CLINICAL APPLICATION STUDY OF EXTERNALLY POWERED UPPER-LIMB PROSTHETICS SYSTEMS: THE VA ELBOW, THE VA HAND, AND THE VA/NU MYOELECTRIC HAND SYSTEMS

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INTRODUCTION

The major thrust of the Artificial Limb Research Program in the United States after World War II and continuing into the 1950's was in the area of conventional upper-limb prosthetics. The development of externally powered limbs began some 30 years ago. Many improved devices and techniques resulted from intensified research efforts; examples of early devices are the Vaduz Hand (now the French Electric Hand) and the Alderson-IBM Electric Arm. Since then, however, body-powered elbows and terminal devices have not changed significantly, and they remain the prescription of choice outside of research settings.

During the past 5 years, research in the field of upper-limb prosthetics has concentrated on the development of externally powered elbows and hands. Several externally powered devices are now under development in the United States, Canada, Europe, and

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Asia. Criteria guiding the development of externally powered components have been simplicity, economy, function, cosmesis, and minimal maintenance.

In contrast to European countries, few electric units have been prescribed in the United States. The majority of prosthetic devices in the United States are fabricated by private commercial facilities in a decentralized system which requires each limb facility to be fully informed on the nature and application of each device. In Europe, however, the distribution of prosthetic devices and the followup of patients is far more centralized.

At the beginning of this Study in 1970 the real value of externally powered components was not clear. The main purpose of this Study has been to determine whether externally powered components offer a significant contribution to the needs of the upper-limb amputee, or whether they represent novelties which duplicate the functions of conventional mechanical components.

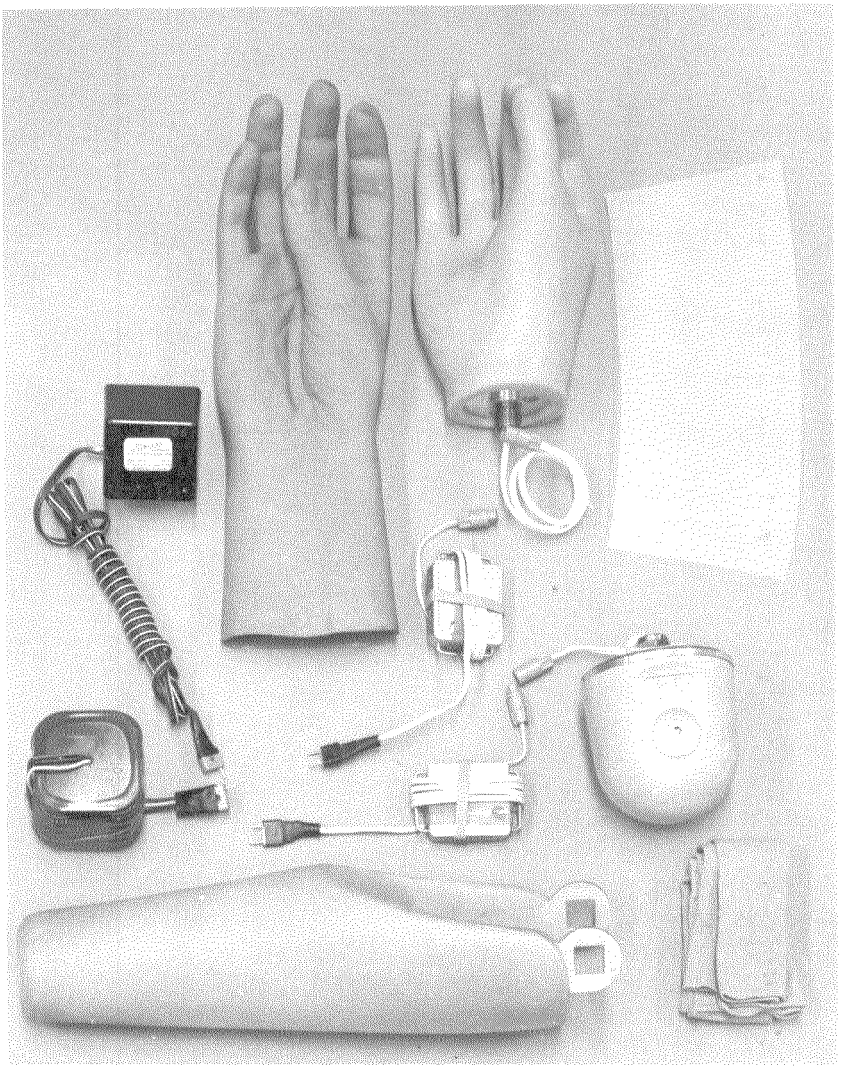
The Veterans Administration Prosthetics Center in New York City has researched and advanced the development of an electric elbow, an electric hand, a control system utilizing a pull switch, and, in conjunction with the VA-supported research project at Northwestern University, a myoelectric hand control system for below-elbow amputees. When this Study began, the components within these devices represented the most simple, economical, and functional electric units available. To investigate their clinical usefulness, the Research and Development Division, Prosthetic and Sensory Aids Service, of the Veterans Administration, was authorized to perform a Clinical Application Study of Externally Powered Upper-Limb Prostheses, using these components (1). The areas analyzed in this Study follow:

a. Prescription indications and contraindications
b. Advantages, functional utility, and overall acceptability, as compared with conventional components
c. Fitting and harnessing procedures
d. Training considerations
e. Installation and adjustments
f. Maintenance and repair
g. Implications for prosthetics education and information programs
h. Directions for future research

DESCRIPTION AND FUNCTION OF SYSTEMS

The VA Switch-Controlled Elbow

The VA Electric Elbow (Fig. 1) is essentially the same size and



VA HAND-ELBOW SWITCH SYSTEM

FIGURE 1

weight as the conventional Hosmer E-400 elbow (2). The permanent magnet electric motor, operated from a 25-V battery pack, is coupled directly to a planetary roller harmonic drive wave generator. The wave generator forces the flexible spline of the harmonic drive to

engage the rigid spline of the elbow housing. A square output tang, fixed to the flexspline, engages a square hole in the forearm saddle; as the flexspline rotates, the forearm moves. The rigid spline acts as a reaction point in the gear reduction process. The high motor speed (11,000 rpm) is reduced approximately 12:1 by the planetary wave generator, with the harmonic drive achieving a ratio of 80:1. The limits of flexion and extension are controlled by two limit switches consisting of two microswitches and four diodes. Attempts to extend or flex the elbow beyond these limit points activate the microswitches, and the power is shut down (3). These individual components of the VA Elbow are shown in Figure 1.

A soft foam endoskeletal forearm to be used with the powered elbow was introduced in December 1971. This forearm claims to be lighter and more cosmetic, puts less load on the elbow, and may reduce damage to clothing and furniture. It may be used only by amputees with short to mid-length stumps. In cases where amputees have long above-elbow stumps, it is necessary to place the battery pack in the forearm section. Since the soft forearm does not make provision for battery-pack placement within the forearm shell, those amputees with long above-elbow stumps are limited to the use of the conventional, hard crustacean-type forearm.

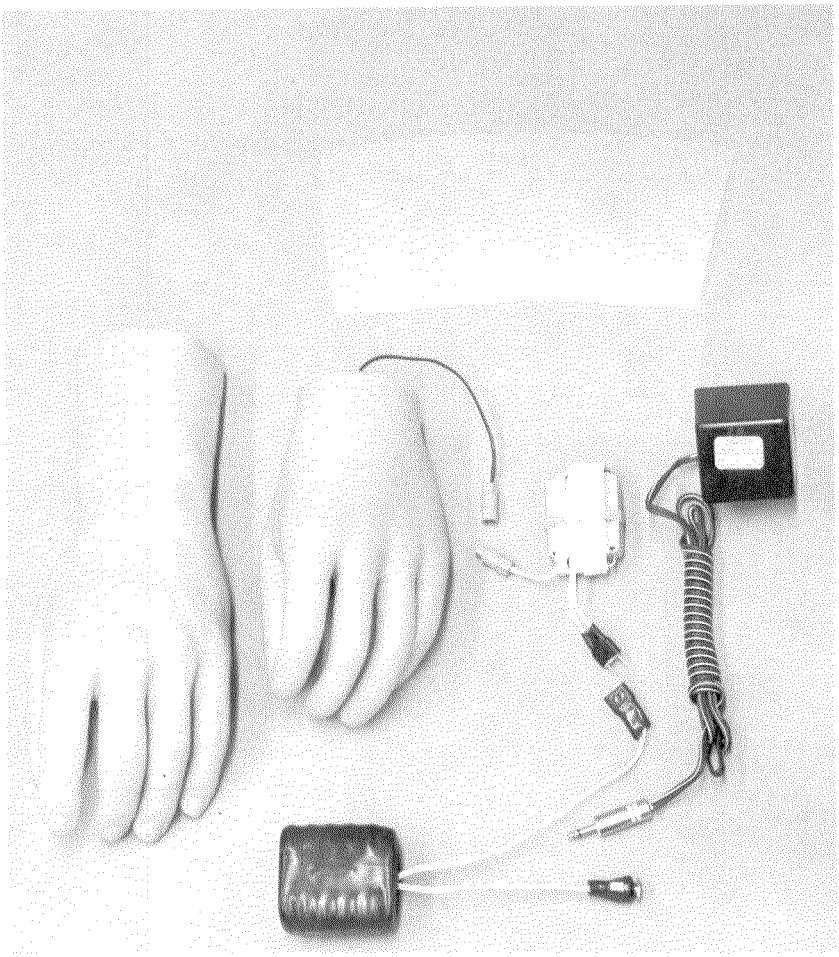
The VA Switch-Controlled Hand

The VA Hand (Fig. 2) is the same size and shape as the Viennatone and the Otto Bock hands. The hand consists of a skeletal framework covered by a PVC shell and a cosmetic glove. A special feature of the hand, introduced by the VA, is its safety breakaway that permits the fingers to open mechanically when subjected to a load of greater than 40 lb, as in the case of a wearer inadvertently grasping a handle on a moving vehicle. The small, efficient motor and the special-drive, four-stage gear arrangement are compatible with the VA Electric Elbow.

The power pack for the hand consists of a rechargeable 12-V battery pack, which is placed in the distal forearm section of the prosthesis. If the hand is used with the powered elbow (above-elbow amputee), it operates from the same 25-V battery pack that is used for the elbow, using a tap to provide the necessary voltage.

The VA Switch-Controlled System

Both the VA Elbow and the VA Hand are controlled by means of a five-position pull switch. For the above-elbow patient the elbow switch is usually placed in the front support strap of the Figure-8 harness and is controlled by shoulder extension. The switch may also be operated by chest expansion or from a waist strap. For the below-



VA HAND SWITCH SYSTEM

FIGURE 2

elbow amputee using the VA Hand, the switch is usually placed in a "butterfly" harness that fits loosely around the axilla. If an above-elbow amputee is fitted with *both* the VA Elbow and the VA Hand, two switches are necessary. The placement of these switches can vary, but they are usually placed as follows: The hand switch is placed in the control attachment strap (CAS) and the elbow-switch is placed in the front support strap (FSS) of the above-elbow Figure-8 harness. The switches *may* be placed in series in the CAS; varying tension by the amount of rubberbands on each switch will differentiate function. However, this configuration is not recom-

OPERATION OF VAPC SWITCH
(H A N D)

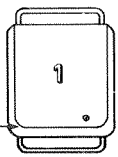
Switch Position		Function
1. Normal rest position, amputee relaxed, no tension on switch.		1. Hand remains locked.
2. First active position requiring 1/16 inch of excursion. This position must be maintained by amputee. If he relaxes, the switch will return to position No. 1.		2. Hand closes continuously while switch is in this position.
3. Neutral position requiring 1/16 inch of additional excursion.		3. Hand stops closing and locks.
4. Second active position reached by additional excursion of 1/16 inch.		4. Hand opens while in this position.
5. Neutral position requiring another 1/16 inch of excursion. End point is a stop which transmits force to control cable.		5. Hand stops opening and locks.

