Contributions of the Lower-Extremity Prosthetics Program

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WHEN, in 1945, the National Research Council launched its program for improvement of artificial legs, the original concept was that the major portion of the work would in all probability consist simply of devising mechanically improved artificial knees, ankles, and feet and of applying new materials to existing designs. But it soon became apparent that, if any appreciable success were to be had, the scope of the work would have to be broadened considerably[7]. For new items that were designed failed Lo satisfy the amputee, and there were insufficient fundamental data on which to base improvements. Such information as was available on the mechanics of the lower extremity was either incomplete or else not presented in such form as to be useful to designers.

The character of the fit was shortly found to be a matter of paramount importance in determining the success or failure of a given device. But fitting itself was based largely on the personal experience of individual fitters, and there were in existence no formalized standards or rules for guidance in obtaining proper fit. Moreover, the results of testing of devices were too often based on the impressions of only a few amputees and casual observers, either or both generally not qualified to express a competent opinion. There was not even general agreement on some of the principles involved in the surgery of amputations. Before any real progress could be made, information had to be secured in all these fields and coordinated with data from others.

The task of obtaining the required information was assigned by the National Academy of Sciences to a number of subcontractors. At the outset, basic research on problems concerned in lower extremities, including studies on surgery, pain *(9,25),* and fitting *(18),* was placed with the University of California at Berkeley *(22).* To assist designers and fitters, and to provide a record of the devices and techniques being used in the limb industry, a review of prior art was carried out at Northwestern University *(15),* and the Surgeon General of the Army sent to Europe a commission *(26)* to study and report on the prosthetics art as practiced in various other countries. Solutions attempted in the past for many problems in leg design are cataloged and described in the Northwestern report *(15)* and in the report of the European commission *(26).*

Development of devices was undertaken by Goodyear Tire and Rubber Company *(10);* Vickers, Inc. *(20),* Detroit; C. C. Bradley and Son *(2);* Catranis, Inc. *(4);* Adel Precision Products (/); A. J. Hosmer Corporation *(11);* Northrop Aircraft *(14);* the U.S. Naval Hospital at Oakland, California *(21);* National Research and Manufacturing Company *(12);* the Aero-Medical Laboratory of the U.S. Air Force, Wright-Patterson Air Force Base; the Army Prosthetics Research Laboratory, Walter Reed Army Medical Center; and the University of California at Berkeley *(22).* Later in the program, the Denver Research Institute *(6)* of the University of Denver carried out an investigation of below-knee prostheses, some additional basic data have been supplied by New York University *(13)* and by the Prosthetic Testing and Development Laboratory of the Veterans Administration in New York City, and another commission *(23)* was sent to Europe to observe

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progress abroad after 1945. Testing and evaluation of devices has been developed and carried out at New York University *(13),* and the Orthopedic Appliance and Limb Manufacturers Association has cooperated in general program guidance.

DEVELOPMENT OF BASIC DATA

Because prior to 1945 little study had been conducted on the characteristics of human locomotion, because of the complexity of the problem, and because of its highly specialized nature, it was necessary first to devise special equipment for collecting information which, ultimately, would lead to determination of the mechanical and physiological changes occurring during various activities of the lower extremity. A number of pieces of unusual apparatus, such as force plates, a glass walkway (Figs. 1 and 2), and special photographic equipment were designed *(7,22),* and from the data collected using this equipment it was possible to determine such factors as the forces and moments in human and artificial legs and the roles played by major muscle groups under a series of conditions. From such findings it has been possible to describe fully the phenomenon of human locomotion and thus to establish a set of realistic criteria for the design and evaluation of artificial-leg components. Aside from applicability to the field of prosthetics, the data collected are useful also to designers of leg braces and to

Fig. 1, The University of California glass walkway. With this device, motion pictures taken from a single camera yield sufficient information to determine relative motions of various segments of the body during level walking. Subject shown here is wearing an above-knee experimental leg.

