

## CLINICAL APPLICATION STUDIES

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The evolution of a major prosthetic device—from its inception as an idea in the mind of a developer or inventor until it is actually worn and used by a disabled person—has typically involved a long painstaking process. This is as it should be, since making seemingly interesting devices available quickly, but possibly prematurely, constitutes no real service to the disabled. With the purpose of assuring a high quality of prostheses for disabled veterans, the Prosthetic and Sensory Aids Service therefore decided some five years ago to undertake clinical application studies whenever the development of major prosthetic devices had reached a stage where they were ready for clinical tryout on substantial numbers of cases in various parts of the country.

This program, which further implements the research, development, and evaluation services of the PSAS, has already served a number of purposes. Responsible officials of the Veterans Administration are provided with a body of information to enable them to determine the overall acceptability of the device under study. The clinical studies on a large number of patients under a wide variety of conditions of climate, terrain, and occupation yield helpful information as to prescription criteria, maintenance problems, fitting and alignment considerations, and training requirements. The advantages of a device, if any, over existing devices are verified and, to some extent, quantified on a broader statistical basis. The procedures used in the studies lead to tests and analyses which determine the conformity of the manufactured devices to established standards and specifications. Recommendations for changes in design and components repeatedly have been acted upon by the manufacturers of devices thus far studied; indeed, the manufacturers have neither rejected nor resented suggestions but instead have welcomed the advantages of clinical experience and consulting engineering. Of major importance are the educational byproducts of the studies in familiarizing the clinical personnel who participate in such studies with the unique features of the devices and in making meaningful information available to prosthetics education centers.

Responsibility for the conduct of clinical application studies has been placed with the Research and Development Division of the Prosthetic and Sensory Aids Service of the Veterans Administration Central Office. Situated in New York, this Division works in close cooperation with various sections of the VA Prosthetics Center, also located in New York, and with the Plans and Policies Division of the Prosthetic and Sensory Aids Service in Washington. Selected clinic teams in various VA facilities throughout the country serve as the main source of clinical information and feedback. The effective participation by prosthetists from commercial facilities in such clinic team activities is critical and much appreciated.

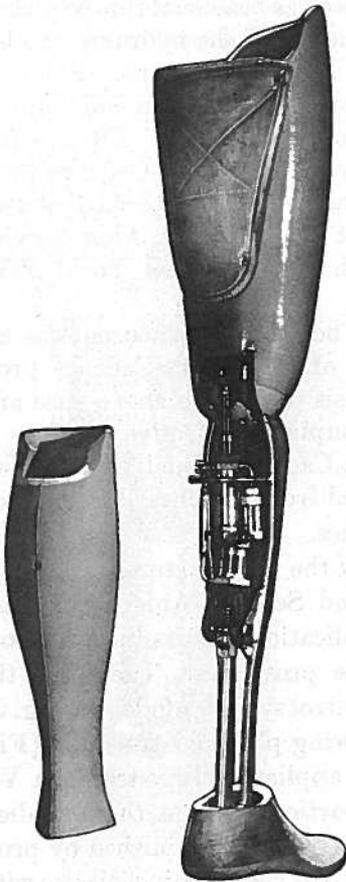


FIGURE 1. *Hydra-Cadence Hydraulic System, Model D* (cover removed to expose unit).

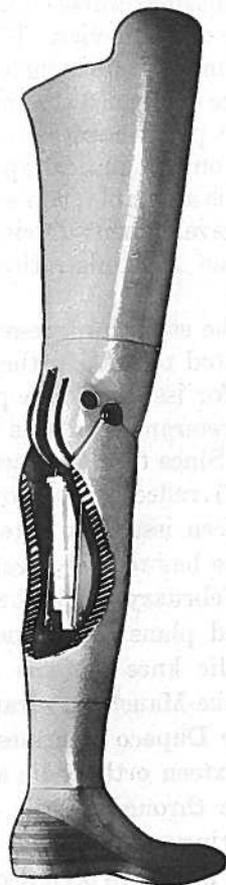


FIGURE 2. *Henschke-Mauch "Hydraulik" Swing Control System* (installed in demonstration prosthesis with posterior of shank cut away; socket and ankle-foot sections are detachable).

The first such clinical application study, initiated late in 1959, dealt with the Hydra-Cadence above-knee prosthesis. One hundred subjects were fitted with this prosthesis by prosthetists from 68 limb-fitting facilities. The experiences of these 100 subjects over a period of a year with the Hydra-Cadence prosthesis, Models B and C, were followed and reported by 27 VA orthopedic and prosthetic appliance clinic teams.

The study demonstrated the superiority of fluid-controlled mechanisms in controlling the swing of above-knee prostheses. The acceptance of the Hydra-Cadence prosthesis was overwhelmingly favorable, in spite of a number of malfunctions. The device was found to offer the amputees improved performance at a variety of cadences of their own choosing. Most of the subjects viewed as beneficial the toe pickup feature of the device. With the introduction of the hydraulic mechanism, important changes in alignment became necessary. Field experience confirmed the important roles which motivation and training play in prosthetics restoration. (A limited supply of TR-2, a full report on the clinical application study of the Hydra-Cadence prosthesis, is available; copies may be obtained by writing to the Research and Development Division, Prosthetic and Sensory Aids Service, Veterans Administration, 252 Seventh Avenue, New York, N.Y., 10001.)

