CLINICAL APPLICATION STUDY OF THE HENSCHKE-MAUCH HYDRAULIK MODEL "A" SWING AND STANCE CONTROL SYSTEM

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INTRODUCTION

In December 1964, the Research and Development Division published Technical Report TR-3, a report on the Clinical Application Study of the Henschke-Mauch HYDRAULIK Swing Control System. It was on the basis of this study that the Model "B" system was accepted for VA contract. Those readers who are interested in some of the background on the development of both the Henschke-Mauch "A" and "B" models are referred to that report (1).

The Research Division, New York University School of Science and Engineering under contract to the Veterans Administration evaluated the Henschke-Mauch HYDRAULIK Swing and Stance Control System, Model "A," by an intensive series of tests, both bench and with amputee wearers in the laboratory and in long-term clinical use. They also attempted to assess "its applicability to a selected portion of the general amputee population" (2) by study of 12 above-knee amputees over a 2-year period. Their report recommended areas of possible improvement of the device and also recommended acceptance for clinical field testing by the sponsoring agency. Accordingly this present study was authorized in October 1966.

PURPOSE OF STUDY

As with all of our clinical studies, the prime purpose was to determine the desirability of placing this device on contract for issuance on a prescription basis to disabled veterans. In addition, we hoped to gather data which would aid clinicians and limb facility personnel in determining:

a. Indications and contraindications.

b. Advantages or disadvantages compared with conventional knee mechanisms and other hydraulic devices.
c. Frequency and nature of maintenance and repair.
d. Training procedures and problems.
e. Fitting and alignment considerations.
f. Instructions for installation and adjustment.
g. Implications for prosthetics education and information programs.

DESIGN OF STUDY

Following the procedures used in the past clinical studies conducted by this Division, data were to be gathered by station personnel. Instruction, test forms, and a manual of instruction were provided. All fabrication was to be performed at commercial limb facilities. Personnel of the Research and Development Division provided orientation to the experimental system and to the study procedures. Upon request or when incoming data indicated a need, a followup visit was scheduled. Information was provided by station personnel based on evaluations and interviews at the time of acceptance of the subject, upon delivery and acceptance of the limb, and at two followup visits approximately 2 months and 6 months after delivery.

Units and setups were purchased by the VA Prosthetics Center for use in the study. The Prefabricated Appliances Section was responsible for inspection of all units prior to shipment to participating limb facilities and for stocking and shipping of components. They also examined all units returned from the field with reported malfunctions.

PARTICIPATING VA INSTALLATIONS AND PROSTHETIC FACILITIES

Twelve VA installations having regularly scheduled Orthopedic and Prosthetic Appliances Clinic Teams were selected to participate in the study. Though special training for prosthetists in fitting and aligning the Henschke-Mauch Model "A" had not been available, prosthetics facilities which had current contracts covering the Mauch "B" system (including requirement for a prosthetist especially trained in fluid-controlled swing-phase prostheses) were eligible to participate. The VA stations and the commercial prosthetics facilities which cooperated in this study are shown in Table 1.

INSTRUMENTATION

Participating stations and limb facilities were provided with a publication entitled "Explanatory Notes on Clinical Application Study of the Henschke-Mauch HYDRAULIK Swing-and-Stance Control System, Model 'A' for Above-Knee Prostheses" (3). Nine different forms were used to gather

TABLE 1.—*Cooperating Clinic Teams and Prosthetic Facilities*

Station [a] (N = 12)	Prosthetics facility (N = 25)	No. of cases (N = 33)
VAH, Allen Park, Michigan	E. H. Rowley of Detroit, Inc.	1
	Okeomos Limb Shop	2
VAH, Atlanta, Georgia	Atlanta Artificial Limb Co.	1
	J. E. Hanger, Inc.	2
	Harvey's Shoe & Brace Shop	1
VAOPC, Boston, Massachusetts	Anthony & Williams, Inc.	1
	United Limb & Brace Co.[b]	1
VAH, Chicago (West Side), Illinois	American Limb & Orthopedic Co.	2
	J. E. Hanger, Inc.	1
	Merrick-Hopkins Artificial Limb Co.	1
VAH, Dallas, Texas	J. E. Hanger, Inc.	2
	Rupley Artificial Limb Co.	1
VAH, Denver, Colorado	Long's Limb Shop	2
	Kleiber Orthopedic Appliance Co.	1
VAOPC, Los Angeles, California	Long Beach Artificial Limb Co.	1
	Adept Prosthetics	1
	Jack Vollmer Co.	1
VAOPC, Philadelphia, Pennsylvania	Modern Limb & Brace Co.	2
	Frank J. Malone & Son, Inc.	1
	J. E. Hanger Co.	1
VAH, Providence, Rhode Island	Rhode Island Limb Co.	1
VAC, St. Paul, Minnesota	Botko Artificial Limb Service	1
VAH, Seattle, Washington	Ta oma Brace & Limb Co.	1
	Dodge & Lundquist Co.	1
	Lundberg's	2
VAC, Togus, Maine	United Limb & Brace Co. (Boston)[b]	1

[a] VARO—Veterans Administration Regional Office
VAOPC—Veterans Administration Outpatient Clinic
VAH—Veterans Administration Hospital
[b] Participated at two VA stations

data during the study. A brief description of these forms follows, and copies of the forms are appended to this report.

CAS 1, Unit Inspection Report, was used by the Prefabricated Appliances Section of the VA Prosthetics Center for recording inspection data prior to shipment of individual hydraulic units or knee "setups" to limb facilities.

CAS-2A, Amputee Selection Record, was used by the Clinic Team to provide the Project Director with objective and subjective data concerning the amputee's prosthetics experience. This form was completed at the time an amputee was being considered as a test wearer. A section of the form provided for an evaluation of the amputee's performance on his prestudy prosthesis. An additional segment, Appendix C, was completed if the candidate was wearing a Mauch Model "B" system.