FIGURE 3

mended for the above-elbow amputee with both a powered terminal device and a powered elbow, because it increases the force and excursion necessary to operate the terminal device.

The switches operate by means of two actuators with a dead zone on either end of the excursion and in the middle zone. The first motion produced should be elbow extension or, in the hand, closing; the second motion would then be elbow flexion, or hand opening. The switch positions are demonstrated in Figures 3 and 4.

The VA/NU Myoelectric Hand System

The hand used in the VA/NU Myoelectric System (Fig. 5) is essentially similar in structure to the VA Switch-Controlled Hand.

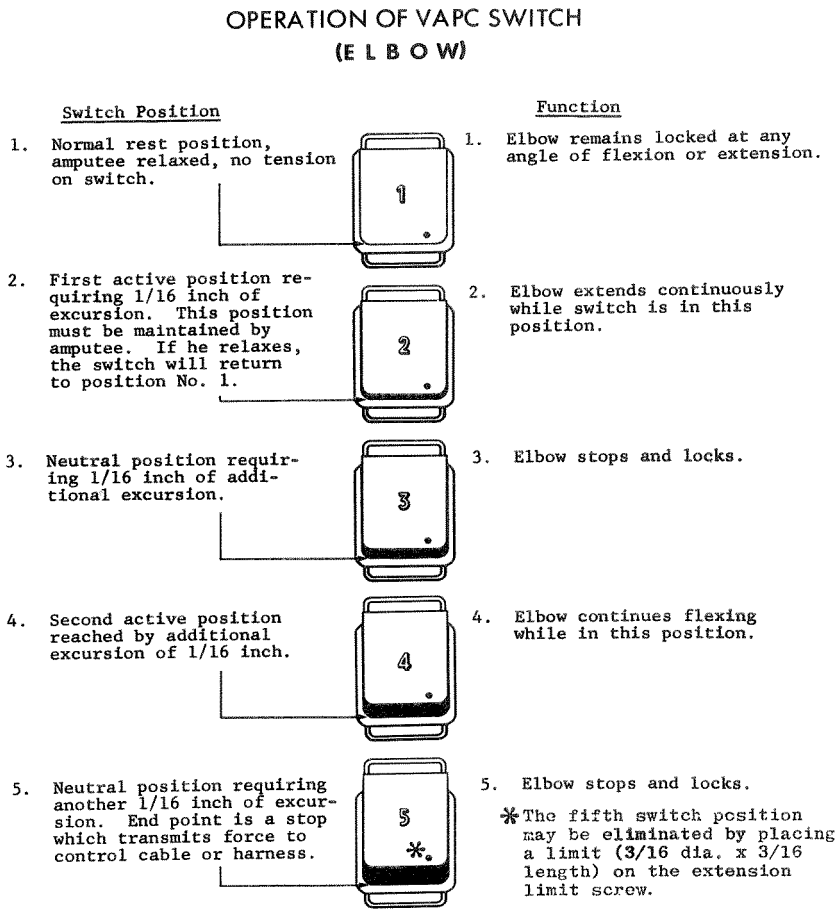


FIGURE 4

The end plate of the hand has been reduced in diameter to fit the wrist unit, which contains the EMG amplifier, the leads, and the 12-V battery pack. Operation of the hand is controlled by the detection and amplification of the electrical activity of two stump muscle groups (in this case, the flexors and extensors of the "wrist" and the "hand"). These myoelectric signals are sensed by two stainless steel button electrodes that are connected to the input stage of the amplifier by internal leads. The signals are then amplified and are transmitted through the output stage of the amplifier to actuate the motor. The degree of muscle contraction produces proportional myoelectric signals and thus proportional hand-speed control. The hand is inactive when the muscles are relaxed.

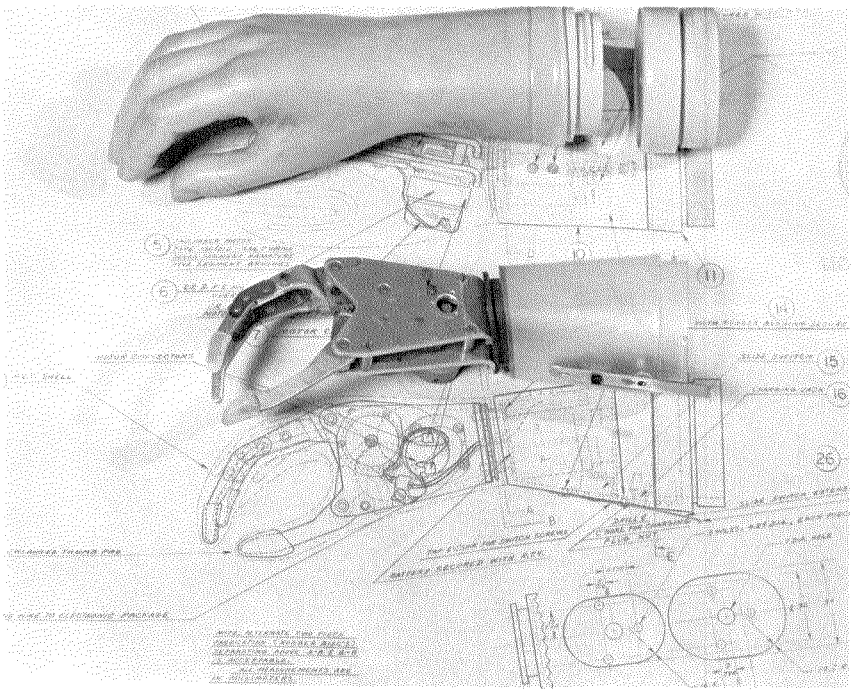


FIGURE 5.—The VA/NU Myoelectric Hand System.

The VA/NU Myoelectric System utilizes the Northwestern University self-contained, self-suspended supracondylar socket (Fig. 6) which requires no harnessing. For more detailed information, see Reference 2.

DESIGN OF STUDY

This project was designed to apply the experimental devices in clinical settings, with a minimum of direct guidance and supervision by the office of the Project Director over the field personnel participating in the Study.

Originally, the intent was to provide all Study participants with a basic knowledge of the concepts and mechanics of the experimental components involved by means of the Orientation Course in Upper-Extremity Powered Components, held at the Northwestern University Prosthetic-Orthotic Center and at the Sheraton-Chicago Hotel, Chicago, Illinois, April 5-9, 1971. Participants were provided with instruction and fitting manuals, test forms, and specialized equipment including a Myo-Indicator, a Volt-Ohm-Milliammeter, and a repair kit. The office of the Project Director was to receive, record,

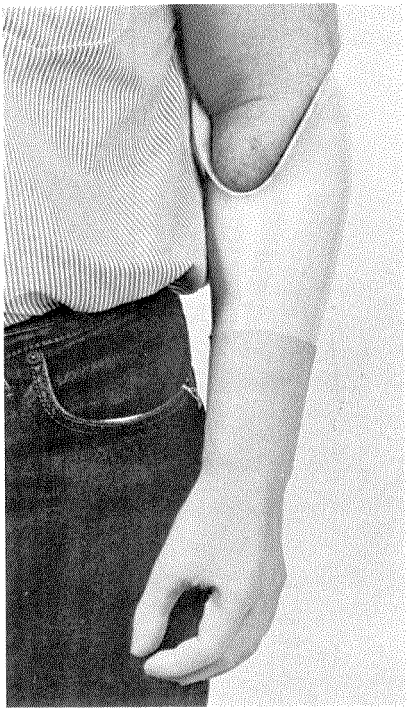


FIGURE 6.—VA/NU Myoelectric Self-Suspended Supracondylar Socket.

and evaluate data submitted by the field on the experiences of the amputees fitted with the various externally powered components. However, during the course of the Study, it was found necessary to visit six Clinic Teams for assistance with the selection of subjects. In addition, the telephone was used heavily in calling subjects to assist with complex problems and to answer many questions, because of the relatively unfamiliar concept of external power.

The design of the Study consisted of "before" and "after" evaluations. A detailed evaluation was made of each subject's medical and prosthetic history and of his performance with his conventional body-powered prosthesis. After the subject was fitted with a new prosthesis incorporating the experimental units, a thorough checkout was performed by the Clinic Team. After training and delivery, the veteran was scheduled for evaluation of his performance and reactions twice during the first month (after 15-day intervals). A final evaluation was conducted 3 months after delivery. During the intervening months, problems were reported to the office of the Project Director and necessary action was taken.

Patients who were prescribed the externally powered hand (either myoelectric or switch-controlled) were selected on the basis of previous experience with a prosthetic mechanical hand in order to

avoid bias due to comparisons of hook and hand functions, irrespective of power sources. Except for this selection factor, no attempt was made to recruit any set classes of amputee performers.

It must be emphasized that none of the prosthetists nor any other members of the Clinic Team had any significant experience with externally powered components prior to participating in the Study. This Study, therefore, was both educational and evaluative.

Participating Study Teams

Eighteen Clinic Teams (including two at Army hospitals and the Prosthetic-Orthotic Center at Northwestern University) were selected for participation in the Study. Fitting and fabrication of the prostheses incorporating the VA Elbow, the VA Hand, the VA Elbow/Hand, and the VA/NU Myoelectric Hand Systems were performed by prosthetics facilities which met the following requirements:

1. "Have a prosthetist who has satisfactorily completed either one of the upper-limb prosthetics orientation courses in fitting the externally powered elbows and hands, conducted by the Veterans Administration and Northwestern University at Northwestern University, on April 5-9, 1971, and December 4-17, 1971, respectively.
2. 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.
3. Have an interest in research activities.
4. Have an approved VA contract covering upper-limb prostheses.
5. Agree to study and to follow the prescribed installation and maintenance instructions.
6. Agree to make only authorized adjustments on the unit, and to report all repairs and adjustments.
7. Agree to provide prosthetic service in accordance with the price structure established specifically for this Study."

The participating teams, including representatives from the commercial facilities cooperating in this Study, all attended one of the orientation courses and are shown in Table 1.

Selection of Amputee Subjects

Eighty-four amputees were fitted with new prostheses incorporating the various externally powered components. The following qualifications were to be met by each subject selected by the Clinic Team for participation in the Study:

1. Below-Elbow. For both switch-controlled and myoelectric hands, the amputee

   a. "must have a stump at least 2½ in. shorter than the medial epicondyle to the ulnar styloid measurement on the sound side;

TABLE 1.—*Participating Clinic Teams and Prosthetics Facilities*

Clinic Teams[a]	Prosthetics Facilities	Eligible Prosthetists	No. of Cases
VAH, Atlanta, Ga.	Atlanta Artificial Limb Co.	H. Grant Rice	1
	Georgia Prosthetics	J. Alex McKnown	1
	J. E. Hanger, Inc., of Georgia	Mark Phelps	3
VAOPC, Boston, Mass.	Anthony & Williams, Inc.	Theodore Williams	0
	Boston Artificial Limb Co., Inc.	William Rogers	1
	J. E. Hanger, Inc., of New England	Samuel Polsky	1
	Massachusetts Limb & Brace Co., Inc.	Rene Robillard	1
	Starkey Artificial Limb Co., Inc.	Joseph Martino	1
VAH, Chicago, Ill.	Bardach-Schoene Co., Inc.	Harold Schoene	0
	Greher-Jouett, Inc.	William W. Schumann	0
	J. E. Hanger, Inc. of Illinois	Edward Roman II	0
	Koeber's Artificial Limb Co.	Joseph Smerko	1
	Merrick-Hopkins Co., Inc.	Edward Valestin	2
	Scheck & Siress Prosthetics, Inc.	John Seibt	1
	Universal Artificial Limb Co.	Stephen Kramer	4
VAH, Cleveland, Ohio	Paul Leimkuehler, Inc.	Paul Leimkuehler Jon Leimkuehler	6
	Shamp Prosthetic Center, Inc.	George A. Gorman	4
	Youngstown Limb Co., Inc.	Theodore Pirtea	0
VAH, Dallas, Texas	Currell Artificial Limb Co.	Ian J. Currell	1
	J. E. Hanger, Inc., of Texas	Robert F. Reich	2
	John E. Daggs		