As the study progressed, a sufficient body of information was accumulated to justify the acceptability of the Hydra-Cadence prosthesis for issuance on a prescriptive basis to eligible above-knee amputee veterans, and this step was accomplished effective January 2, 1962. Since that time some 900 Hydra-Cadence Model D prostheses (Fig. 1), reflecting improvements derived from the clinical experience, have been issued to veteran beneficiaries. Model E of the Hydra-Cadence has recently been developed by the manufacturer.

In February 1963, the Prosthetic and Sensory Aids Service announced plans to conduct clinical application studies on two more hydraulic knee systems for above-knee prostheses. These are the Henschke-Mauch "Hydraulic" swing control system, Model B (Fig. 2) and the Dupaco "Hermes" hydraulic swing phase control unit (Fig. 3). Sixteen orthopedic and prosthetic appliance clinic teams in VA stations throughout the country are participating in these studies. The fitting of these hydraulic systems is being accomplished by prosthetists who have been deemed qualified to fit veteran beneficiaries with fluid-controlled mechanisms. It is expected that 50 subjects will be fitted with the Henschke-Mauch system and 50 with the Dupaco unit by the conclusion of the study. Comparative data will also be obtained by converting a limited number of wearers of the Hydra-Cadence

prosthesis to one of the two devices under study. Similarly, the studies will yield data on an additional group of amputees who had participated in the 1958 New York University field test of the Henschke-Mauch Model B unit and who have been converted to either the Dupaco or Hydra-Cadence system. It is expected that these studies will be completed by the summer of 1964, and a report issued to the field. In the meantime, results to date indicate that both the Mauch B and the Dupaco devices are being very well received in the field. Almost all of the amputees have reported an improved ability to vary their overall walking speeds with these hydraulic systems. In general, the subjects report that the experimental prostheses require less effort to use than did their conventional prostheses. Similarly, less fatigue has been reported. A relatively low replacement rate has been experienced.

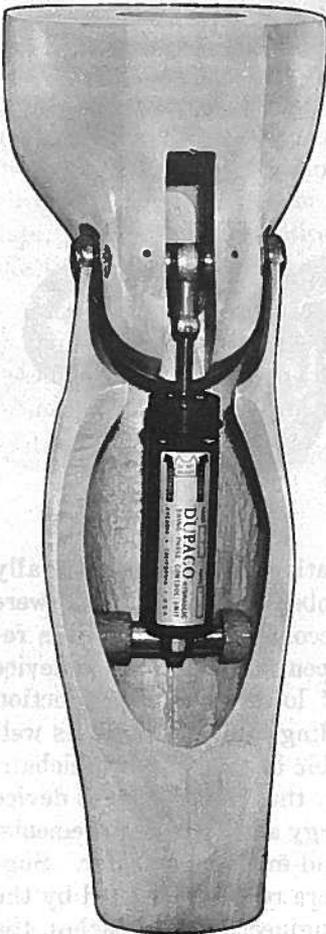


FIGURE 3. Dupaco Hermes Hydraulic Swing Phase Control System (back of shank cut away to show unit).



FIGURE 4. *Stand-Alone Therapeutic Aid.*

Although the program of clinical application studies was originally set up in connection with artificial limbs, its applications were anticipated for other devices as well. Accordingly a study was recently conducted on the Stand-Alone therapeutic aid (Fig. 4), a device designed to enable patients with loss of lower-extremity function to attain an upright position, as in a standing table or frame, as well as to achieve mobility somewhat comparable to that of a wheelchair. Extensive bioengineering evaluation of the Stand-Alone device yielded information on such factors as energy and force requirements, stability, maneuverability and mobility, and mode of transfer. Suggested changes in design and materials were readily accepted by the manufacturer. Concurrent with the bioengineering approaches, the

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device was tested clinically in five VA hospitals having Spinal Cord Injury Services. The experiences of 32 hospital patients who used the device under controlled conditions for periods ranging up to 3 months were followed and evaluated. A report has been submitted on this study. As of this writing, a decision is being considered as to the acceptability of the Stand-Alone therapeutic aid for selected VA beneficiaries.

A number of other clinical application studies are planned. A study of the Henschke-Mauch Swing-and-Stance Control system, Model A, will probably be undertaken after July 1, 1964. The evaluation of clinical experiences of patients wearing temporary prostheses will be initiated within several months. Several devices resulting from the research and development activities on aids to the blind which are supported by the Prosthetic and Sensory Aids Service will be field-tested.

There can be no doubt about the important role which well-timed and well-planned clinical application studies can play in assuring the availability not only of safe and satisfactory devices for disabled people but also of prescription criteria, fitting principles, and training methods. The experiences gained in clinical settings away from the protecting, understandably biased, and necessarily limited environment of the developer or manufacturer yield realistic and helpful data. The clinical application study has been shown to be a most effective technique for bridging the gap between laboratory and field.