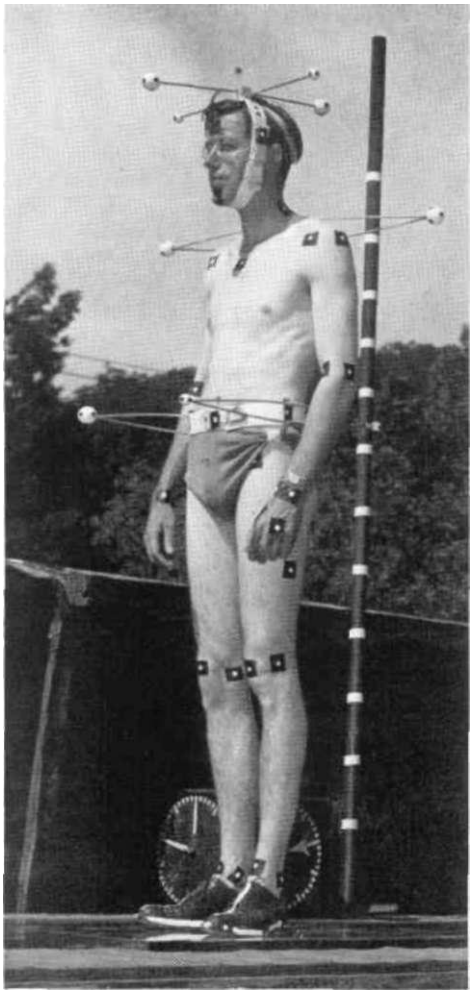

Fig. 2. Normal subject prepared for participation in studies using the University of California glass walkway. Some targets are mounted on levers to amplify motions otherwise of small magnitude.

the medical profession in the treatment of pathological gait *{19).*

The major portion of this work was performed at the University of California, Berkeley, and many of the results have been documented in reports and in the journal literature. Of the many reports issued, most, such as those of Cunningham (5), of Bresler and Berry (J) and of Radcliffe *(17),* generally cover a single phase of the subject.

CREATION OF DESIGN OBJECTIVES

From study of the basic data, and from careful review of current practices, it has been possible to set up a listing of design objectives for leg prostheses, it being understood that above all the prosthesis must satisfy the amputee. Arranged in generally decreasing order of importance, these requirements are as follows:

1. Security from [all.
2. Minimum consumption of energy in normal walking
3. Appearance of the walking pattern to compare favorably with that of a normal person.
   a. Smooth swing phase, including deceleration of the prosthesis at the end of extension, control of heel rise at the end of flexion, and deceleration of the prosthesis just prior to heel contact.
   b. Smooth stancephase, includingattainmentof full extension without final snapping action.
   c. Ability to change gait to maintain smooth, normal-appearing gait.
4. Ability to extend the leg under load at any time.
5. Proper phasing of the locking action, if used, with all portions of the stance and swing phases.
6. Performance of incidental operations—such as going up and down stairs and ramps, turning, and sitting down—with reasonable ease and smoothness.

A listing of the features desired of leg prostheses at three functional levels (Table 1) has finally evolved.

IMPROVEMENT or FITTING AND ALIGNMENT

As a result of the early attempts to improve existing knee-brake devices, it was found that fitting and alignment were together often more of a determining factor in amputee acceptance than was the performance of the device itself. In the two trips to Europe *(23, 26),* various techniques and several mechanical aids for obtaining greater uniformity in fitting were observed. These techniques and devices have been analyzed, and from the resulting knowledge, together with information from the basic studies, improved methods of fitting and aligning above- and below-knee legs have been formulated. All of these observations have been published in a report of the University of California at Berkeley *(18).*

In order to make these principles of fitting and alignment easier to apply, an adjustable leg (page 23) for above- and below-knee prostheses, with provisions for individual adjustment of major elements, was designed by the project at Berkeley and turned over to the limb industry. This leg, once adjusted, can be worn by an amputee for periods of a

Table 1

DESIRABLE FEATURES OF LEG PROSTHESES[a]