TABLE 1.—*Participating Clinic Teams and Prosthetics Facilities*

Clinic Teams[a]	Prosthetics Facilities	Eligible Prosthetics	No. of Cases
VAH, Denver, Colo.	Gaines Orthopedic Appliance Co.	Lawrence Jones	1
	Scott-Thorton Orthopedics, Inc.	Arnold Lund	1
	Western Orthopedic Appliances, Inc.	Norman Effinger	1
Fitzsimons Army Hospital	Fitzsimons Orthopedic Appliance Facility	Sfc. Robert G. Schlesier	2
	Scott-Thornton Orthopedics, Inc.	Arnold A. Lund	1
	Western Orthopedic Appliances, Inc.	Norm Effinger	1
VAH, Houston, Texas	Muilenburg Prosthetics, Inc.	William Brunner	2
VAH, Los Angeles, Calif. (Wadsworth)	Adept Prosthetics	Jesus G. Nunez	1
	Alpha Orthopedic Appliance Co.	Woodrow T. Yamaka	3
	Harry Campbell Prosthetics	Harry Campbell	3
	Karg Prosthetics	Ferdinand J. Karg	3
VAH, Miami, Fla.	J. E. Hanger, Inc., of Florida	Hugh Panton	3
	Reid Brace Service	Robert Reid	3
VAH, Nashville, Tenn.	J. E. Dillard Co.	John E. Dillard	1
	Snell's Artificial Limb Co.	L. D. Lane, Jr.	3
Northwestern University	NU Prosthetic-Orthotic Center	John N. Billock	1
VAOPC, Philadelphia, Pa.	Frank J. Malone & Sons, Inc.	Frank J. Malone, Jr.	1
	J. E. Hanger of Philadelphia, Inc.	Charles Wright	2
	Modern Limb & Brace Co.	Edward J. Sulima, Jr.	3
	Nu-Way Limb & Brace Inc.	Blondell Smith	0

VAH, San Francisco, Calif.	California Orthopedics	Walter Willis	0
	Laurence's Orthopedic Appliance Co., Inc.	Matthew Laurence	0
	Robin-Aids, Inc.	George B. Robinson	1
	VAH Prosthetic Laboratory	Leigh Wilson	2
VAH, Seattle, Wash.	American Artificial Limb Co.	Joseph Zettl	2
	Dodge & Lundquist	Morris Dodge	2
	Lundberg's, Inc.	Harold Allen	1
	Tacoma Brace & Limb Co.	Loren Ceder	2
VAH, St. Louis, Mo.	Standard Artificial Limb Co.	Francis Bandy	2
VAC, Wood, Wisc.	Doerflinger's Artificial Limb Co.	William Pachner	2
Valley Forge General Hospital (Army) Phoenixville, Pa.	Frank J. Malone & Son, Inc.	Frank J. Malone, Jr.	4

Totals:

Cases	– 84
Clinic Teams	– 18
Prosthetists	– 53
Prosthetics Facilities	– 51

[a]VAH–Veterans Administration Hospital
VAOPC–Veterans Administration Outpatient Clinic
VAC–Veterans Administration Center

b. must be emotionally stable;

c. if a previous wearer, must wear present prosthesis at least 8 hours a day, 5 days a week; must wear a functional hand at least 50 percent of the time; and must be considered by the Clinic Team a good "user" of his prosthesis rather than simply a wearer."

2. Above-Elbow and Shoulder Disarticulation. The amputee

a. "must have a stump *at least* 3 in. shorter than the acromion-to-lateral epicondyle measurement on the sound side;

b. must not have a forequarter amputation;

c. must not have extremely limited or absent scapular motion;

d. must be free from extensive scarring in fitting areas;

e. must be emotionally stable;

f. if a previous wearer, must wear his present prosthesis at least 8 hours a day, 5 days a week, and must be considered by the Clinic Team a good "user" rather than simply a wearer."

3. "Bilaterals. Bilateral amputees will be accepted for participation in the Study. It is planned to fit four bilateral below-elbow cases and as many bilateral above-elbow and shoulder-disarticulation cases as possible. They should meet all the criteria established for unilateral amputation levels described in this section, with the inclusion of such common practices as permitting lower-elbow centers for long bilateral above-elbow amputations and slightly longer forearm lengths for long, bilateral below-elbow amputations."

4. "Other Selection Considerations. In addition to the above criteria, each amputee participating in the Study should

a. be a service-connected veteran who at the time of prescription would normally be entitled to a new prosthesis under existing policies;

b. not require prosthetic devices other than artificial legs or lower-limb orthoses (no crutch or wheelchair users);

c. either have never worn a prosthesis or have a history of continuous, satisfactory wear;

d. be an individual who can be depended upon to participate in the Study and to furnish reliable information, and who understands he is expected to report to the prosthetic representative for followup visits;

e. understand that the Veterans Administration cannot guarantee that another prosthesis of the present test design or a similar one will be issued after the Study has been completed and/or when a replacement prosthesis is necessary at a later date;

f. agree to return the externally powered component(s) to the Clinic Team if he withdraws from the Study before its completion or if he rejects the prosthesis for any reason. In such instances, the station will prescribe a new prosthesis, utilizing, if possible, the remaining arm components;

g. agree to refrain from making unauthorized adjustments to the unit, and report to the selected prosthetist for any repairs or adjustments;

h. accept responsibility for first echelon maintenance and care of the power supply, battery-charger, switch, or electrodes if myoelectric control is used;

i. not be an employee of a commercial limb facility;

j. expect to continue residence for at least 3 months within the jurisdiction of the prescribing Clinic Team after he has received the experimental prosthesis;

k. be willing to be photographed, and sign appropriate releases on use of photographs for publication purposes;

l. not wear a pacemaker with external leads."

Instrumentation

Each participating Clinic Team was initially provided with detailed instructions in the Manual for Clinical Application Study of Upper-Extremity Prosthetics. As the Study progressed, "Information Sheets" were issued on specific problems, prescription contraindications, and similar information which developed and which came to the attention of the Project Director.

Various instruments were used to gather data, and a description of each follows. (Copies of the forms used are available from the Project Director, Research Center for Prosthetics, Veterans Administration, 252 Seventh Avenue, New York, N.Y. 10001.)

Form UE-IS, *Selection and Prescription,* was completed by the Clinic Team at the time an amputee was being considered as a test wearer. Both objective and subjective data relating to the amputee's social and medical background and to his prosthetic experience were gathered. One section of this form asked for an evaluation of the amputee's performance with his conventional prosthesis. The last section was used for the prescription of the particular components requested.

Form 10-1068 (VA), *Shipping Notice and Malfunction Report for Artificial Limb Components,* was prepared by the office of the Project Director upon acceptance of a subject for participation in the Study. This form was used to request shipment of the prescribed components by the VA Prosthetics Center to the limb facility selected to fabricate the experimental prosthesis.

Form UE-2P, *Prosthetist's Fitting Report,* was completed by the prosthetist when the new prosthesis was finally fitted to the test wearer and was ready for delivery.

Form UE-3D, *Delivery Report,* was completed by the therapist at the conclusion of the training period. Appendix A of Form UE-3D,

Checkout (Part 1—Below-Elbow Checkout; Part 2—Above-Elbow Checkout; and Part 3—Shoulder-Disarticulation Checkout), was completed by the Clinic Team when the externally powered prosthesis was deemed acceptable.

Form UE-4F, *Followup Report*, was completed by the Clinic Team on two occasions: after 15 days and again after 1 month of prosthesis wear, following the completion of training, amputee and Clinic Team reactions to the experimental limb were recorded.

Form UE-5P, *Report of Malfunction, Repair, and Request for Replacement Components,* was completed by the prosthetist designated to participate in the Study and was submitted to the office of the Project Director on any of several occasions: when requesting replacement components; when reporting a field malfunction which was repaired with parts available at the local facility; or when reporting a field malfunction not requiring parts which was repaired at the local facility.

Form UE-LR, *Bioengineering Research Service Malfunction Report,* was completed by the VA Prosthetics Center and/or the developer to report all findings on repairs, replacements, and rejected components to the Project Director.

Form UE-6F, *Followup Report,* was completed by the Clinic Team after 3 months of wear of the experimental prosthesis by the subject. This form provided most of the data from which this report has been prepared. The subject was rated on his performance with the new limb, and both amputee and Clinic Team reactions were recorded. This form was also completed if a subject discontinued participation in the Study prior to completing the test wear period.

Form UE-7C, *Summary Report,* was completed by the Clinic Team at the conclusion of the Study, after all subjects had completed the required test wear period, to report objective and subjective findings on all of the externally powered components prescribed by that particular Study Team.

Data Collection Procedures

The progress of the amputee subjects was followed during a 3-month wear period, although data *after* the required period of wear were also recorded and analyzed when available. Reports were prepared by the Clinic Team and sent to the Project Director. Table 2 reflects the nature and distribution of reports on which this final report is based.

A total of 69 subjects completed the designated 3-month test wear period. One of the subjects is counted as two cases: a below-elbow amputee with a cineplasty who wore two different systems sequentially for 3-month wear periods. The bilateral amputees are each counted as one case.

TABLE 2.—*Nature of Followup Report Reviewed*

Report form	No. rec'd.	Cumulative total of dropouts after reporting
Selection and prescription	84	1
Fitting	81	3
Delivery	72	12
15-Day followup	72	12
1-Month followup	70	14
3-Month followup	69	15

SAMPLE CHARACTERISTICS

Tables 3 through 5 summarize some general characteristics of the 69 test subjects. Wherever possible, data have been grouped in step intervals, and the means and ranges computed from the ungrouped data. As is true with all of our clinical studies, these subjects probably do not represent a true cross section of the entire amputee population in this country, since they are mainly male veterans of World War II, the Korean conflict, and the Vietnam conflict. The facts that all subjects received their prostheses and related medical treatment in accordance with VA (or military) regulations and that the subjects were eligible to receive prostheses and treatment without cost, could have affected their reactions to the various devices being evaluated.

TABLE 3.—*Subject Data*

Amputee Data	No. of Subjects	Total	Range	Mean
Age, yrs				
18 - 19	1			
20 - 24	23			
25 - 29	18			
30 - 34	3			
35 - 39	5			
40 - 44	4			
45 - 49	8			
50 - 54	4			
55 - 59	3	69	18-58 years	31.9 yrs

TABLE 3.—*Subject Data (Cont'd)*

Amputee Data	No. of Subjects	Total	Range	Mean
Height, in.				
64 - 65	3			
66 - 67	3			
68 - 69	13			
70 - 71	21			
72 - 73	19			
74 - 75	6			
76 - 77	4	69	64-77 in.	70.7 in.
Weight, lb				
100 - 109	1			
110 - 119	0			
120 - 129	2			
130 - 139	3			
140 - 149	6			
150 - 159	13			
160 - 169	7			
170 - 179	12			
180 - 189	8			
190 - 199	7			
200 - 209	3			
210 - 219	2			
220 - 229	1			
230 - 239	1			
240 - 249	2			
250 - 259	1	69	105-250 lb	172.5 lb
Education, yrs				
8 - 9	5			
10 - 11	4			
12 - 13	33			
14 - 15	16			
16 - 17	10			
17 +	1	69	8 - 22 yrs	13 yrs
Occupation				
Professional	0			
Semiprofessional	5			
Managerial and Official	6			
Clerical and kindred occupations	4			
Sales and kindred occupations	5			
Personal service	1			
Protective service	0			
Agriculture, horticulture, etc.	3			
Skilled	3			
Semiskilled	9			
Unskilled	2			
Unemployed	11			
Student	20	69	—	—

TABLE 4.—*Amputation Data*

Data	No. of subjects	Total	Range	Mean
Cause of Amputation				
Traumatic	62			
Vascular	1			
Voluntary (flail arm)	1			
Infection	1			
Burns	4	69	–	–
Amputation side				
Left	35			
Right	32			
Bilateral	2	69	–	–
AE stump length, % of sound arm				
0 (SD)	9			
1 - 10	0			
11 - 20	0			
21 - 30	0			
31 - 40	4			
41 - 50	7			
51 - 60	2			
61 - 70	7			
71 - 80	5			
81 - 90	4			
91 - 100	6	44	0-100%	52%
BE stump length, % of sound forearm				
20 - 29	3			
30 - 39	7			
40 - 49	3			
50 - 59	6			
60 - 69	2			
70 - 79	2			
80 - 89	0			
90 - 100	1	24[a]	20-90%	46.5%
Conventional prosthesis wear at time of selection, yrs				
0	10			
Less than 1	9			
1 - 4	30			
5 - 8	1			
9 - 12	1			
13 - 16	3			
17 - 20	2			
21 - 24	2			
25 - 28	11	69	0-28 yrs	7.8 yrs

TABLE 4.—*Amputation Data (Cont'd)*

Data	No. of Subjects	Total	Range	Mean
Years since amputations at time of selection				
Less than 1	12			
1 - 4	33			
5 - 8	4			
9 - 12	1			
13 - 16	0			
17 - 20	2			
21 - 24	2			
25 - 28	13			
29 - 32	2	69	0-29 yrs	8.8 yrs

[a]Does not include one bilateral BE.