Form 10–1068, Request for Artificial Limb Components, was used to request VAPC to ship components and notified intended recipients of the shipment.

CAS–5A, Checkout and Acceptance Report, was a three-part form with the first section completed when socket comfort and alignment were considered acceptable. This first section was prepared while the adjustable coupling was still in place. The second and third sections were completed and the report submitted to the Project Director when the finished experimental prosthesis was accepted by the Clinic Team.

CAS–6A, Followup Report, was completed twice during the study. The first time after 2 months of wear and then again at the conclusion of the study (after 6 months of wear).

CAS–7A, Special Report, was used during each month after delivery, except the second and sixth months when the subjects returned for evaluation by the Clinic Team. They received directly from the Project Director a single-page special report to be completed and returned in the preaddressed envelope. If this report indicated difficulties, the Project Director requested the Clinic Team to contact the subject and resolve the problems.

CAS–8A, Request for Replacement and Shipping Notice for Use by Limb Facility, was used by the prosthetist to request replacement components, if needed, from the Project Director. The prosthetist was to indicate in detail the nature of the problems which necessitated replacement components.

CAS–9A, Return Notice and Replacement Request and CAS–10A, Manufacturer's Report, were used to communicate with the developer when the VA Prosthetics Center returned units for repair or inspection.

DESCRIPTION OF SYSTEM

The Henschke-Mauch HYDRAULIK Swing and Stance Control Unit, Model "A," used in this study is shown in Figure 1. (For description of the rationale of the stance-control system see article by Hans A. Mauch (4) elsewhere in this issue.) The unit was installed in a specially designed setup composed of a plywood knee block and willow wood shank 18 in. long. Left and right setups were available in 3½ in., 3¾ in., and 4 in. knee widths or sizes, each measured between the sidebars. The setup is shown in Figure 2. The unit is a hydraulic mechanism providing knee control during swing and also especially while the prosthesis is in stance phase. Three modes of operation are possible:

Swing and stance phase control.
Swing phase control only.
Hydraulic lock against knee flexion.

Selection of operation mode is by means of a stirrup-shaped lever on the back of the piston rod, while the round head Allen screw on the piston rod of the Model "A" permits adjustment of stance-phase resistance (Fig. 1).

In normal use for control of both swing and stance phases, with the stirrup-shaped lever in the down position, the system functions in the following manner. Two levels of patterned resistance to knee flexion are incorporated into the design of the system; each is independently adjustable. The lower level of resistance provides resistance to achieve flexion characteristics, during swing phase, that are most suitable to the amputee's gait pattern. (Rotation of the serrated portion of the cap in the clockwise direction increases resistance.) The higher level of resistance provides resistance to flexion of the knee at all other times. (Clockwise rotation of the Allen head screw in the head of the piston rod increases resistance to yielding under stance-phase control.)

The design of the system provides that the higher level of resistance acts at all times until the amputee generates a prolonged hyperextension moment about the knee. This hyperextension moment occurs naturally while walking as the amputee rolls over the ball of the prosthetic foot after mid-stance. Prolonged hyperextension moment, which can only occur when the knee is safely extended, results in disengagement of the high resistance range and permits the knee to flex properly to begin swing phase. As the knee nears maximum flexion and the speed of rotation decreases to almost zero velocity, the higher level of resistance is reinstated (similar to the automatic downshift of an automobile's automatic transmission as speed decreases). Thus, if during extension of the shank the toe is stubbed, the high resistance to flex is available to aid in stumble recovery.

FIGURE 1.—Henschke-Mauch HYDRAULIK Swing and Stance Control Unit, Model "A."

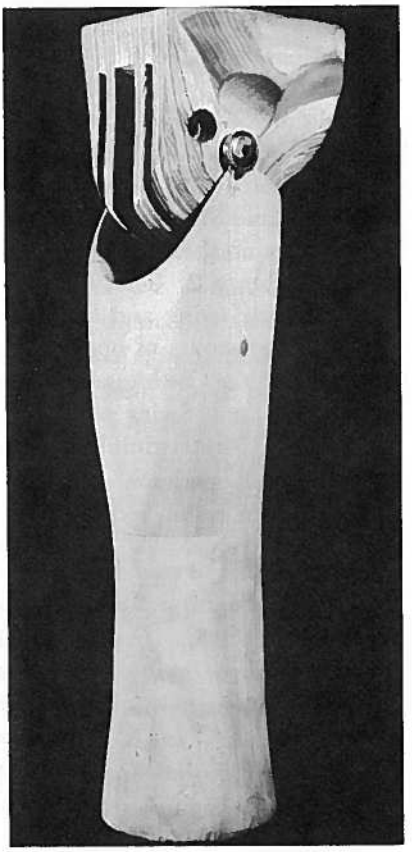

FIGURE 2.—Wooden setup for the Henschke-Mauch HYDRAULIK Swing and Stance Control Unit, Model "A."

Release of the high flexion resistance typically available in stance phase can be accomplished voluntarily by an amputee who is standing and wishes to sit down easily. He simply extends his stump while maintaining the foot in contact with the floor, thus generating and maintaining a hyperextension moment at the knee for at least a tenth of a second. With the high flexion resistance released, stump flexion initiates knee flexion which he continues as he then sits down. Should the amputee walk in such a way that the knee is not fully extended and a hyperextension moment is not generated in stance, then the knee will not flex freely.

The unit may also be set to function without stance-phase control (that is, in a manner identical to the currently available Model "B" system). To disengage stance-phase control, leaving only swing-phase control, the

leg is placed in the fully extended position and while a hyperextension moment is generated, the stirrup-shaped lever is placed in the up position. To reinstate swing and stance control, the lever is replaced in the down position.