Class of leg	Component			
	Foot	Ankle	Shank	Knee[b]
Standard	1. Toe break so set as not to interfere with amputee's gait. Range: 30 deg. Stiffness: 2.5 in.-lb. per deg. 2. Shock absorption at heel contact 3. Proper shape of foot to fit shoe	1. Plantar-flexion stiffness: 10–15 in.-lb. per deg. Range: 10–20 deg. 2. Dorsiflexion stiffness: 60–150 in.-lb. per deg. Range: 2.5–10 deg.	1. Shape similar to normal leg 2. Pleasing color and cosmetic appearance	1. Satisfactory range of motion, min. 110 deg. 2. Predetermined constant knee friction in swing phase 3. Stability in stance phase independent of added mechanism
Improved	1. Toe break 2. Shock absorption 3. Proper shape	1. Plantar flexion 2. Dorsiflexion 3. Transverse rotation with independent adjustment. Range: ±15 deg. Stiffness: 1–6 in.-lb. per deg. Location: any level below knee 4. Lateral-motion range: ±10 deg. Stiffness: 4–8 in.-lb. per deg.	1. Proper shape 2. Cosmetic appearance 3. Sufficient space for installation of knee-friction device	1. Range of motion: 120 deg. min. 2. Predetermined variable friction in swing phase 3. Stability in stance phase independent of added mechanism 4. Involuntary control, yielding-type knee brake. Resisting moment: 750–2500 in.-lb.
Maximum function	1. Toe break 2. Shock absorption 3. Proper shape	1. Plantar flexion 2. Dorsiflexion 3. Transverse rotation 4. Lateral motion 5. Toe pickup 6. Ankle extensor for push-off	1. Proper shape 2. Cosmetic appearance 3. Space for knee-friction device 4. Additional inner space required for mechanisms 5. Cosmetic covering	1. Range of motion: 120 deg. min. 2. Predetermined variable friction in swing phase as a function of angular velocity for cadence control 3. Stability in stance phase independent of added mechanism 4. Yielding-type knee brake 5. Voluntary control, positive-action knee brake, with provision for initial knee flexion. Resisting moment: 1500–5000 in.-lb. 6. Anatomical knee motion

[a] All components of the leg prosthesis must have sufficient strength to meet structural and durability requirements. Proper alignment is required to derive maximum benefit of the leg prosthesis. All components affecting alignment must be capable of adjustment during assembly. The socket or other method of attachment used must support the weight of the amputee comfortably and suspend the leg satisfactorily during the swing phase.

[b] The column "Knee" must be interpreted according to whether the prosthesis is for above or below knee. It applies almost in its entirety to very short below-knee stumps.

few days to determine if the fitting is satisfactory. To transfer to the permanent prosthesis the measurements thus determined by the adjustable leg, there has been designed a fixture which holds the elements of the prosthesis in position while they are being assembled with the predetermined alignment. With these two devices, which are now available commercially, fittings become quite exact. The ease with which minor adjustments can be made in the adjustable leg makes it possible to try variations in fitting which, previously, were avoided because of the time and expense involved. Moreover, the adjustable leg has the psychological advantage of demonstrating to the amputee that the fit of the device he is obtaining is the optimum for him.

METHODS OF SUSPENSION

A major factor involved in fitting of both above- and below-knee legs is the socket. On the first trip to Europe *(26)*, a number of exceptionally well-fitted suction sockets (page 29) were observed in Germany. This type of suspension had been tried previously in the United States *(16)* and in England with poor results. The successful cases seen in Germany

in 1946, however, prompted another trial of the technique in the United States. A thorough study of the shape of the socket and other features involved in fitting of suction sockets was undertaken at the University of California at Berkeley *(8,24)*. As a result of the successful conclusion of this work, the suction socket has since been widely applied by the United States limb industry and has been accepted by the Veterans Administration as an improved method of fitting prostheses for above-knee amputees where there are no contraindications. The knowledge gained in perfecting the technique of suction-socket fitting and in determining the optimum shape of the suction socket has contributed to improvement in the fitting of other sockets. Development work is now proceeding on suction sockets for below-knee amputees.

In addition to the work on suction sockets, a "soft" socket for below-knee amputees, consisting of a thin, resilient pad under a conventional leather or plastic socket lining in a plastic or wooden socket, has reached the testing stage at New York University.

SCHOOLS FOR PROSTHETISTS AND SURGEONS

Since the suction socket was as much a technique as a device, it was determined that, if the suction socket was to be as successful in general practice as it had been in the development period under the supervision of the University of California, the technique had to be taught to limbfitters throughout the United States. Accordingly, plans were laid for a series of schools to be held in various cities in the United States. A course of instruction was laid out, and under the auspices of the Veterans Administration, with the assistance of the Orthopedic Appliance and Limb Manufacturers Association, a series of schools was held throughout the country. The Veterans Administration, by requiring that fitters and surgeons have certificates from one of these schools before suction sockets could be provided beneficiaries, ensured that the best practices were provided. Establishment of these schools was an important advance, for it provided a mechanism for bringing to the commercial limb industry and medical profession the new techniques and ideas developed. Their success has led to expansion of the principles of the clinic-team approach for handling both upper- and lower-extremity cases.