TABLE 5.—*Additional Disability Data*

Data	Description		No. of cases	No. of subjects	Yes	No	Total
Additional major disabilities:[a]							
Ipsilateral limb	Loss of range of motion or paralysis		3	—	—	—	
	Burns, lacerations, etc.		0	—	—	—	
Contralateral limb	Amputation		2	—	—	—	
	Loss of range of motion or paralysis		6	—	—	—	
	Burns, lacerations, etc.		2	—	—	—	
Lower limbs	Amputation(s)		6	—	—	—	
	Orthopedic problems		1	—	—	—	
	Neurological problems		3	—	—	—	
Cardiovascular disease			1	—	—	—	
Visual handicap	Unilateral		1	—	—	—	
Hearing loss	Unilateral		1	—	—	—	
None			43	—	—	—	69
Amputated side vs. dominant side	*Amputation*	*Dominance*					
	Left	Left	—	5	—	—	
	Right	Right	—	29	—	—	
	Left	Right	—	27	—	—	
	Right	Left	—	2	—	—	
	Left	Ambidextrous	—	3	—	—	
	Right	Ambidextrous	—	1	—	—	
	Bilateral	Left	—	1	—	—	
	Bilateral	Right	—	1	—	—	69

TABLE 5.—*Additional Disability Data (Cont'd)*

Data	Description	No. of cases	No. of subjects	Yes	No	Total
Phantom limb symptoms	Phantom sensation	—	—	54	15	69
	Phantom pain	—	—	19	50	69
	Can move phantom limb	—	—	43	11	54

[a]Includes multiple handicaps.
Number of subjects with other disabilities: 26
Number of subjects without other major disabilities: 43

TABLE 6.—*Length of Wear of Pre-Study Prosthesis (N = 9 SD, 34 AE, 24 BE, 2 Bilaterals)*

Wear of pros.	SD	AE	BE	Bilateral
No. of yrs				
0	2	2	5	1 (SD)
Less than 1	4	3	4	0
1 - 2	0	14	6	0
3 - 4	2	7	7	0
5 - 6	1	0	2	1 (BE)
7 - 8	0	1	0	0
9 - 10	0	3	0	0
11 - 12	0	1	0	0
13 - 14	0	1	0	0
15 +	0	2	0	0
Range: 0 - 20.2 yrs				
Mean: 3.9 yrs				
Duration				
Hours per day				
0	4	3	3	2
1 - 5	2	0	2	—
6 - 10	0	1	5	—
11 - 15	1	25	5	—
16 - 20	2	5	9	—
Average [a]	7.2	14.3	13.1	0
Days per week				
0	4	3	3	2
1 - 2	—	—	—	—
3 - 4	—	—	1	—
5 - 6	1	7	4	—
7	4	24	16	—
Average [a]	3.7	6.2	5.8	0

[a]Averages computed for wearers only.

TABLE 7.—*Clinic Team Evaluation on Use of Conventional Prosthesis*

(N = 9 SD, 34 AE, 24 BE, 2 Bilaterals)

Data	SD[a]	AE[a]	BE[a]	Bilateral
Extent of use				
Dressing				
Used at all times	1A, 1P	9A, 1P	9A	–
Used frequently	1P	6A, 1P	1A, 2P	–
Used rarely	1A	3A, 3P	6A, 1P	–
Not used	5	11	5	2
Eating				
Used at all times	–	7A	10A	–
Used frequently	1P	5A	1A, 2P	–
Used rarely	2P	3A, 6P	3A	–
Not used	6	13	8	2
Working				
Used at all times	2A	21A, 1P	14A	–
Used frequently	2A	5A, 1P	3A, 1P	–
Used rarely	–	1A	1P	–
Not used	5	5	5	2
Recreation				
Used at all times	2A	12A, 1P	8A, 1P	–
Used frequently	2A, 1P	15A, 1P	4A, 1P	–
Used rarely	–	2A, 1P	2A, 1P	–
Not used	4	2	7	2
Extent of skill				
Eating				
Excellent	2	12	10	–
Very good	2	13	5	–
Average	1	5	4	–
Poor	–	1	–	1
Very Poor	2	1	–	–
No prosthesis	2	2	5	1
Rating of control				
TD position at mouth				
Good	1	19	16	1(BE)
Fair	2	6	1	–
Poor	2	6	2	–
TD position at waist				
Good	4	25	19	1 (BE)
Fair	–	3	–	–
Poor	1	3	–	–
TD position at floor				
Good	2	26	19	1 (BE)
Fair	–	3	–	–
Poor	3	2	–	–

TABLE 7.—*Clinic Team Evaluation on Use of Conventional Prosthesis (Cont'd)*

(N = 9 SD, 34 AE, 24 BE, 2 Bilaterals)

Data	SD[a]	AE[a]	BE[a]	Bilateral
Generally				
Good	4	24	17	—
Fair	—	6	2	1 (BE)
Poor	1	1	—	—
No prosthesis rating	4	3	5	1 (SD)

[a]A = Active use
P = Passive use

Use of Conventional Prosthesis

The Pre-Study or conventional prostheses were, in general, serviceable at the time the subjects entered the Study. There were 10 nonprevious prosthesis wearers. The average length of wear of the Pre-Study prosthesis was 3¾ years, ranging from 9 to 20.2 years. Table 6 summarizes the years of wear of the limbs and the duration of wear in hours per day and days per week.

The Clinic Teams were asked to report on the following: the use of the subjects' Pre-Study prostheses in dressing, eating, working, and recreation; the amputees' skills as prostheses *users* (not *wearers*); and the amputees' control and amount of use of their prostheses. Table 7 reflects the responses to these questions.

FITTING PROCEDURES

Each limb facility participating in the Study was represented by at least one prosthetist at either of the two courses (April 5-9, 1971, or December 15-17, 1971) held at the Northwestern University Prosthetic-Orthotic Center, Chicago, Illinois. During the course, each prosthetist participated in fitting the VA/NU Myoelectric Hand System with the self-suspended supracondylar socket, the VA Switch-Controlled Elbow, and the VA Switch-Controlled Hand. Each prosthetist was provided with a copy of the draft manual for fitting the VA/NU Myoelectric Hand System and a copy of the preliminary draft of maintenance procedures for the VA Switch-Controlled Elbow. These manuals were prepared by Northwestern University and the Veterans Administration for use in the Study. In addition, a repair kit, a soldering iron, a Myo-Indicator, and a Volt-Ohm-Milliammeter were loaned to each facility or field station for the duration of the Study. Approval for selection of specific components was made by the office of the Project Director in New York, based

on information provided in the Form UE-IS, *Selection and Prescription.*

Suspension Systems

Many types of harness and suspension systems were used in conjunction with the externally powered systems. These included Figure-8 and cross-chest harnessing for above-elbow and shoulder-disarticulation amputees; the Northwestern University supracondylar self-suspended below-elbow socket, without harnessing for myoelectric control or with harnessing ("butterfly") for switch control; and various configurations and combinations of harnessing for above-elbow amputees wearing the VA Elbow/Hand System.

Below-elbow amputees wearing the Northwestern University self-suspended supracondylar socket utilizing myoelectric control *all* stated that they liked the absence of a harness. The ability to operate the terminal device without restriction in any position was the most favorable reaction to this system.

Conventional Terminal Devices

An above-elbow prosthesis incorporating *only* the VA Switch-Controlled Elbow does not include a specific terminal device in the "package." The Clinic Team therefore had the option of prescribing any conventional terminal device. In almost all of these cases, the terminal device selected was the same type as the amputee had used with his Pre-Study limb. Thirty-two of the above-elbow prostheses with the VA Elbow incorporated a mechanical hook, three incorporated a mechanical hand, and five used both. Clinic Team comments on the 3-month followup report suggested that if a hand were to be prescribed, a *powered* one should be selected to take advantage of the ease of effort and reduced excursion. Otherwise, the advantages of having a powered elbow were defeated. The type of hook used did not influence the pattern of responses to the function of above-elbow externally powered systems.

Inspection

Each unit purchased by the Veterans Administration was tested upon receipt by the Testing and Distribution Service of the VA Prosthetics Center. Prior to shipment, a second inspection was made of each system. As a result of this procedure several elbows and myoelectric hand systems were rejected or repaired. Problems included a current draw above specifications, poor solder joints on the elbow circuit boards (limit switches), and malfunction of the EMG amplifiers in either the input or output stages. In addition, batteries occasionally were found to have a reduced charge life, and

some chargers were not functioning. Minor repairs were performed by the Testing and Distribution Service, VAPC, or items were returned to the manufacturer for replacement or repair.

Inspection procedures included examination of the elbow and motor, the hand motor and skeletal framework, and all electronics. Testing and inspection included elbow cycling (for flexion and extension limits, current draw, and time from full extension to full flexion with an 18-in.-lb weight at the end of a simulated forearm); tests for continuity and strain relief of wires and all electronics; battery charge-life tests; and alignment measurements between individual components of each unit. The breakaway of the hand was also tested for at least a 40-in.-lb load.

In no instance was a unit which was known to be defective issued to the field. There is no doubt that these inspection procedures were extremely valuable in reducing the incidence of field failures. Because units issued to the field were routinely inspected, the office of the Project Director was able to determine the cause of failure once the unit was issued.

RESULTS

Fitting Procedures

VA Elbow

Except for 3 cases involving long above-elbow stumps, the prosthetists did not have adequate room to install the battery pack in the humeral section and thus use the soft (foam) forearms. Aside from these instances, few problems were experienced in fitting the VA Elbow. Several problems were encountered in fitting the switch control: 8 cases were reported to have difficulty with the harnesses, which were either too tight or placed incorrectly and thus created inadvertent operation and/or difficulty in controlling the fine switch movement; 4 complained that the leads were too short between the switch and the battery, and/or the battery and the elbow; 4 reported switch malfunctions during the fitting process. Note that at the very beginning of the Study, 10 elbow flexsplines were broken during the fitting procedure.

VA Hand

Ten problems in fitting the VA Switch-Controlled Hand were reported: one prosthetist complained of trouble in stabilizing the battery pack in the distal forearm section; one switch malfunctioned (cold solder joint on printed circuit board); one charger malfunctioned (short in charger plug); one dead battery was reported; one

patient complained of a very tight harness that caused inadvertent operation, which the prosthetist corrected in the harness configuration; two amputees had difficulties in operating the fine switch control; and three cases had stump problems—one neuroma, one stump irritation due to socket fit, and one patient required surgery, which delayed the fitting.