The third functional mode available to wearers of this system is a setting which provides a relatively positive lock against knee flexion. To engage the lock, the stirrup-shaped lever is placed in the up position while the knee is in a slightly flexed position. The prosthetic knee may be extended voluntarily, but flexion moments will not produce yielding during use of this control. All changes in the lever's position should be made with the shank in an upright position, otherwise the desired mode may not be engaged.

Speed of yielding under stance-phase control (lever down) is adjustable by means of a round head Allen screw near the top of the piston rod. Full clockwise rotation of the screw provides the greatest resistance to flexion of the knee under load. This adjustment is very sensitive, and a counterclockwise rotation of about 120 deg. (⅓ rotation) brings the resistance to its minimum value.

Flexion and extension resistance during swing phase are adjustable, independently, in the same way as in the Model "B" (5).

SELECTION PROCEDURES

Subjects

Amputees selected to participate in the study were required to:

a. Be a male, service-connected veteran who, at the time of prescription, would normally have been entitled to a new prosthesis under established policies.
b. Be a unilateral above-knee or hip-disarticulation amputee with no significant stump problems or other disabilities affecting locomotion.
c. Be a routine wearer of a prosthesis, or a recent amputee who had never worn a prosthesis. Amputees who had worn, were wearing, or had in their possession Dupaco or Hydra-Cadence Systems were not eligible to participate. Current wearers of the Henschke-Mauch Model "B" System could be included as test subjects.
d. Have a usable spare prosthesis which could be worn for a period of several weeks. (Obviously, this requirement did not apply to recent amputees who had never worn a prosthesis.) No spare experimental prosthesis was to be provided during the study.
e. Have a relatively satisfactory prosthetics history.
f. Be an emotionally stable individual who could be depended upon to furnish reliable information.
g. Be strongly motivated to participate in the study, understanding that he would be expected to report for checkouts on the adjust-

able coupling and on the finished prosthesis as well as for at least two followup visits. He was also expected to complete and mail special followup forms.

h. Understand that the Veterans Administration would not guarantee that another prosthesis of the test design or a similar design would be issued to him after the study had been completed and/or when a replacement limb was necessary at a later date.

i. Agree to return the unit to the Clinic Team if he withdrew from the study before its completion or if he were rejected for any reason after the unit had been issued to him. In such instances, the station would prescribe a new prosthesis, utilizing, if possible, the socket, suspension, and any components other than the hydraulic unit.

j. Agree to refrain from making any adjustments to the unit other than the authorized adjustments. He was to report to the selected prosthetist for any other adjustments or repairs.

k. Not be an employee of a commercial limb facility.

l. Expect to continue to reside for at least 6 months within the jurisdiction of the prescribing Clinic Team after he had received the experimental prosthesis.

m. Sign appropriate releases for use of photographs for publication purposes and be willing to be photographed.

Limb Facilities

VA members of Clinic Teams were responsible for the designation of commercial limb facilities to participate in the study. Each facility had to:

a. Have a prosthetist who had satisfactorily completed a specialized training program in fluid-controlled above-knee mechanisms conducted by the Veterans Administration or by one of the universities. This prosthetist was to fit the new socket, align it by using the adjustable coupling, finish the prosthesis, and perform necessary adjustments and repairs.

b. Be willing to cooperate with the Clinic Team in all aspects of the study, including attendance at Clinic Team meetings by the prosthetist responsible for the fitting and completion of reports.

c. Have an interest in research activities.

d. Have an approved VA contract covering hydraulic prostheses.

e. Be willing to use the adjustable coupling (contract requirement).

f. Agree to study and to follow the prescribed installation instructions.

g. Agree to make only authorized adjustments on the unit, and to report all repairs and adjustments.

h. Agree to provide the complete limb at the accepted contract price for a limb with the Henschke-Mauch Model "B" System. (The

Veterans Administration supplied the hydraulic unit and knee setup in either case.)

SAMPLE CHARACTERISTICS

Thirty-three above-knee amputees were selected to participate in the clinical evaluation of the Henschke-Mauch Model "A" System. Included were two recent amputees who had never worn prosthetic devices and one amputee who was a bilateral above-knee as well as a unilateral above-elbow amputee. This latter subject was included at the request of the Clinic Team personnel who felt he would benefit from the use of the test device. He was fitted bilaterally with the Henschke-Mauch Model "A" System. All of the subjects were veterans whose amputations were rated as service-connected. This sample is typical of the sample populations of our previous studies with one minor exception attributable to the Viet-Nam conflict; mean age shows a slight decrease from previous studies. Most (27) of the amputees believed that they were good walkers. Twenty-three of the 31 with previous prosthetics experience had received gait training at some time since receiving their first limb. Tables 2 through 15 summarize some of the characteristics of the sample.

TABLE 2.—*Occupations*

N = 33

Classification	No. of cases
Professional & Managerial	13
Clerical & Sales Occupation	4
Service Occupations	3
Processing Occupation	1
Machine Trades	3
Bench Work	2
Structural Work	2
Miscellaneous	2
Student	1
Unemployed	2

TABLE 3.—*Age*

Years	No. of cases
20–24	4
25–29	2
30–39	5
40–44	12
45–49	7
50–54	3

Range: 20–51 years
Mean : 39.4 years

TABLE 4.—*Height*

Inches	No. of cases
65–66	5
67–68	7
69–70	12
71–72	4
73–74	4
75–76	1

Range: 65½–75 inches
Mean : 70 inches

TABLE 5.—*Weight (Wearing Conventional Prosthesis)*

Pounds	No. of cases
130–139	3
140–149	8
150–159	6
160–169	3
170–179	1
180–189	6
190–200	1
200+	3

Range: 135–226 lb.
Mean : 163.6 lb.
Note: 2 cases without prostheses, 160 lb. and 185 lb.