In connection with the suction-socket schools, manuals were issued on how to fit suction sockets. They constituted the first attempt to present, in a manner that would be useful to the limbfitter, data developed in the program. Their success has led to the issuance of manuals on other subjects.

AMPUTATION SURGERY

In the early investigations, it became apparent that relative difficulty of fitting rather than surgical considerations often dictated the site of amputation. This circumstance led to a study of the sites of election and to a consideration of whether some changes might not be advisable. Studies have since clearly shown that the longer the stump the more function and control can be obtained—a matter that has not always been fully appreciated. In the above-knee amputee, the increased length of stump is particularly important, since it is one of the governing factors in obtaining stability of the prosthesis in abduction. In the above-knee amputation, it has also been found advantageous to tie the muscles together across the bottom of the stump or otherwise to attach muscles to the bone to aid in obtaining stability in abduction. These new concepts are leading to a revision of amputation practices. There will, no doubt, be other such advances in amputation surgery as more is learned about body mechanics.

PAIN STUDIES

Pain, both phantom and real, has always been a troublesome problem in amputee management. In order to obtain a clearer understanding of and possible solutions to the pain syndrome, a project was instituted at the University of California. Although practical applications of methods to alleviate pain and eliminate phantom pain have been meager to date, the mechanism of pain radiation has been elucidated, and the results *(9,25)* form the basis for future work in this field.

NEW DEVICES

One of the most important parts of the lower-extremity program is the development of new devices. Consequently, device development has been one of the major efforts. In the early stages of the program especially, there was an urgent demand from new Service-connected amputees for improved devices. At the time, the data from the basic studies at the University of California were not available. But because of the urgent demand, a program for invention and development of devices was undertaken simultaneously with the program for developing basic data. While most of these devices were unsuccessful, the time, money, and effort expended developing them were not entirely wasted. For in trying these devices, much needed information was developed, and the need for long-range research on several items of a basic nature was pointed out. As the data were collected at the University of California, devices were produced incorporating features which seemed desirable.

A great deal of effort was expended in attempting to perfect a knee lock for above-knee amputees. But most of these designs were abandoned for one reason or another after a few models had been made and tried on amputees. The particular difficulty in obtaining smooth and reliable action in a knee lock was found to reside in the method of control. In addition to knee locks, considerable effort has been expended on coordinated motion between the knee and ankle, toe pickup, transverse rotation in the leg, and control of the swing phase. Numerous devices incorporating such features have been made. Both mechanical and hydraulic devices, with varying degrees of complexity, have been tried.

Of all the knee locks tried to date, only two, the Stewart-Vickers (Fig. 3) and the Henschke-Mauch (Fig. 4), appear to have reached the