VA/NU Myoelectric System

Fifteen problems related to the fitting of the VA/NU Myoelectric Hand and/or the Northwestern University supracondylar self-suspended socket were reported: 2 cases with poor socket fit required refitting; 1 patient complained of socket irritation over the olecranon (this was relieved and after approximately 1 week the socket was reported to be comfortable); 1 prosthetist had some difficulty in locating the sites on the stump for electrode placement—the amputee was subsequently converted to switch control; 2 amputees had difficulty in separating the flexor-extensor muscle groups and therefore required preprosthetic training. Of 9 malfunctions reported during fitting procedures, 2 were broken leads to the EMG amplifier. The other 7 malfunctions were errors made by one prosthetist: 4 complaints that the hand would not close completely were due to a failure to reset the breakaway after it had been used; 3 complaints that the batteries were dead were based on partially discharged batteries which only required recharging.

Prosthetic Training

Of the 72 subjects fitted with either the VA Elbow, the VA Hand, the VA Hand/Elbow System, or the VA/NU Myoelectric Hand System, 66 were reportedly "trained" in their use. The training ranged from 10 minutes to 45 hours, and averaged 4½ hours. Tables 8 and 9 summarize the number of sessions and approximate training times. Fifty-six of the 66 amputees who received training had no previous training on any prosthesis. Three subjects had worn temporary prostheses made of plaster with a Dorrance hook for the terminal device for approximately 2 months prior to receiving externally powered hands.

The followup reports have tended to strengthen the belief that amputees receiving an externally powered prosthesis must have some period of training as soon as possible. This is especially true of nonprevious prosthesis wearers and bilateral amputees. There is no correlation between amount of training and acceptance of the device; however, there is a significant trend toward a higher malfunction rate for those patients who received little or no training. Patients fitted with externally powered devices require training not so much with the function as with the control of an external power system.

TABLE 8.—*Prosthetic Training by Level*

(N = 69)

Total training time (hrs)	SD	AE	BE	Bilaterals
0	—	1	2	—
Less than 1 hour	—	2	—	—
1 - 2	6	10	9	—
3 - 4	—	15	8	—
5 - 6	1	2	3	—
7 - 8	—	2	—	—
9 - 10	1	—	1	—
11 - 12	1	1	—	—
12 - 13	—	—	—	—
14 - 15	—	—	—	—
16 +	—	1	1	2
Ranges:	1 hr to 11.5 hrs	10 min to 21 hrs	0 to 22 hrs	21¾ hrs to 45 hrs
Means:	3.8 hrs	3.2 hrs	3.6 hrs	33.4 hrs

All patients

Range: 0 - 45 hrs

Mean: 4.5 hrs

TABLE 9.—*Training by Experimental Unit*

(N = 69)

Sessions/time	SD	AE	Bilateral	BE	Range	Mean
VA Elbow						
Sessions						
0	—	1	—	—		
1 - 2	5	18	—	—		
3 - 4	—	5	—	—		
5 - 6	—	3	—	—		
7 - 8	2	—	—	—		
9 - 10	1	1	—	—		
11 +	—	1	1	—	0-58 ses	4.6 ses
Time (hrs)						
0	—	1	—	—		
Less than 1	—	2	—	—		
1 - 2	5	7	—	—		
3 - 4	—	14	—	—		
5 - 6	1	1	—	—		
7 - 8	—	2	—	—		
9 - 10	1	—	—	—		
11 - 12	1	1	—	—		
13 +	—	1	1	—	10 min to 45 hrs	4.8 hrs

TABLE 9.—*Training by Experimental Unit (Cont'd)*

Sessions/time	SD	AE	Bilateral	BE	Range	Mean
VA Elbow/Hand						
Sessions						
2 - 3	1	5	—	—		
4 - 5	—	—	—	—	2 - 3 ses	2.5 ses
Time (hrs)						
2 - 3	1	3	—	—		
4 - 5	—	2	—	—	2 hrs to 4½ hrs	3.1 hrs
VA Hand						
Sessions						
0	—	—	—	1		
1 - 2	—	—	—	4		
3 - 4	—	—	—	2		
5 - 6	—	—	—	2		
6 +	—	—	—	1	0 - 11 ses	3.6 ses
Time (hrs)						
0	—	—	—	1		
1 - 2	—	—	—	3		
3 - 4	—	—	—	3		
5 - 6	—	—	—	2		
6 +	—	—	—	1	0 - 22 hrs	4.9 hrs
VA/NU Myoelectric Hand						
Sessions						
0	—	—	—	1		
1 - 2	—	—	—	7		
3 - 4	—	—	—	4		
5 - 6	—	—	—	1		
6 +	—	—	1	1	0 - 22 ses	4.1 ses
Time (hrs)						
0	—	—	—	1		
1 - 2	—	—	—	6		
3 - 4	—	—	—	5		
5 - 6	—	—	—	1		
6 +	—	—	1	1	0 - 21 hrs	4 hrs

(Note: No attempt was made to influence the length of training sessions. Based on the usual scheduling of patients, 1 hour sessions were most frequently selected.)

Previous wearers of an above-elbow prosthesis have been accustomed to using a great deal of force in pulling the cable, a separate locking and unlocking motion, and much more excursion to operate the terminal device. They therefore require training to unlearn these gross motions and become proficient in operating the switch, which requires very little force and only 5/16 in. excursion.

Wearers of the VA Elbow must learn its load limitations, its maintenance and charging procedures, and its position in space (since there is no force feedback).

Wearers of the VA Hand must learn the fine control of the pull switch. In addition, they must be taught the breakaway function, how to reset the breakaway, maintenance and charging, and position of the hand in space.

Amputees fitted with the VA Elbow/Hand System must learn all of the above as well as the differentiation of switch control to operate either the elbow or hand.

Wearers of the VA/NU Myoelectric Hand System must be taught how to don the socket properly, how to separate muscle group function to operate the hand, the processes of maintenance and charging, the breakaway feature, and the position of the hand in space. Most of all, they must be taught how to *relax* the muscles, when the hand is not in use, to avoid a continuous input signal which might overheat the electronics and/or motor.

In all cases, wearers must learn the capabilities and the limitations of externally powered devices. The devices themselves do not offer any different function (i.e., the elbow still flexes and extends); control is what makes these prostheses unique. It is possible that experience amputees may attempt to use these devices without training, as they are deceptively simple to operate. However, in doing so, the amputees may experience many more malfunctions than necessary, due to abuse, misuse, neglect, or a lack of understanding of the particular unit. Also, they may accept, through ignorance, a lower level of performance than should be possible.

Weight of Prostheses

As in the case of a conventional body-powered upper-limb prosthesis, a physician prescribing either the VA Elbow, the VA Hand, the VA Elbow/Hand System (all switch controlled), or the VA/NU Myoelectric Hand System was also required to specify a socket type and as needed, a harness, a forearm, and a terminal device (above-elbow cases). The completed prosthesis was therefore subject to some variation in final weight due to the components selected, the prosthetist's finishing techniques, the placement of the battery pack, and the length of the prosthesis. In the above-elbow case, the VA Elbow weighs approximately the same as the Hosmer E-400 mechanical elbow; however, if the battery pack was placed in the forearm section (requiring a hard forearm and placing additional load on the elbow), amputees tended to complain of a substantial weight increase. The addition of the VA Hand to this system would, of course, add even more weight. The VA Hand or the VA/NU

Myoelectric Hand on a below-elbow amputee added additional weight at the end of the "lever arm." However, most of these amputees stated that they were able to accommodate the change, and that weight was no longer a significant factor.

TABLE 10.—*Reaction by Subjects to Weight of Limb*

(N = 69)

Weight	VA Elbow	VA Elbow/Hand	VA Hand	VA/NU Myo-Electric Hand
An advantage	5	1	1	1
A disadvantage	4	3	3	21
Immaterial	29	2	6	12

At the 3-month followup evaluation, the test wearers were asked if the increased overall weight of the experimental prosthesis was an advantage, a disadvantage, or immaterial. Table 10 summarizes their statements.

Three patients actually felt that the prosthesis (a below-elbow prosthesis, Northwestern Univeristy self-suspended socket with VA Switch-Controlled Hand, and 2 above-elbow prostheses with the VA Elbow and conventional hook) was lighter than the conventional prosthesis. The other 5 patients who felt the weight was an advantage commented: "The muscles hypertrophied because of the weight"; "The increased weight helps maintain (or improve) my balance"; and "The weight helps me feel where my arm is."

Noise Factor

It is well known that externally powered prostheses tend to make a "whirring" noise because of the motors and/or gears. The noise level varies from unit to unit because of differences in friction, specifications, and tolerances, and the use of a hard-versus-soft forearm with the VA Elbow. On the 3-month followup report, each amputee was asked if this noise was either an advantage, a disadvantage, or immaterial.

All 5 tests wearers who claimed that noise was an advantage stated that the noise acted as a feedback mechanism to let them know the position of the unit and/or the presence of inadvertent operation.

Reduced Excursion and Effort

Since the entire principle of external power is to reduce the amount of effort and excursion required to operate the elbow or hand, reactions were solicited as to whether or not these factors were an advantage, a disadvantage, or immaterial.

The 12 test wearers who felt that the reduced effort was a disadvantage, and, likewise, the four amputees who felt that the reduced excursion was a disadvantage, all commented that these factors reduced the amount of sensory feedback that they previously received from the tension on the cable and/or harness. Eight patients felt that operation of the pull switch required *more* effort, because of the increased amount of concentration they felt was necessary. Those patients who stated that these two factors were an advantage gave the reason that terminal device positioning and operation became easier; in some cases, terminal device positioning and operation became possible, whereas with their conventional prostheses they were unable or barely able to operate the hand or hook at the mouth or side (see Table 7).

Reactions to Practice of Battery Charging

Because of the nature of externally powered devices and the nicad batteries which act as the power sources, the test wearers were instructed in the practice and necessity for daily recharging of battery packs. Since this practice is not required with conventional prostheses, it was thought necessary to solicit reactions of the test wearers to this practice.

TABLE 11.—*Reactions by Subjects to Reduced Effort and Excursion, Noise, and Practice of Recharging Batteries*

(N = 69)

Reaction	VA Elbow	VA Elbow-Hand	VA Hand	VA/NU Myoelectric Hand
Reduced effort				
An advantage	21	5	7	14
A disadvantage	10	0	2	0
Immaterial	7	1	1	1
Reduced excursion				
An advantage	16	5	5	14
A disadvantage	2	0	2	0
Immaterial	20	1	2	1
Noise				
An advantage	1	1	2	1
A disadvantage	15	3	1	2
Immaterial	22	2	7	12
Practice of recharging batteries				
Convenient	2	0	0	3
Inconvenient	6	0	0	0
Immaterial	30	6	10	12

The test wearers' responses on the 3-month followup report to the characteristics of noise, reduced excursion and effort, and the practice of recharging batteries, as encountered in externally powered devices, are summarized in Table 11.

Maintenance

Analysis of Service Record

Although amputee reactions to the externally powered systems were limited to a 3-month wear period, each system was followed from the day it was issued until the termination of the Study. Seventy-one VA Elbows, 29 VA Hands, and 46 VA/NU Myoelectric Hands were issued (all systems included accessories such as switches, battery packs, chargers, cosmetic gloves) from May 26, 1971, through June 15, 1973. Wear periods ranged from 0 days to 1,007 days for the VA Elbows, 2 days to 463 days for the VA Hand, and 0 days to 439 days for the VA/NU Myoelectric Hand; mean wear periods per unit were 202.3 days, 162.1 days, and 102.0 days respectively. A few units, which for various reasons were used for only short periods during the Study, have had disproportionate effects on the various means. Several units returned with reported "malfunctions" subsequently proved to be in good working condition.