TABLE 6.—*Education*

Years	No. of cases
5–6	1
7–8	1
9–10	3
11–12	17
13–14	4
15–16	4
17–18	2
19–20	1

Range: 5–19 years
Mean : 12.5 years

TABLE 7.—*Cause of Amputation*

Cause	No. of cases
Traumatic	27
Vascular	2
Tumor	3
Burns	1

TABLE 8.—*Side of Amputation*

Left	15
Right (1 bilateral)	19

TABLE 9.—*Years of Prothetic Wear (At Time of Selection)*

Years	No. of cases [a]
Less than 1 year	1
1–4	3
5–8	3
9–12	0
13–16	5
17–20	1
21–24	17
25–28	1

Range: 5 mo.–26 yr.
Mean : 16.6 yr.
[a] Does not include two subjects who had never worn prostheses.

TABLE 10.—*Getting About Without Prosthesis*

Technique	No. of cases
Wheelchair	2
Full crutches	8
Forearm crutches	7
Hopping	19

Note: Multiple responses were permitted.

TABLE 11.—*Routine Use of Cane*

No	30
Yes	1

Note: Does not include two subjects who had never worn prostheses.

TABLE 12.—*Use of Hand Rail on Stairs and Ramps*

Routinely, if available	19
Occasionally	8
Rarely or Never	4

Note: Does not include two subjects who had never worn prostheses.

TABLE 13.—*Terrain and Ground Most Usually Walked On*

Terrain	No. of cases
Flat	30
Hilly	3
Ground	
Paved	27
Rocky	3
Sandy	2
Muddy	2
Gravelly	7
G assy	17

Note: Multiple responses were permitted.

TABLE 14.—*Means of Transportation To and From Work*

Vehicle	No. of cases
Car	25
Pick-up truck	1
Bus	2
Train	[a] 1

[a] Drives car to station and takes train.

TABLE 15.—*Above-Knee Stump Length (% of Sound Thigh)*

Percent	No. of cases
10–19	1
20–29	0
30–39	2
40–49	4
50–59	5
60–69	8
70–79	4
80–89	6
90–99	2

Range: 18%–93%
Mean : 64%
Note: Bilateral—stump length 14 in. each.

All (31) of the amputees who had been wearing prostheses, at the time they entered the study, drove automobiles. Three of them including the bilateral above-knee amputee, who also was an above-elbow amputee, required driving aids.

The aids used were:

Left foot accelerator.
Hand dimmer switch.
Full hand controls (bilateral amputee).

ATTITUDES TOWARD PRESTUDY PROSTHESIS

Although the prestudy prostheses were generally considered to be satisfactory by both Clinic Teams and wearers, there were some areas of performance in which the amputees felt that the limbs were functionally limiting (Table 16).

The majority of amputees indicated that walking at different speeds and negotiating inclines were problem areas. As shown in Table 17 most of the prostheses had been worn for less than 4 years. A significant number of limbs had been worn for 5–8 years and, surprisingly, two had been worn for more than 17 years. The amputees' overall ratings of the prostheses are shown in Table 18 and Clinic Team ratings of socket fit and comfort in Table 19.

TABLE 16.—*Amputees' Opinions of Ability of Prestudy Prosthesis to Meet Certain Needs*

(N = 31 [a])

Activity	Yes	No
Walking at various speeds	10	21
Ascending stairs	20	11
Descending stairs	18	13
Ascending ramps and hills	15	16
Descending ramps and hills	12	19
Walking on various kinds of terrain	18	13

[a] Two subjects had not previously worn a prosthesis.

TABLE 17.—*Length of Wear of Prestudy Prosthesis*

(N = 31)

Years	No. of cases
Less than 1 year	3
1–4	16
5–8	9
9–12	1
13–16	0
17–20	1
21–24	1

Range: 5 months-21 years
Mean : 4.8 years

All of the selected amputees were full-time wearers. Knee buckling appeared to be a problem for seven of the subjects, including the bilateral amputee. Five of the seven stated that they fell frequently, one indicated that he experienced buckling "often in summer—seldom in winter," and another stated that he experienced knee buckling about 12 times a year.

TABLE 18.—*Overall Rating of Prestudy Prosthesis*
(N = 31)

Ratings	No. of cases
Excellent	2
Very Good	10
Good	14
Fair	5

TABLE 19.—*Socket Fit and Comfort*
(N = 31)

Excellent	3
Very Good	12
Good	6
Fair	7
Poor	3

For the remaining 24, who wore a prosthesis at the time of selection, knee buckling was an infrequent experience.

Three subjects felt that walking with a prosthesis required considerable effort. Fourteen of the wearers thought that effort requirements were moderate, and 14 felt that little effort was required.

FITTING PROCEDURES

Prosthetists were instructed to follow the text "Prosthetic Principles—Above Knee Amputations" by Anderson et al., published by the Charles C Thomas Co., Springfield, Illinois, 1960, for basic procedures and the Manual for the Henschke-Mauch "HYDRAULIK" Swing Control System for Above-Knee Prostheses published by Mauch Laboratories, Inc., October 1963, for instructions which were specific to the hydraulic unit and setup. Additional materials relating to adjustments were provided by the Project Director. The adjustable coupling, as required in the VA limb contract, was to be used in aligning the prosthesis. Selection of setup size was made by the office of the Project Director, based on measurements made by the Clinic Team and included on the selection form.

All prosthetists selected to participate in the study had been qualified to fit the Henschke-Mauch Model "B" system which utilized the same wooden setup. It was therefore assumed that prosthetists would not have any difficulty with the Model "A." This proved to be true except that two prosthetists cut the knee block off much too low, contrary to instructions, and thereby weakened the knee block beyond safe limits. One knee block was replaced, and the other was reinforced in the areas of greatest stress.

