair Walker.** This novel device is a type of wheeled invalid walker to which is attached a chair (Fig. 16). The chair is attached to the uprights of the hand rest and by means of pivots can be "swung away" to either side. According to the literature provided, this device is designed to enable partially ambulatory patients to sit in a chair, rise, and relocate themselves elsewhere in a room by pushing the wheeled walker. The swing-away chair feature is designed to enable the patient to enter the walker from a low bed without assistance. The seat cushion is of the "lift up" variety to permit a patient to use a commode while in the device.

The unit's design was evaluated with respect to structural integrity, center of gravity location with and without patient, adequacy of foot clearance, handrail height when used as a walker, and patient ability to lock and unlock the chair. The details of this analysis were reported to the manufacturer.

4. **Swail-SFB Folding Cane.** This cane is a long cane designed for use by the blind. It features folding and fitting into the handle (Fig. 17). The Swail cane is currently being used routinely in Canada. The unit evaluated was procured in the United States from Science for the Blind.
The Swail-SFB Folding Cane was checked against construction drawings provided by the manufacturer. Several discrepancies concerning excessive clearances and insufficient wall thicknesses have been brought to the attention of the manufacturer.

A. Standards Development Program

Over the past several years, the standards development program has produced functional specifications for prosthetic components, lift-aids, and wheelchairs. Currently under development are standards for stump socks and elastic hosiery. A preliminary stage has been reached in revising specifications for invalid walkers. These devices are designed to assist disabled persons in walking and climbing stairs in hospitals, homes, and outdoors.

B. Compliance Testing

1. Upper-Extremity Components. One model of the APRL #44 Hook was checked for compliance with current specifications. The unit failed during cycling and was returned to the manufacturer for repair.

2. SACH Feet. During this period, four manufacturers submitted samples of SACH feet for annual compliance testing. The results of the tests indicated that one manufacturer's product was in substantial
compliance with the requirements. The other samples could not be rated as acceptable in view of two significant deviations from the specification requirements: a. toe-break too short and b. heel compression too low to meet the standard for "regular" heel. Minor discrepancies in alignment reference lines were found in three of the four products tested. One sample developed a crack in the toe-break area during cyclic test. The manufacturers have been informed of the test results.