The VA Elbow

As can be seen from Table 12, 71 elbows were issued 97 times to 47 subjects; on an average almost half the subjects were issued two elbows. The most common failures were as follows:

Cracked Flexspline due to overload (3)
Cracked Flexspline due to shock load (23)
Cracked Flexspline due to abuse (2)
Total Cracked Flexspline (28)
Improper installation of forearm and switch (14)
Malaligned forearm saddle (8)

Of the 71 elbows issued during the Study, 3 elbows were returned three times, 9 were returned twice, and 46 were returned once. Of these 58 units, 19 were returned because of rejection or subject withdrawal and were not reissued, 3 had reported malfunctions (which later were found to be in working order), and 36 were returned because of failure. Twenty-four VA Elbows were still in use at the completion of the Study; of these, 13 had no failures.

Of the 55 VA Elbows that "failed," 18 were so listed because of prosthetist error in fitting, harnessing, or attempted repairs. The

TABLE 12.—*VA Elbow Service Record*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
5	3	Flexspline cracked, subject withdrew					3
8	462	In use, no failures					462
9	44	Rejected—on inspection, found elbow installed improperly, very heavy forearm; wire from elbow twisted and mangled (electrically torn)	231	Flexspline cracked (overload); wire from motor mangled; forearm saddle malaligned			275
10	3	Reported malfunction, no failures	0	Motor shaft pulled out of commutator assembly	356	Rejected, no failures	359
11	26	Flexspline cracked, subject withdrew					26
12	258	Deceased—no failures					181
13	40	Subject withdrew from Study—no failures	100	Early model—small motor shaft (obsolete)			140
14	649	In use, no failures					726
18	724	In use, no failures					724

TABLE 12.—*Accessories Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
19	20	Prosthetist drilled holes in housing; overtightened set screw, jamming motor shaft					20
21	8	Flexspline cracked (overload)					8
22	33	Flexspline cracked (overload)					33
24	40	Battery pack in forearm abutting humeral section; saddle distorted by retainer	511	In use, partial reject, no failures			551
26	207	Incomplete case—on inspection, found cold solder joint on limit switch, saddle malaligned; thrust washer in wrong place; early model—small motor shaft					207
27	32	Flexspline cracked, subject withdrew					32
29	68	Limit switch improperly set (field-repairable)					68

30	170	Flexspline cracked (overload); flexion limit switch broken					170
35	1,007	In use, no failures					1,007
36	100	Motor burned out; Flexspline cracked (abuse)					100
37	120	Flexspline cracked (shock load)					120
38	90	Flexspline cracked (shock load)					90
40	364	Rejected—on inspection, found small motor shaft and malaligned forearm saddle					364
42	207	Rejected—steel crutch attachment on forearm put strain on elbow	195	Subject withdrew from Study, no failures	68	In use, no failures	470
45	13	Microswitch failure					13
49	68	Subject withdrew from Study, no failures					68
50	50	Limit switch bent	63	In use, partial reject			113
51	130	Rejected—on inspection, found broken motor shaft and rigid flexspline					130
54	663	In use, no failures					663
58	649	In use, no failures					649

TABLE 12.—*Accessories Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
59	220	Rejected—on inspection, found cracked flexspline and binding from poor installation of forearm					220
62	663	In use, no failures					663
63	16	Flexspline cracked in hyperextension					16
69	289	Motor burned out	207	In use			496
75	176	Subject withdrew from Study, elbow very noisy	65	Excessive endplay and damage to commutator assembly			241
79	599	Rejected—no failures	178	Flexspline cracked (overload)	96	In use, partial reject, no failures	873
88	109	Subject withdrew—on inspection, found improperly installed forearm, which caused elbow to act erratically	2	Rejected, no failures			131
89	664	In use, no failures					664
91	24	Flexspline cracked (overload)					24

92	187	Rejected—on inspection, found wire mangled and forearm saddle mal-aligned, binding on elbow					187
93	238	Rejected—on inspection, found improper installa-tion of forearm and switch					238
96	171	Early model—small motor shaft; motor burned out					171
97	15	Flexspline cracked (shock load)					15
98	155	Rejected—on inspection, found: missing thrust washer, off a gear tooth, saddle malaligned, dust in sun bearing causing noise, and loose motor shaft	337	In use			492
99	111	Subject withdrew from Study—on inspection, found cracked flex-spline					1
100	60	No thrust washers; flexspline cracked in hyperextension	370	In use			430

TABLE 12.—*Accessories Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
102	60	Rejected—on inspection, found jammed limit switch and malaligned saddle	30	Flexspline cracked (overload)	222	Rejected—on inspection, found cracked flexspline, bent limit switch (jammed)	312
103	156	Rejected—on inspection, found that "Locktite" between sun bearing and wave generator worked loose, causing excessive play and noise					156
104	126	Reported malfunction, no failures					126
105	60	Flexspline cracked (overload); metal chips found in housing					60
106	102	Flexspline cracked (overload); screwdriver used on motor, creating burrs which interfered with efficiency					102
108	483	In use, no failures					483
109	89	Motor insufficiently set into flexspline					89

110	353	Flexspline cracked (overload)					353
114	239	Subject withdrew from Study—on inspection, found loose thrust washer and saddle malaligned					239
116	138	Rejected—on inspection, found missing thrust washer, broken connector, and saddle malaligned	57	Flexspline cracked (overload); missing thrust washer			195
119	51	Limit switch screw jammed behind microswitch (field-repairable)					51
122	85	Flexspline cracked in hyperextension	292	In use			377
123	150	Flexspline cracked (overload); solder pieces inside housing					150
124	452	In use, no failures					452
125	159	No strain relief for wire to motor—wire broken					159
126	109	Rejected—no failures	284	In use, no failures			393

TABLE 12.—*Accessories Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
127	33	Improperly installed	77	Operating on wrong voltage from *hand* switch; screws drilled into rigid spline; saddle malaligned	364	In use	474
128	232	Rejected—on inspection, found binding from poor installation of forearm					232
130	249	In use, no failures					249
131	398	In use, no failures					398
132	67	Reported malfunction, no failures	284	In use, no failures, partial reject			351
133	138	Subject withdrew from Study, no failures	178	Rejected, no failures			316
134	397	In use, no failures					397

135	53	Conventional lift loop used to retain hook cable (put strain on elbow); saddle warped; thrust washer in wrong place (elbow binding); dirt inside housing; main wire twisted and mangled from battery (jammed into small "window")	60	Flexspline cracked (overload)	172	Subject withdrew from Study; saddle malaligned	285
136	164	Subject withdrew from Study—no failures					164
137	314	Rejected—no failures					314

No. of Elbows = 71
No. of Elbows Failed = 55
Mean Wear Period = 202.3 days
Range = 0 - 1,007 days

other 37 were actual electro-mechanical defects. Ten failures were due to *both* causes. (Note: Of the 31 elbows returned from the field because of rejection or incomplete cases, 18 were found to have been either improperly installed, or malfunctioning. In most cases, *no* malfunctions had been reported. The remaining 9 of these 31 were unused and not included in the total 71.)

Maintenance requirements (specifically, the ease with which the flexspline cracks) were one of the major reasons for rejection of the VA Electric Elbow. Of significance is the fact that *all* subjects who had frequent breakdown of the VA Elbow were active wearers or were in heavy-duty occupations; the elbow was not strong enough for their needs. The flexspline was found to be the weak part of the elbow.

During the course of the Study, the 71 VA Elbows were used for a total of 19,621 man-days of wear, with a mean of 276.4 days per unit. Mean times to failure were calculated but were of no significant value to the Study.

Because of the small number of elbows which had multiple failures, and because only a small number of elbows which failed were reissued, no definite conclusions based upon mean time to failure can be reached. However, it has been noted that those patients who continually crack flexsplines will usually reject the elbow. Also as seen from Table 12 and from field responses, those failures which were caused by prosthetist error reduced in number due to time and learning as the Study went on.

The VA Switch-Controlled Hand

Table 13 shows the service record of the VA Switch-Controlled Hand. During the course of the Study, 29 VA Hands were issued 35 times to 17 subjects. The most common failures were as follows:

Broken leads (3)
Motor burned out (4)
Stripped or worn back-lock (3)

Of the 29 VA Hands issued, only 3 hands were returned twice, while 17 were returned once. Of these 20 units, 2 were sent back because of patient rejection or withdrawal from the Study and were not reissued, 2 came back with reported malfunctions and were found to be in good working order, and 19 revealed genuine failure. Fourteen VA Hands were still in use at the end of the Study; of these, 9 had never failed.

Of the 19 VA Hand failures, 6 were traced to prosthetist error in fitting or repairs; 3 were left with the power "on" while the hand was in closed position, thus burning out the motor; the remaining 10 had other mechanical defects.

TABLE 13.—*VA Switch Controlled Hand Service Record*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
1167	47	Thermal burn-out of motor (hand "on" in closed position)					47
1169	24	Broken thumb; thermal burn-out in attempt to open hand					47
1172	122	Reported malfunction no failures					122
1174	8	Breakaway not reset (field-repairable)	40	Broken lead	190	In use, partial rejection, no failures	238
1175	59	Polarity reversed, (not a failure)	369	Partial rejection, no failures			637
1180	258	Subject deceased, worn back-lock assembly					49
1192	177	Subject withdrew from Study, no failures					177
1193	11	Broken wire in connector (field-repairable); rust and corrosion	45	Worn back-lock assembly; break-away overused			56
1195	95	Internal motor failure	90	Rejected—on inspection found small motor shaft; brushes worn			185

TABLE 13.—*VA Switch Controlled Hand Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
1202	5	Base-plate attachment screws loose (field repairable)	340	In use, partial rejection, no failures			345
1205	39	Operated by wrong switch (elbow switch) high voltage stripped gear for back-lock					39
1210	150	Motor terminal burned out (switch kept "on" with hand in closed position)					150
1214	68	Internal motor failure					68
1237	94	Worn back-lock mechanism					94
1282	269	Wrong (elbow) switch operated hand; high voltage burned out motor					269
1286	47	Reported malfunction, no failures	200	In use, partial rejection, no failures			247
1372	391	In use, no failures					391
1373	61	In use, no failures					61
1405	2	Thumb bent					2

1425	20	Batteries jammed into "window," heat damage	71	In use, partial rejection, no failures			91
1433	448	In use, no failures					448
1437	452	In use, no failures					452
1444	463	In use, no failures					463
1448	412	In use, no failures					412
1457	143	Subject withdrew from Study—no failures					143
2409	143	In use, no failures					143
2411	150	In use, no failures					150
2413	54	Poor solder joint of positive wire to motor					54
2446	87	In use, no failures					87

No. of VA Hands = 29
No. of VA Hands Failed = 19
Mean Wear Period (No. = 35) – 162.1 days
Range = 2-463 days

Maintenance requirements have *not* been a reason for rejection of the VA Switch-Controlled Hand. Of significance is that all but one of the subjects who required more than one unit elected to continue wearing the hand at the conclusion of the Study. This one person wore a VA Elbow/Hand. His rejection was based on the breakdown and maintenance requirements of the *hand* not elbow). Prosthetist error and lack of knowledge in diagnosing "failure" resulted in an undue loss of wear time and subsequent frustration for this subject which probably resulted in his rejecting the system.

During the course of the Study, the 29 VA Hands were used for a total of 5,674 man-days of wear, with a mean of 195.7 days *per unit*.

Again, because of the small number of hands which failed more than once, no definite conclusions could be reached. It should be noted that hands issued after February 1972 (No. 1200 series) had problems with the motor burning out (Table 14). The main cause was that these particular units were 12-V systems rather than 18-V systems; since these hands were often operated by an elbow switch instead of the hand switch, the higher voltage allowed by the elbow switch burned out the motor. The No. 1400 series hands had heavier-duty motors and fewer failures. The No. 2400 series hands, issued after February 1973, incorporated other changes.

The VA/NU Myoelectric Hand

As shown in Table 14, 46 myoelectric hands were issued 82 times to 15 subjects. Wear periods ranged from 0 days to 439 days, with a mean wear period of 102 days. Forty-two of the 46 hands failed one or more times, with the following causes being the most common (multiple causes included):

EMG amplifier failure (17)
Electronics and/or hand damaged (19)
Failure of back-lock mechanism (7)
Battery failure (7)
Breakaway worn or not properly reset (11)
Thermal overload (3)

Of the 46 myoelectric hands issued during the Study, 5 were returned three times, 16 were returned twice, and 21 were returned once. Twelve myoelectric hands are still in use; of these, 3 have never failed.