WEIGHT OF PROSTHESES

Variability in fabrication techniques, length of prosthesis, as well as selection of components other than the hydraulic components resulted in completed prostheses that were quite variable in weight. Each of the

experimental prostheses worn by the amputees was heavier than the prestudy limb. There was, of course, one exception: the subject who wore a Henschke-Mauch Model "B" system as a prestudy limb. In that case, only the hydraulic unit was exchanged, with, of course, no appreciable change in the weight of the prosthesis. The range of weight difference between the prestudy and test limbs was from 1 oz. to 4 lb. 4 oz. with an increase in the mean of 2 lb. 0 oz. Data on the weights of both conventional and experimental prostheses are shown in Table 20.

TABLE 20.—*Comparative Weights of Conventional and Hydraulic Prostheses*

Conventional Prosthesis (N = 32)
Range: 6 lb. 8 oz.—13 lb. Mean: 8 lb. 8 oz.
Henschke-Mauch Model "A" Prosthesis
Range: 8 lb. 4 oz.—13 lb. 14 oz. Mean: 10 lb. 8 oz.

Although all but one of the experimental limbs were heavier than the prestudy limbs, amputee perception of weight was frequently in disagreement with the figures. Table 21 summarizes the amputee estimate of the weight of the experimental prosthesis compared to the prestudy limbs when questioned at delivery of the new prosthesis, after 2 months of wear and after 6 months of wear.

TABLE 21.—*Perception of Weight of Experimental and Conventional Limbs*

Experimental limb thought to be:	Delivery	2 months' wear	6 months' wear
Heavier than conventional	14	15	10
Same as conventional	12	11	13
Lighter than conventional	4	4	7

The pattern appeared to remain the same during the first 2 months of wear. By the time, however, that the amputee had been wearing the prosthesis for 6 months, only one-third of the subjects indicated that they felt that the experimental prosthesis was heavier. These findings are similar to our experience in previous studies. The weight increase

in fitting a hydraulic limb seems to have little significance, being more than offset by the improvement in leg function provided by the hydraulic component. The variability in weight, particularly of the prestudy limbs, must be attributed chiefly to variability among prosthetists. It was assumed that the metal and plastic socket limbs would be among the lightest. The two metal socket limbs were among the lightest, weighing 6½ and 7½ lb.; however, not all the plastic limbs were lightweight. Two of the five limbs with plastic sockets weighed 10 lb., two were slightly under the mean at 8 lb. 6 oz., while one weighed 7 lb.

The patient who experienced the greatest increase in the weight of prosthesis from 6 lb. 8 oz. (conventional) to 10 lb. 12 oz. (experimental) indicated at time of delivery that both limbs seemed to be about the same weight, although the test prosthesis required more effort to use. The Clinic Team stated "There is considerable improvement in the gait on the experimental prosthesis." After 6 months of use the amputee indicated that it required less effort to use the test prosthesis than his prestudy limb. He also indicated that the new limb was less fatiguing and that he felt more like doing things. "I feel more like getting up and walking when necessary. It seems more stable. I descend stairs in a normal fashion now and can descend stairs faster with more security."

MAINTENANCE

One of the major objectives of this study was to gather data on maintenance requirements with a view toward aiding the developer to improve the product, if deficiencies were noted, and in general to determine if maintenance requirements were excessive. As a direct consequence of this study a number of design changes have been made and incorporated in the production model now being manufactured. These design changes are discussed later in this report.

Prosthetists were requested not to attempt any repairs to the hydraulic unit but were permitted to make repairs to the setup. Units were, therefore, sometimes returned to the VA Prosthetics Center and then to the manufacturer with minor complaints which could not always be verified. Some complaints of noise which could not initially be confirmed were substantiated by a later discovery by the manufacturer. This too will be discussed later.

Fifty Model "A" Swing and Stance Units were purchased for evaluation. Thirty-three subjects requiring 34 units were selected as test wearers. To gather as much information as possible on maintenance requirements a number of the units were put into service in other special projects, and some were retained as spare units for exchange purposes. Although the results of these special projects are not a part of this report, all data relating to maintenance are included. All fifty of the units were used for

cumulative periods of time from 1½ to 19½ months with an average length of service of 10¼ months. Twenty of the units were maintenance free for the entire study. Length of use for these 20 units ranged from 2 to 19½ months with a mean length of wear of 11 months. Minimum subject participation in the study was 167 days; maximum participation was 613 days (this patient had no problems with his unit during the study [19½ months of wear]).

Seven units were returned with complaints of "noise," some of which could not be verified while some could definitely be traced to the side straps. Unless installation and removal of systems from the setups are accomplished in a specified sequence of operations, there is a strong possibility of enlarging the holes in the straps, thereby inviting clicking noises. In addition, the lower attachment of the knee straps should not permit rotation on the attachment shaft. Cases have been noted where the prosthetist had deliberately loosened the fit of the straps at that attachment—in the mistaken belief that they should be free. A loose fit at this distal end results in noise. (Note: The production model of the Model "A" system has been redesigned to eliminate the side straps. See section of this report on Design Changes.)

One unit was returned after ½ month of wear because it was noted that the rubber boot on the piston rod had been damaged. The boot was replaced and the unit put back in service. It then performed without problems for 13 months. *Four* units were returned to the manufacturer before being issued to patients when inspection revealed functional problems.

The major cause for returning units to the manufacturer (16 of all returns) was due to an oil contamination problem resulting from an additive in the oil which reacted with the rubber parts and in addition had an adverse effect on the metal parts. This resulted in intermittent failure of the stance-control function. The type of oil used in the system and the composition of the rubber parts have since been changed. These changes appear to have eliminated the problem of intermittent loss of stance-phase control.