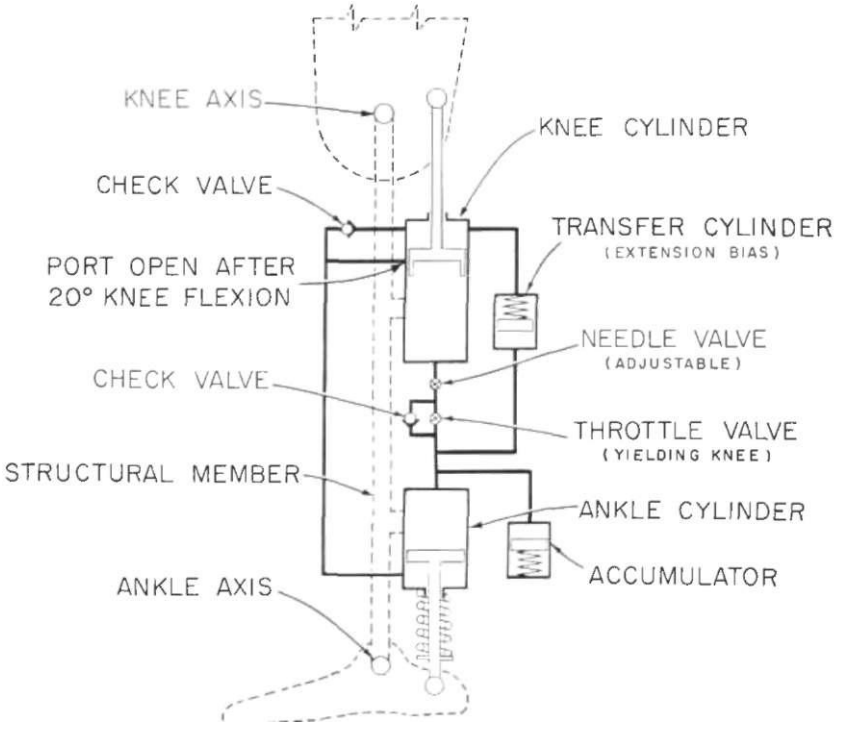

Fig. 3. Schematic diagram of the Stewart-Vickers hydraulic leg incorporating knee lock, swing-phase control, and coordinated motion between ankle, shank, and thigh.

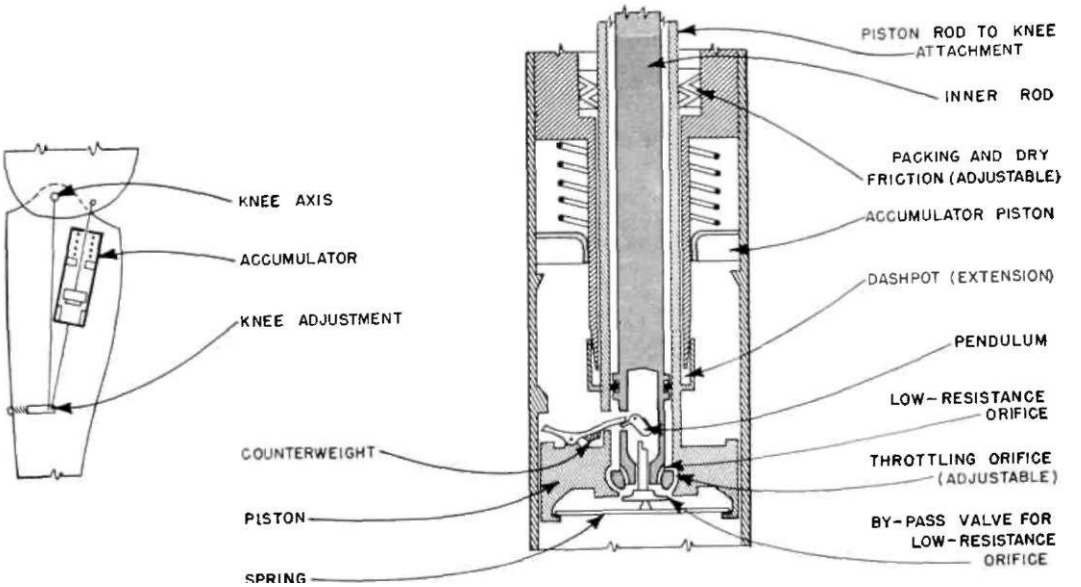

Fig. **4.** Schematic diagram of the Henschke-Mauch hydraulic leg incorporating knee lock and swing-phase control.

point of having commercial possibilities. More recently, however, there have been indications that proper swing-phase control, coupled with alignment stability or limited stability over the first few degrees of flexion, are all that the average above-knee amputee may need. The more or less elaborate knee locks might therefore be indicated for special cases, for older persons, or for those who prefer "the best" and can afford it. Both Stewart and Henschke-Mauch have swing-phase control devices incorporated in their designs, and both have under test legs in which only the swing phase is controlled.

Another lower-extremity device now under test is the University of California four-bar-linkage or polycentric knee (Fig. 5). The four-bar-linkage knee is not a new idea, but the UC version has been so designed that the toggle action existing in prior designs to provide extreme stability as the knee approaches full extension has been eliminated. Instead, it depends for its stability on alignment in fitting. It has the advantage, like many other four-bar linkages, of providing at the start of flexion a pivot point about 6 in. above the actual knee joint—a feature which provides a very favorable mechanical advantage for the amputee to start the leg to flex.