Of the 62 myoelectric hands that "failed," 13 were due to prosthetist error in fitting, fabrication, or attempted repairs; 3 were due to the subjects' failing to relax muscles while the hand was closed, causing a thermal overload that resulted in burned-out motors; 9 hands were broken in the wrist section; 2 hands with a reported

TABLE 14.—*VA/NU Myoelectric Hand Service Record*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
1	28	Broken (abuse)	94	Subject withdrew from Study			122
2	200	Prosthetist removed tape that secures electronics in wrist section—damaged EMG amplifier	459	In use			659
2A	6	Broken B- lead on printed circuit board; blown output power transistor					6
3	90	Grease caked in back-lock mechanism; batteries shorted from short in charger plug	282	B+ lead on printed circuit board loose	439	In use	811
3A	7	Subject withdrew from Study, no failures	36	Prosthetist tightened wrist—PVC shell was removed, and wires and batteries damaged			43
4A	1	Batteries partially discharged (field-repairable)					1
5	1	Batteries partially discharged (field-repairable)					1

TABLE 14.—*VA/NU Myoelectric Hand Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
6	13	Breakaway not reset (field-repairable)					13
7	9	Batteries damaged	40	Broken wrist section (abuse)			49
8	11	Lead on printed circuit board burned out					11
9	33	Breakaway not reset (field-repairable)	22	Poor electrode protrusion	35	Subject required socket refitting	90
10	91	Subject could not use myoelectric hand (poor signals)	126	Wrist section broken (abuse)	207	Fingers spread apart, allowing thumb to close too far—spring in back-lock failed, causing clicking noise	424
11	30	Thermal overload and short circuit due to failure to relax muscles	44	Broken wrist and EMG amplifier (abuse)			74
2000	115	Grease caked in back-lock mechanism	102	In use			217
2001	145	Battery leads cut by battery edge (prosthetist removed securing tape)	24	Cold colder joint on EMG amplifier			169

2002	286	Finger breakaway overused and worn; gain broken by use of metal screw driver, damaging stops					286
2003	7	Intermittent failure of EMG amplifier					7
2004	1	Cold solder joint on EMG amplifier	46	Prosthetist reversed leads, producing wrong motions	46	Malfunction in EMG amplifier; dead batteries; broken lead; thumb bent; breakaway worn	93
2005	114	Reported malfunction, no failures	76	Wrist broken (abuse); batteries excessively discharged and shorting			190
2007	110	Skeletal framework bent (abuse); breakaway overused and worn; cold solder joint on EMG amplifier	360	Wires from charger receptacle crossed and touched, shorting batteries			470
2008A	30	Lead on EMG amplifier broken					30
2008B	50	Left "on"—overheated battery, electronics, and motor					50
2008C	45	Defective casting of wrist—broke near screw holes					45
2008	421	Gear teeth sheared					421

TABLE 14.—*VA/NU Myoelectric Hand Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total days of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
2009A	120	Breakaway overused and worn	167	Batteries and PVC shell damaged in house fire			287
2009B	70	Gear teeth of back-lock mechanism broken off	365	Plus (+) lead on charger receptacle broken; breakaway overused and worn; PVC shell split in web space; gears in back-lock stripped	425	In use	860
2010	142	Cold solder joint on EMG amplifier—gain pulled out of printed circuit board					142
2011	25	Breakaway overused	159	Wrist section broken (abuse)	68	Wrist piece cracked	252
2012	152	Blown transistor; open circuit					152
2013	166	Poor structural integrity of plastic wrist piece; blown output stage on EMG amplifier					166

2015	15	3 leads broken on EMG amplifier; biased toward opening	113	Breakaway sheared in half by over-tightened set screw; loose lead to EMG amplifier			128
2016	274	Partial rejection—no failures					274
2017	7	Wrong screw used to hold charger receptacle in hand	60	Blown circuit on EMG amplifier			67
2021	177	Subject withdrew from Study, no failures	11	Broken wire in charging receptacle			188
2404	80	On/off switch loose	7	Reported malfunction no failures	68	Partial rejection, no failures	155
2413	83	Motor burned out					83
2419	0	Wrist piece broken off at junction	15	Loose connection of electrode leads to amplifier	85	Broken lead from battery to on/off switch (field-repairable)	210
2419 (cont'd)	110	(4th wear period): In use					
2428	283	In use, no failures					283
2432	70	In use, no failures					70
2433	190	In use, no failures					190
2434	65	Breakaway overused and worn	9	Broken clutch			74
2435	140	Subject required socket refitting, no failures					140

TABLE 14.—*VA/NU Myoelectric Hand Service Record (Cont'd)*

Serial no.	1st wear period		2nd wear period		3rd wear period		Total day of wear
	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
2438	105	Breakaway overused and worn; thumb bent					105
2439	35	EMG amplifier failure; poor solder joints	45	Cold solder joints on EMG amplifier			80
2442	80	On/off switch broken	96	In use			176
2444	85	Gains set at maximum; subject getting ambient noise	95	In use			180

Total No. Myoelectric Hands Issued = 46
Total No. Myoelectric Hands Failed = 62
Mean Wear Period (No. = 82) = 102 days
Range = 0 - 439 days

malfunction were found to be in good working order; and 37 were returned because of actual mechanical failure. (Multiple causes are included above.)

In spite of the high failure rate, maintenance requirements were *not* a reason for rejection of the VA/NU Myoelectric Hand. All subjects who required more than one replacement unit elected to continue wearing the hand at the conclusion of the Study. Furthermore, neither of the three subjects who rejected the VA/NU Myoelectric Hand for full-time wear did so as a result of breakdown, malfunction, or maintenance requirements.

During the course of the Study, the 46 VA/NU Myoelectric Hands were used for a total of 8,544 man-days of wear, with a mean of 185.7 days per unit.

One major defect in the myoelectric system design was the EMG amplifier. These failures have been attributed to extraneous noise entering the input stage of the amplifier. This problem was brought to the attention of the developer and remedied by modifying the EMG circuit so as to be less susceptible to noise and extraneous signals.

Accessories Service Record

Table 15 indicates all of the accessories used with the three major externally powered components.

The VA Switch

The VA Switch is a pull switch with five positions: off, extension, off, flexion, and off. As shown in Table 15, 87 switches were issued 112 times to 57 subjects (for hand, elbow, or both). Wear periods ranged from 0 days to 727 days, with a mean of 237.3 days per wear period.

Of the 87 switches issued during the Study, 1 was returned four times, 10 returned twice, and 53 returned only once. Of these 77 returned units (multiple causes included), 27 resulted from rejection or subject withdrawal from the Study, 17 reported malfunctions were found to be in good working order, and 28 actually failed. The remainder (5) were returned because of prosthesis rejection and were not reissued because the switches were obsolete and not compatible with the newer systems, or for reasons not related to function. Thirty-eight switches were still in use at the conclusion of the Study; of these, 30 had no failures.

Of the 28 "failures," 13 failed because of prosthetist error or failure on the part of the prosthetist to attempt simple repairs. The

TABLE 15.—*Accessories Service Record*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
VA Switches	1	74	Reported malfunction, no failure	181	Prosthesis was rejected, no failures	337	In use, no failures, partial rejection	592
	2	275	Subject withdrew from Study, no failures	271	In use, no failures			546
	Unknown	29	Actuators bent	8	Reported malfunction, no failures	347	In use, no failures, partial rejection	384
	4	445	In use, no failures					445
	7	100	Loose connectors					100
	Unknown	116	Reported malfunction, no failure	663	In use, no failures, partial rejection			779
	16	122	Reported malfunction, no failure	449	In use, no failures			571
	17	397	In use, no failures					397
	21	44	Prosthesis rejected—wires mangled					44
	27	88	Incompatible with new (3-prong) system	5	Incompatible with new (3-prong system)			93
	28	60	Cold solder joint					60
	30	281	Subject withdrew; no strain relief for leads					281

32	58	Allen Screw hole cracked (casing)	46	In use, partial rejection, no failures			104
36	247	Reported malfunction, no failure					247
40	134	Thin rubber band insufficient to return switch to first position	231	Prosthesis rejected; no switch failures			365
42	89	Broken wire	325	In use, partial rejection			414
44	212	Subject withdrew from Study, no failures					212
Unknown	726	In use, no failures					726
Unknown	677	In use, no failures					677
50	102	Broken wire	378	Prosthesis was rejected			480
53	192	Prosthesis was rejected, no failures					192
56	323	In use, no failures					323
Unknown	239	Reported malfunction, no failure					239
Unknown	258	Patient deceased					258
Unknown	258	Patient deceased					258
62	92	Case cracked from overtightened set screw					92
Unknown	649	In use; has on/off switch; no failures					649
76	177	Subject withdrew from Study, no failures					177

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total day of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	78	167	Subject withdrew from Study, no failures					167
	Unknown	663	In use, no failures					663
	Unknown	727	In use, no failures					727
	Unknown	727	In use, no failures					727
	83	124	Subject withdrew; switch wire mangled					124
	89	9	No strain relief; signs of water damage, possibly from perspiration	100	Partial rejection, in use, no failures			109
	90	328	Reported malfunction, no failure					328
	92	377	In use, no failures					377
	95	304	Prosthesis was rejected; no switch failures					304
	100	235	Prosthesis was rejected; no switch failures					235
	103	15	Casing cracked from overtightened set screw					15

104	248	No strain relief	169	In use			417
105	364	Subject withdrew; no strain relief					364
109	621	In use, no failures					621
113	435	In use, no failures					435
121	58	Printed circuit board burned out					58
122	441	Prosthesis was rejected; no switch failures					441
125	40	Lead torn off of printed circuit board, subject withdrew					40
126	235	Prosthesis was rejected; no switch failures	294	Reported malfunction, no failures			529
128	412	In use, no failures					412
129	2	Actuators bent					2
130	187	Subject withdrew; wire was mangled					187
131	342	In use, no failures					342
132	310	Prosthesis was rejected; on/off switch was installed					310
133	207	Prosthesis was rejected; on/off switch was installed					207
136	110	RTV sloppy—switch sticking	66	In use, partial rejection, no failures			176

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	138	25	Cold solder joint					25
	140	176	Subject withdrew from Study, no failures					176
	147	37	Reported malfunction, no failures	364	In use, no failures			401
	149	58	Reported malfunction, no failures	60	Case cracked by overtightened set screws			118
	151	241	Prosthesis was rejected; no failures					241
	152	507	In use, no failures					507
	153	97	Reported malfunction, no failures					97
	156	111	Subject withdrew from Study, no failures	342	In use, no failures			453
	159	177	Subject withdrew from Study, no failures	1	Cold solder joint; lead crushed (field-repairable)	0	Lead too short to be mounted in harness	184
	159 (cont'd)	6	(4th wear period): Reported malfunction, no failure	0	(5th wear period): In use			6

160	46	Subject withdrew from Study, no failures	178	Prosthesis was rejected; no failures			224
163	284	Prosthesis was rejected; no failures					284
164	20	Switch sticking from excess RTV; cold solder joint					20
166	247	Subject withdrew from Study, no failures					247
169	364	In use, no failures					364
170	84	Incompatible with new (3-prong) system					84
171	482	In use, no failures					482
173	481	Prosthesis was rejected; no failures					481
174	247	Subject withdrew from Study, no failures					247
179	507	In use, no failures					507
180	82	Reported malfunction, no failure	364	In use, no failures			446
181	281	New system incompatible	126	Reported malfunction, no failures			407
185	74	Reported malfunction, no failure	235	Switch case cracked from overtightened set screws, subject withdrew			309