The last *two* units were returned due to low oil level. Several units were returned to the manufacturer during the study due to air entering the system (none was initially returned because of this problem). This entry of air was the result of a combination of circumstances and was known to be possible. Its actual occurrence under field conditions in four cases prompted the developer to install a foam insert in the accumulator piston to act as an oil retaining sponge and thereby reduce the possibility of air contained in the system in the space above the reserve oil level entering the system proper.

The problem of a squeaking noise was traced to the small lower "U" cup contacting the unpolished surface of the lower half of the piston rod. This problem has been remedied by polishing the entire length of the piston rod. Finally a clicking noise (not caused by the side straps) was eliminated by introducing a thin nylon washer between the large Belleville spring and the upper surface of the dashpot.

One patient rejected the Henschke-Mauch system completely, complaining of excessive resistance to motion at the knee. Since it was felt that this might have been a maintenance problem, we requested that the entire prosthesis be sent in for examination. Our findings, which are summarized below, indicate that the prosthetist did not follow the instructions in the installation manual.

Friction between the knee block and the inside of the shank attachment straps prevented the knee block from swinging freely with respect to the shank with the knee bolt installed and the screw tightened without the hydraulic unit installed. Excessive amounts of plastic laminate indicated that the hole saw provided in the installation kit had not been used to remove the laminate from the sides of the knee block. The mechanical friction resulting from this tight fit kept the stance control from working properly. In addition, the top holes in the side straps had been *filed* resulting in excess clearance between knee bolt and straps which could cause noises during swing.

Although we were able to examine the above prosthesis and determine the cause of the "excessive resistance," the amputee had already completely rejected the limb (for reasons which cannot reasonably be attributed to the hydraulic system). One wonders how many other amputees who complain of excessive resistance in a hydraulic system have prostheses which are too stiff because of this same type of fabrication error.

AMPUTEE OPINIONS

Twenty-eight of the 33 subjects testing the system elected to continue wearing the device at the conclusion of the study.

Of the five who rejected the Henschke-Mauch Model "A" system: one returned to his prestudy Henschke-Mauch Model "B" system, one was transferred to a Henschke-Mauch Model "B" system, and the other three returned to the use of conventional limbs.

After a review of the data, it is our opinion that four of the five rejections might have been prevented had the project staff intervened by visiting the Clinic Teams involved. We believe that three of the five rejections were the result of prosthetist error (two were fitted by the same facility), a fourth because of insufficient knowledge on the part of Clinic Team members of system function and training implications, while the fifth was due to faulty selection of subject.

One case in the first category in the section on maintenance has already been discussed. Some extracts from repair invoices submitted to the local station by the prosthetist in another case should indicate the improper actions taken by the facility.

"Brass shim stock installed recently worked itself out of piston rod pin nyliner bearing. Replaced them and . . . we flanged shim stock similar to nyliner bearing flange. Increased shim stock length on medial knee bolt nyliner."

"Removed unit, removed knee adjusting screw from cylinder bolt and from shin attachment."

On the invoice describing exchange of units, ". . . and replaced with updated Model "A" unit *rebond onto side straps* . . . ."

None of the above "service" should ever be attempted by a prosthetist, since in each case system function was probably impaired. This patient returned to his Henschke-Mauch Model "B" system which was quieter in operation.

Another patient fitted by the same shop rejected the Model "A" because it was "very stiff and noisy." He was also dissatisfied with the socket fit, the weight of the prosthesis (13 lb. 14 oz., the heaviest in our sample, as compared with 9 lb. 15 oz. for his prestudy limb), and "to a lack of control." This patient had been shifted to a quadrilateral socket after 20 years on one plug-fit socket. There were also indications that the prosthesis was poorly aligned.

The fourth subject who rejected the Model "A" was given a Model "B" system. This was done because his comments indicated that he liked the swing-phase function but indicated that he "simply does not use stairs and inclined planes enough." He found it difficult to get in and out of a car and, therefore, kept the unit set in swing-phase control mode only. In this case, we believe that the patient did not understand how the stance-phase control benefited him in level walking. He could have been instructed in car entry and exit so as to overcome the stance-phase stability.

The fifth wearer rejecting the system had a very short stump (4½ in.) and had been wearing a prosthesis with a plug-fit metal-saucer-type socket, pelvic belt, metal knee, and metal shank with a wood foot. The entire prosthesis weighed 7½ lb. The experimental socket was to be a modified plastic quadrilateral type. However, it was found necessary to make the socket somewhat saucer shaped. The completed prosthesis weighed 11 lb. The patient experienced considerable difficulty with the socket and the weight of the prosthesis. He stated that the socket kept him "raw." It was necessary to go to the use of a shoulder harness suspension because of the difficulty in maintaining fit. The limb was "less comfortable, more tiring, and harder to use" than his old limb. According to the Clinic

Team all attempts on their part to get this patient to wear something other than a metal socket always met with failure. He had a history of falling a great deal even with the all-metal limbs and it was decided to try a new approach with the Henschke-Mauch Model "A" which they thought might be helpful. "Apparently our [Clinic Team] selection in this case was an error; however, we do feel that the hydraulic system did increase his function. Suspension, weight, socket discomfort are the main reasons for this failure." The team felt that the subject did like the unit's function and they were sure that had he had a longer stump he would have been a successful wearer.

Comparing amputee reactions to the Henschke-Mauch Model "A" system with amputee reactions to other hydraulic systems, we see a very similar pattern as regards hydraulic control of swing. Most patients felt that ability to vary overall walking speed was improved. Less fatigue and less effort to use the prosthesis were commented on by the wearers. Activity level was increased for more than ⅓ of the cases. Four of the subjects resumed activities that they had given up with their previous limbs. Trout fishing, wearing waders, was resumed by one amputee by placing the unit in the lock position. Another resumed step-over-step stair descent. Golf and bowling could again be undertaken by a third, and dancing and badminton by the fourth.