In the UC leg the swing phase is controlled by a radial-vane type of damping device in which hydraulic fluid passes from one side of the vane to the other through suitable needle valves. Hence this device is responsive to gait change and limits excessive heel rise as cadence is increased.

The limbshop at the U.S. Naval Hospital, Oakland, California, has developed and had accepted by ACAL a complete above-knee leg featuring a very simple mechanical device for controlling the swing phase in connection with a more or less conventional knee bolt (Fig. 6). This type of swing-phase control is not nearly so responsive to gait change as are the hydraulic units, but it marks a definite advance in the design of artificial knees. Also featured in the Navy leg are a plastic shank and the so-called "Navy functional ankle." The latter (Fig. 7) uses a rubber block with different degrees of hardness at front and rear to provide for plantar flexion and dorsifiexion and at the same time to permit some rotation about the vertical axis of the leg. It is anticipated that the Navy above-knee leg will be available commercially early this summer.

To summarize the work done on new devices for lower extremities, there is now available a large store of information on devices

which have been tried and found lacking in one respect or another. With what is now known about performance desired in above- and below-knee legs, it is possible that a review of past developments, coupled with some changes based on present knowledge, may lead to the development of more acceptable leg prostheses. At this time, however, only the Navy functional ankle and the swing-phase control have been accepted as completed devices. Others appear very close to acceptance.

TESTING AND EVALUATION

Throughout the early stages, the development of new devices in the lower-extremity program was retarded by the lack of techniques and organization for objective testing and evaluation. Until the data on the mechanics of walking had been developed, it was almost impossible to set up means for objective evaluation because no satisfactory standards of comparison were available. In addition to this lack of standards, it became apparent early in the program that some means had to be established for testing, under a controlled set of conditions, the devices which appeared ready for production. A testing laboratory at New York University was therefore set up. With its entry into the program, there was obtained a much better evaluation of the desirability of the devices proposed and a much better idea of their mechanical performance *(13)*. It was soon found that most of the devices submitted had minor mechanical shortcomings, and as a result many devices which two or three years ago appeared almost ready for release are only now approaching that point. The field-testing procedure has avoided premature release of several supposedly completed items and has indicated the need for more information on several basic points. It has thus proven to be a very valuable step in the development program, and the information gained in

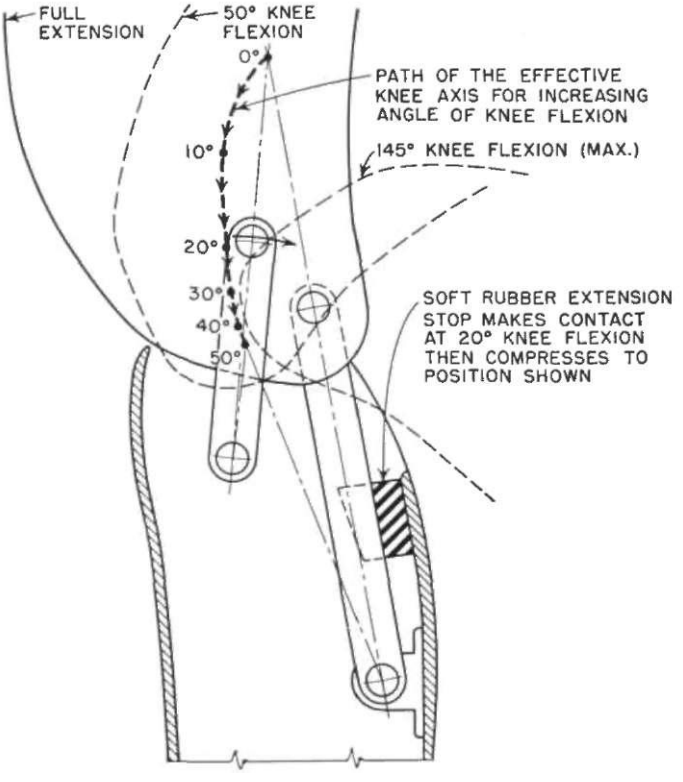

Fig. 5. Schematic diagram of the University of California four-bar-linkage (polycentric) knee showing change in center of rotation of shank as knee is flexed.

the field tests has fully justified the time and cost of field-testing.

CLINICAL PROGRAM

When the program for development of new devices had reached a certain stage, it became apparent that, if there could be instituted a clinical program to try devices on various amputees under as nearly identical conditions as possible, progress would be much more rapid. Information was also needed to confirm conclusions about the suitability of certain devices for various sites of amputations and for various physical and mental characteristics of the amputee and to determine new types of devices which might be needed under certain sets of conditions. Among others, such questions as the need for, or suitability of, a knee lock, or whether limited stability coupled with swing-phase control would be better, needed investigation and decision.

A clinical study was therefore set up under the direction of the University of California at the U.S. Naval Hospital, Oakland, with certain facilities provided by the Surgeon General of the Navy. It is expected that, by providing a complete staff of surgeons, prosthetists, physiotherapists, engineers, and research

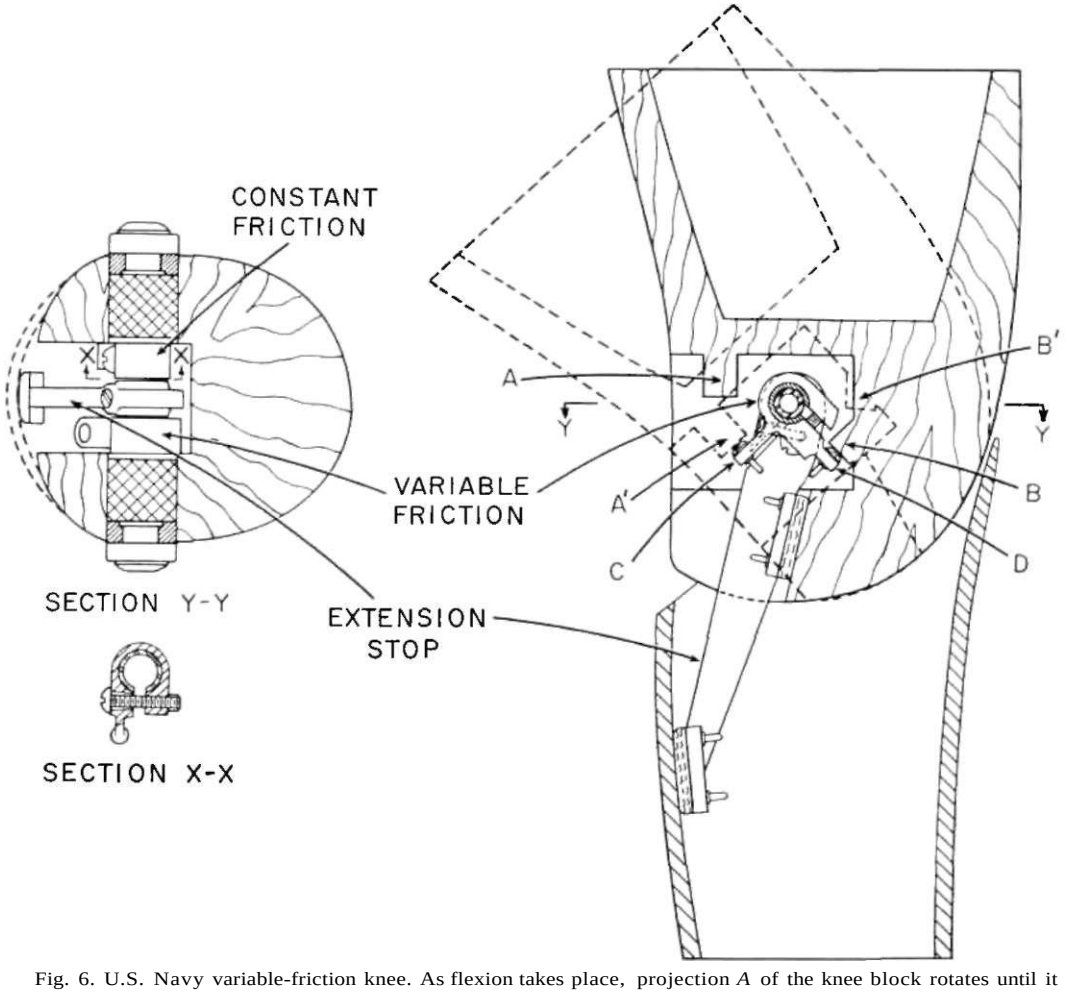

Fig. 6. U.S. Navy variable-friction knee. As flexion takes place, projection *A* of the knee block rotates until it contacts lever arm C, which induces additional friction about the knee bolt to limit heel rise. As extension occurs, projection *B'* rotates to contact lever arm *D*, which induces additional friction to decelerate the shank (terminal deceleration).