Of particular interest are some of the reactions of the bilateral amputee fitted with this device. This individual, as noted earlier, was also an above-elbow amputee. He was 26 years old, weighed 142 lb., and with his prostheses was 5 ft. 5 in. tall. He suffered traumatic loss of his limbs in 1959 and had worn prostheses for 7 years at the time he entered the study. As a result of wearing the experimental device his activity level increased significantly. He was able to work 35 hours a week and experienced less time lost from work. The test limbs seemed lighter than his previous limbs (though actually heavier). Although they appeared to require more effort to use, he was no more fatigued by these limbs than with his previous limbs. He stated that his gait had been improved, and that he was able to walk at different speeds. Control had been improved, and these limbs aided him in ascending and descending stairs and ramps. He found snow a problem, but not as much as anticipated by using short steps on snow. His standing balance was improved, and although he still used a Canadian crutch he hoped to go without support.

Negative reactions were few and did not seem to fall into any pattern except that 10 of the wearers indicated that the experimental prosthesis felt heavier than their conventional limb (it was in fact heavier). Six of these amputees felt that the Henschke-Mauch Model "A" system required more effort, and seven were more fatigued than with their prestudy limbs. Since these reflected significantly higher percentages of negative comments

in these areas than was found during the study of the Henschke-Mauch Model "B" system, a closer look at the eight cases involved was indicated. As already mentioned, the bilateral amputee noted increased effort but not increased fatigue. Three of the cases involved were among those who rejected the limb. Three others had what appeared to be very stable alignment which would result in additional effort at toe-off. Nothing significant was noted in our records on the eighth case.

CLINIC TEAM REACTIONS

In addition to eliciting amputee opinions concerning the test unit, the Clinic Teams' opinions of the Henschke-Mauch Model "A" system were solicited. Except in the cases of two patients, clinical personnel indicated that the test unit provided functional benefits to the wearers. Benefits included improved gait, smoother cadence, ability to descend stairs in a step-over-step manner, increased stability, reduced number of falls, less fatigue, and increased level of activity. One team reported that a subject was able to run again. Twenty-four of the subjects who had previous experience with prostheses were rated as being able to sustain a greater speed while walking 100 ft. than previously possible. Twenty-eight wearers were rated as having a more graceful gait.

Earlier in this report, one case who rejected the system for a number of reasons, including a short stump, was discussed. A few comments made by the same Clinic Team on another patient who had a 2 in. stump are of interest. "Clinic Team feels that this unit has improved this patient's gait considerably. This is very pleasing, as we had doubts regarding this man being a successful user in the early stages of the study. Extremely short stump, suspension problems, and excessive stability made success seem doubtful. He now likes the prosthesis, and function has been increased by its use. . . . It seems obvious that much care must be taken in the alignment so that the limb is not too stable. Too much stability seems to decrease the effectiveness of the unit." Apparently, of greater significance than length of stump are factors such as experience with very lightweight limbs, and previous use of little or no swing-phase resistance.

DESIGN CHANGES

The production model based upon the Henschke-Mauch HYDRAULIK Swing-and-Stance Control Unit, Model "A," reflects a number of changes from the design which we used at the inception of this study. A number of the changes were incorporated in the unit as the study progressed. All of those changes were in the internal workings of the system and were therefore not apparent to the personnel involved in the study. All of the units worn at the end of the study by the test wearers incorporated most,

and, in some cases, all of the internal changes. In addition, a number of external changes have now been made (and checked on amputees not involved in the Clinical Application Study).

All of these changes are summarized here:

A. General Changes

1. The production model has been renamed as the Henschke-Mauch HYDRAULIK Model S-N-S (SWING-N-STANCE) (Fig. 3).

FIGURE 3.—Henschke-Mauch HYDRAULIK Model S–N–S (SWING–N–STANCE).

B. External Changes

1. The plywood knee block has been discontinued and replaced by a more conventional knee block that has been reinforced to accept the hydraulic unit.
2. The two straps on the sides of the unit have been eliminated permitting a more cosmetic shank and eliminating a possible source of clicks. Laminating, rather than riveting, the side straps to the shank provided the necessary strength.
3. Attachment of the piston rod pin now is 1⅛ in. directly behind the knee bolt instead of above and behind the bolt. As a result

of this change in geometry, weight-bearing resistance begins to decrease significantly after 30 deg. of knee flexion instead of after 60 deg. as was previously the case.

4. The fully extended length of the hydraulic unit has been reduced by 1 in. (½ in. off the piston rod, ½ in. off the cylinder).
5. The distal attachment to the shank and the shank itself have been changed as follows:
   a. pin through side walls instead of anterior-posterior screw
   b. attachment point ½ in. higher on the shank
   c. anterior-posterior adjustment shifted to knee
   d. because of a, b, and c, shank is slimmer and more cosmetic
6. Initial knee flexion-extension adjustment in full extension formerly made by means of a screw on the anterior aspect of the shank, is now made by means of eccentric insert bushings of phenolic and installed at the upper attachment of the hydraulic unit in the knee block.
7. The upper and lower attachment bolts are made of ⅜ in. LaSalle "Stressproof" steel.

C. Internal Changes

1. Oil used in the system has been changed. Stoddard solvent (used for a time to reduce viscosity and hence allow lower minimum swing-phase resistance) had a detrimental effect on parts within the system. Deposits formed were causing intermittent failure of the stance-phase control.
2. The rubber compound used in making all internal rubber parts was changed to make it more resistant to attack by oil.
3. A new design accumulator piston includes a polyurethane open cell foam element which will tend to prevent air from entering the system proper even if the hydraulic system were manipulated in an upside-down position.
4. The high turning resistance of the adjustment cap will be reduced by stricter concentricity tolerances for the parts involved. Additional clearance will be provided between the underside of the adjustment cap and the upper cylinder rim.
5. The small lower "U" cup in contact with the unpolished surface of the lower half of the piston rod was found to be contributing to a squeaking noise. This problem has been corrected by polishing the entire length of the piston rod.
6. Installation of a thin (.008 in.) nylon washer between the large Belleville spring and the upper surface of the dashpot eliminated a clicking noise caused there sometimes by corrosion.