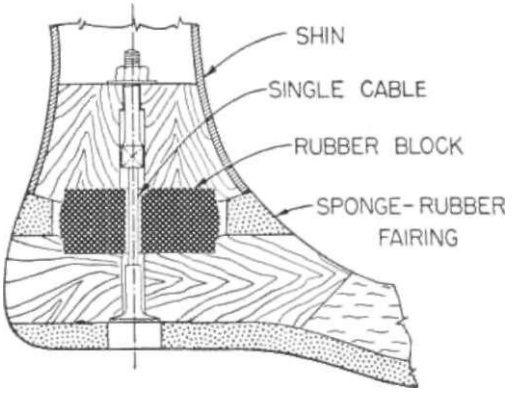

Fig. 7. U.S. Navy functional ankle. Single cable extends through rubber block of different degrees of stiffness at front and back.

workers, with the opportunity for controlled fitting and follow-up of patients, rapid progress will be made in improving fitting and alignment techniques, in surgical procedures, and in the development of improved devices.

DEVELOPMENT PROGRAM

Since the establishment of the lower-extremity clinic, a development group, staffed with people skilled in lower-extremity prosthetic art, including representatives from the industry, has been established. This group has headquarters at the U.S. Naval Hospital at Oakland, California, in close proximity to the clinic. It is expected that they will complete the development of some of the devices partially completed in the past and develop new devices, possibly combining or utilizing some of the ideas and data resulting from development work on these new devices. It is expected that this group will bring the program for new devices somewhere near its required level within the next two years.

CONCLUSION

Because the improvement of leg prostheses has required research and investigation in many fields, and because of the broad scope of much of the work, its full usefulness will not be realized until some time in the future. Time and study are required to analyze the data and to apply the results of such analyses. Nevertheless, the basic data developed under the ACAL program have already been useful, not only in the design of above- and below-knee prostheses but also in the design of leg braces, and they have proved extremely helpful in the diagnosis of pathological gait. Among the developments of more or less immediate practical applicability are the new techniques introduced for fitting and aligning above- and below-knee prostheses. Devices to facilitate adjustments in fitting so that optimum results can be attained quickly have been developed and introduced to the industry, as has also the equipment for transferring the dimensions determined for the prosthesis.

As a result of efforts of ACAL, the suction socket for the above-knee amputee has come into general use in the United States. In addition, the principles developed in the suction-socket program have helped to improve techniques used with other types of sockets, thus contributing generally to the well-being of the leg amputee. Experience gained in the suction-socket program has led either directly or indirectly to the development of the clinic-team concept which is proving so useful in the management of amputees of all types.

Certain changes in the surgical procedures of amputation have been suggested, especially in regard to the so-called "sites of election" and to stabilization of the above-knee stump in adduction. Study of the nature and propagation of pain in stumps has yielded results which should be the basis for future advances in treatment and prevention of pain arising from amputation.

Outgrowths of the lower-extremity clinical study may be expected to confirm, apply, and develop further the principles of fitting and alignment, to advance further the use of the suction socket, to improve the fitting of conventional above- and below-knee sockets and the "soft" socket for below-knee amputations, and to develop prostheses for other types of amputations. With the above-knee clinic established, the work in surgery, prescription, fitting, and training of the amputee is likely to advance even more rapidly than has been the case in the past.

The development of devices with increased function, reliable enough and with benefit enough to the amputee to justify the increased complexity and cost, has proven difficult.

Many devices have been built, tested, and found wanting in one detail or another mechanically or else have proven too costly to be practical at the present time. Although thus far only two devices, the Navy variable-friction knee and the Navy functional ankle, have been accepted by ACAL and made ready for distribution, several experimental ones appear to be almost ready for general use. The groundwork in the field of lower-extremity prosthetics has been laid. By 1956 we should see the appearance of many more, and more practical, accomplishments resulting from the preceding eight years of pioneering work.

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