TRAINING

In accordance with the study protocol, each amputee fitted with the Henschke-Mauch Swing and Stance Control System was to receive training in its use. For a variety of reasons beyond the control of the participating stations, five subjects, four of them from one station, never received any training. All the others received training ranging from 1 to 33 hours, with an average of 6 hours of training. The 21-year-old Viet-Nam veteran, one of the two amputees who had never worn a prosthesis before the study, received 6 hours of training; the other, a 45-year-old World War II veteran, received 33 hours of training. Because of the problem of fatigue, relating to circulation in his other leg, the Viet-Nam veteran was unable to progress past ambulation with a cane during the period of our evaluation. He did, according to the Clinic Team, ambulate well with the cane. The World War II veteran experienced considerable difficulty learning to articulate the knee. We attribute this to the fact that his training was only on an outpatient basis and unfortunately was spread over a long period of time. He used the prosthesis between training sessions and because he was working did not devote time to practicing proper walking patterns. We believe that had his training been performed intensively as an inpatient, he would have required less training. On the other hand, the Viet-Nam veteran received his treatment while an inpatient. That fact, coupled with his youth and the characteristics of the test system, contributed to the minimal training required in his case.

Obviously, since only two cases were new prosthetics users, we can only speculate, but we believe that new amputees fitted with the test system will require less training to achieve good gait than amputees who have worn prostheses without stance-phase control. We also believe that higher levels of achievement are possible with the Henschke-Mauch Model "A" system than with any other knee mechanism. Factors such as age, motivation, neuromuscular coordination, general health, etc. will, of course, influence results with this system as they will with any prosthesis. What makes training essential is the stance-phase control function. Without training the amputee will not derive the benefits possible on stair descent and ramp travel. Similarly, without training the amputee will experience problems negotiating rough terrain, car entry and exit, as well as sitting down. None of these situations presents any difficulty if the patient is trained to take advantage of the stance characteristics of the unit. Complaints of excessive effort to use the prosthesis can frequently be traced to either needlessly stable alignment or improper walking technique. Problems in training should be few; any which do occur will probably result from the habit patterns of years with conventional prosthetic knees.

The importance of proper training in aiding the amputee to derive maximum functional benefits from the test system may be gathered from a brief discussion of stair descent techniques. An amputee wearing the Henschke-Mauch Model "A" system may descend stairs one step at a time or may use the jackknife technique as can amputees wearing other types of knee mechanisms. He may, however, go down stairs in a step-over-step manner using a controlled weight-bearing technique. In order to take advantage of this technique, the amputee is taught to begin flexion at the hip at the time he begins to bear weight on the prosthetic foot. Were he wearing a more conventional knee mechanism, he would have done the opposite (strong extension at the hip) at that instant. Hip flexion, on a conventional prosthesis, would have resulted in uncontrolled knee flexion, ending in a fall. Thus, to achieve stair descent utilizing the stance-phase control of the Henschke-Mauch Model "A" the amputee must accept a pattern of action which, in the past, with another knee mechanism, would have resulted in a fall. Without training by a competent instructor and a willingness by the amputee to try, it is unlikely that this different stair descent pattern would be learned or even attempted.

Well coordinated amputees have been taught to walk (for demonstration only) keeping the prosthetic and sound knees bent at all times during weight bearing. They have also been taught to jump, landing on the prosthesis with the prosthetic knee bent. Only with training can maximum potential of the Henschke-Mauch Model "A" be derived by some amputees; with training most amputees can obtain significant improvements in performance.

SUMMARY

Twelve VA stations having Orthopedic and Prosthetic Appliance Clinic Teams, 25 prosthetic facilities, and 33 male veterans with service-connected amputations above the knee were selected to evaluate the Henschke-Mauch HYDRAULIK Swing and Stance Control System Model "A." Two of the amputees were new amputees without experience on artificial legs, and one amputee was a bilateral above-knee case who also had an above-elbow amputation. The objective findings, the opinions of the test wearers, and the evaluations of Clinic Teams were used to aid in a determination of the acceptability and desirability of issuing this device to veteran beneficiaries.

The system was well received by the majority of amputees and all of the Clinic Teams. Five of the test wearers rejected the system for reasons which we believe were not attributable to the hydraulic system but were related to lack of attention to the installation instructions which had been provided to the prosthetists. Appropriate alignment and adequate

training were found to reduce the effort required to use the prosthesis and to permit derivation of maximum benefit from its advanced features during both swing and stance phase.

Except for the problem resulting from the effects on the rubber and metal parts of the oil additive formerly used (a problem now corrected), the Henschke-Mauch Model "A" system has been demonstrated to be reliable and to require little maintenance. With the changes in oil and in rubber parts, the system should prove to be one of the most dependable of the fluid-controlled systems available to the above-knee amputee.

As a direct consequence of the study, major changes have been made in the setup, the unit, and the attachment of the unit to the setup. The new model will be known as Henschke-Mauch S-N-S (Swing-N-Stance).

RECOMMENDATIONS

The Henschke-Mauch HYDRAULIK Swing-and-Stance Control Unit Model "A" was found to be a highly reliable system offering significant advantages to selected above-knee amputees. When the unit has been installed properly, according to the manufacturer's instructions and with training provided by a knowledgeable therapist, amputees should experience improved performance and increased protection against loss of knee control.

We recommend that this device (now the Henschke-Mauch Model S-N-S) be made available on a prescription basis to eligible veteran beneficiaries.

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