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	187	45	Excess RTV interfering with switch function					45
	194	180	Reported malfunction, no failure					180
	195	50	Reported malfunction, no failure	364	In use, no failures, partial rejection			414
	196	335	Prosthesis rejected; no failures					335
	197	651	In use, no failures					651
	322	145	In use, no failures					145
	332	67	Incompatible with new (3-prong) system					67
	336	61	In use, no failures					61
	337	145	In use, no failures					145
	341	10	Leads too short to be mounted in harness					10
	345	89	In use, no failures					89

Total No. Switches = 87
Total No. Switches Failed = 28
Mean Wear Period (No. = 113) = 237.3 days
Range = 0–727 days

Batteries (E = Elbow H = Hand)	1H	20	Reported malfunction, no failure	71	Battery cells dead			91
	1E	129	Jammed into small space; elbow lock nut cut into batteries, damaging cells					129
	2	120	Plus (+) lead wired incorrectly					120
	3	257	Subject withdrew from Study, no failures					257
	4	177	Subject withdrew from Study, no failures					177
	5	214	Reported malfunction, no failure	260	Two cells ruptured	322	In use, partial rejection	796
	Unknown	35	Wires pulled out					35
	6	412	In use, no failures					412
	7	247	Subject insufficiently charged batteries (field-repairable)	67	In use, no failures, partial rejection			314
	8	1	Poor solder joint of negative (-) lead					1
	9	70	Low charging current from bad charger created bad cell					70
	10H	435	In use, no failures					435
	10E	507	In use, no failures					507
	Unknown	663	In use, no failures					663

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	Unknown	482	In use, no failures					482
	13	383	In use, no failures					383
	17	61	In use, no failures					61
	18	130	Lost by patient					130
	Unknown	116	Reported malfunction, no failure					116
	19	569	Subject withdrew; no failures					569
	21	192	Subject withdrew; no failures	145	In use, no failures, partial rejection			337
	22	14	Reported malfunction, no failure	507	In use, no failures			521
	23	337	In use, no failures					337
	Unknown	258	Subject deceased					258
	26	491	Prosthesis was rejected; no failures					491
	27	481	Prosthesis was rejected, no failures					481
	29	461	In use, no failures					461
	30	30	Loose connector	181	Prosthesis rejected			211

32	111	Subject withdrew; no failures					111
35	355	Reported malfunction, no failure	178	Subject withdrew; no failures			533
Unknown	663	In use, no failures					663
Unknown	711	In use, no failures					711
38	177	Partial rejection of prosthesis, no failures					177
43	101	Prosthesis was rejected; no failures	15	In use, no failures			116
45	552	Battery exploded					552
46	372	Subject withdrew; no failures					372
Unknown	726	In use, no failures					726
48	235	Subject withrew; no failures					235
Unknown	649	In use, no failures					649
52	269	Prosthesis was rejected; no failures	231	Subject withdrew; no failures			500
53	154	Prosthesis rejected; battery was rewired for auxiliary charging plug, no failures	323	In use, no failures, partial rejection			477
54	364	In use, no failures					364
56	482	In use, no failures					482

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	57	46	Subject withdrew from Study, no failures					46
	59	187	Prosthesis was rejected, no failures					187
	Unknown	202	Prosthesis was rejected, no failures					202
	62	621	In use, no failures					621
	63	382	In use, no failures					382
	64	335	Prosthesis was rejected; no failures					335
	Unknown	700	In use, no failures					700
	67	134	Poor solder joint	169	In use, partial rejection			303
	68	516	In use, no failures					516
	70	177	Subject withdrew from Study, no failures					177
	72	35	Reported malfunction, no failure					35
	75	651	In use, no failures					651
	76	90	Leads broken and re-soldered; subject to short circuit					90

83	275	Subject withdrew from Study, no failures					275
96	324	Incompatible with new hand system					324
97	740	In use, no failures					740
100E	263	Prosthesis was rejected, no failures					263
100H	180	Had original (470-ohm) resistor (too high—batteries not receiving charge)	39	Reported malfunction, no failure	145	In use, partial rejection	364
101	30	Partially discharged, not a failure (field-repairable)	247	Subject withdrew from Study, no failures			277
102	25	Lead solder on wrong lug; connector not secure					25
103	284	In use, no failures					284
106	407	In use, no failures					407
108	62	Prosthesis was rejected, no failures					62
144	274	Subject withdrew from Study, no failures					274
146	445	In use, no failures					445
149	369	In use, no failures					369
152	284	Prosthesis was rejected, no failures					284

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	156	176	Subject withdrew from Study, no failures					176
	165	77	Loose connectors					77
	168	339	Prosthesis was rejected, batteries failed charge-life test					339
	171	444	Prosthesis was rejected, no failures					444

Total No. Batteries = 74
Total No. Batteries Failed = 17
Mean Wear Period (No. 89) = 282.4 days
Range = 1 - 740 days

Chargers	1X	8	Subject withdrew from Study, no failures	106	In use, partial rejection			114
	4	177	Subject withdrew from Study, no failures	247	Subject withdrew from Study, no failures			424
	5	282	Subject withdrew from Study, no failures	322	In use, no failures			604
	Unknown	200	Lost by patient					200
	5X	46	Reported malfunction, no failures	100	In use, partial rejection			146

8	188	Subject withdrew from Study, no failures					188
8X	60	Reported malfunction, no failure	362	In use, no failures			422
9	284	Subject withdrew from Study, no failures					284
9X	14	Reported malfunction, no failure					14
10	507	In use, no failures					507
10X	621	In use, no failures					621
11	585	In use, no failures					585
13	177	Charger plug pulled from leads (abuse)	67	In use, partial rejection			244
13X	145	In use, partial rejection					145
16	28	Broken plug, field-repairable					28
18	46	Subject withdrew from Study, no failures					46
19	68	Subject withdrew from Study, no failures	501	In use, no failures			569
20	146	Reported malfunction, no failure					146
21	192	Prosthesis was rejected, no failures					192
22	507	In use, no failures					507

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total days of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	23	35	Prosthestist inadvertently pulled wires out	20	Reported malfunction, no failure	412	In use	467
	24	643	In use, no failures					643
	26	491	Prosthesis was rejected, no failures					491
	27	481	Prosthesis was rejected, no failures					481
	Unknown	711	In use, no failures					711
	Unknown	663	In use, no failures					663
	Unknown	84	Reported malfunction, no failure					84
	30	181	Prosthesis was rejected, no failures					181
	32	318	Lost by patient					318
	Unknown	725	In use, no failures					725
	35	152	Reported malfunction, no failure					152
	36	102	Reported malfunction, no failure	68	Reported malfunction, no failure			170

Unknown	202	Prosthesis was rejected, no failures					202
Unknown	649	In use, no failures					649
42	339	Prosthesis was rejected, no failures					339
43	231	Prosthesis was rejected, no failures					231
45	573	In use, no failures					573
45X	152	Reported malfunction, no failure					152
46	372	Prosthesis was rejected, no failures					372
48	235	Prosthesis was rejected, no failures	176	Subject withdrew from Study, no failures			411
50	483	In use, no failures					483
Unknown	17	Reported malfunction, no failure	400	In use, no failures			417
Unknown	663	In use, no failures					663
51	178	Subject withdrew from Study, no failures					178
52	269	Prosthesis was rejected, no failures					269
53	154	Prosthesis was rejected, no failures; rewired for auxiliary charging plug					154
54	141	Incompatible with myoelectric system					141

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total day of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	58	397	In use, no failures					397
	59	187	Prosthesis was rejected, no failures	337	In use, partial rejection			524
	Unknown	258	Subject deceased					258
	Unknown	727	In use, no failures					727
	62	621	In use, no failures					621
	Unknown	230	Reported malfunction, no failure	439	In use, no failures			669
	71	249	Prosthesis was rejected, no failures	439	In use, no failures			688
	74	90	Reported malfunction, no failure					90
	77	369	In use, no failures					369
	78	337	In use, no failures					337
	80	177	Subject withdrew from Study, no failures	247	Subject withdrew from Study, no failures			424
	81	198	Subject withdrew from Study, no failures					198
	82	110	Incompatible with 12-V system (24-V charger)	445	In use, no failures			555

83	335	Prosthesis was rejected, no failures					335
84	83	Subject withdrew from Study, no failures					275
85	461	In use, no failures					461
88	441	Prosthesis was rejected, no failures					441
92	58	Charger plug stepped on (abuse)					58
93	1	Damaged in shipping					1
94	34	Subject withdrew from Study, no failures					34
95	21	Reported Malfunction, no failure					21
96	280	Damaged in house fire					280
98	241	Prosthesis was rejected, no failures					241
101	20	Charger plug incorrectly wired	452	In use, partial rejection			472
102	368	In use, no failures					368
105	472	In use, no failures					472
107	111	Subject withdrew from Study, no failures	260	Reported malfunction, no failure			371
108	113	Reported malfunction, no failure					113
109	482	In use, no failures					482
110	516	In use, no failures					516
115	46	Reported malfunction, no failure					46
117	463	In use, No failures					463

TABLE 15.—*Accessories Service Record (Cont'd)*

Components	Serial No.	1st wear period		2nd wear period		3rd wear period		Total day of wear
		No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	No. of days worn	Status, or reason for removal from service	
	150	257	Subject withdrew from Study, no failures	70	Broken jack			327
	151	740	In use, no failures					740
	152	449	In use, no failures					449
	154	435	In use, no failures					435
	201	444	Prosthesis was rejected no failures					444
	203	407	In use, no failures					407
	Unnumbered (New type)	190	In use, no failures					190
	Unnumbered (New type)	67	Reported malfunction, no failure					67
	Unnumbered (New type)	158	In use, partial rejection					158
	Unnumbered (New type)	18	Reported malfunction, no failure	28	Reported malfunction, no failure	174	In use, partial rejection	220
	Unnumbered (New type)	134	Subject withdrew from Study, no failures					134

Total No. of Chargers = 90
Total No. of Chargers Failed = 6
Mean Wear Period (No. = 106) = 293.1 days
Range = 1 - 740 days

remaining 15 actually had failures attributed to defects in the switches themselves. Fifteen switches were returned with rejected systems; *no* malfunctions were reported for these switches.

Maintenance requirements of the switches have not been a reason for rejection of either the VA Elbow, the VA Hand, or the VA Elbow/Hand Systems. There were other reasons for rejection of the switch control; these will be pointed out in the section Patient Reactions, later in this report.

During the course of the Study, the 87 switches were used for a total of 26,811 man-days of wear, with a mean of 308.2 days per unit.

The major maintenance problem with the switches was lack of strain relief, resulting in broken leads. Although these were field-repairable, none of these switches were repaired in the field even though the prosthetists had been taught the procedure. Also, 17 switches returned as having failed were found to be in good working order upon inspection; the problem occurred elsewhere in the system, such as a broken elbow flexspline or poor connections. These failures could have been discovered in the field either by use of the Volt-Ohm-Milliammeter or by inspection.

Battery Packs

Table 15 also shows that 74 battery packs for VA Hand, VA Elbow, or VA Elbow/Hand Systems were issued 89 times to 57 subjects. Battery packs for the VA/NU Myoelectric Hand are not listed; these batteries were not replaced separately since they are self-contained in the wrist section of the hand.

The most common failures were as follows:

Batteries shorted (4)
Battery incorrectly wired or poor solder joints (4)
Loose connectors (3)
Batteries damaged (abuse) (2)
Insufficient charge (2)
Cells dead (2)

Of the 74 battery packs issued during the Study, 7 were returned twice and 41 were returned once. Of the 55 returned, 26 resulted from rejection of the prosthesis or withdrawal of the subject from the Study (these batteries were not reissued), 7 reported as malfunctioning were found to be in good working order, 4 packs returned because of rejection or withdrawal were reissued, 1 was sent back for reasons not prosthetic, and 17 were returned because of alleged failure. Multiple causes for returned batteries are included in these

figures. Thirty-three battery packs still were in use at the end of the Study; of these, 29 had no failures.

Of the 17 "failures," 5 resulted from prosthetist error in fitting or repairs (or failure to attempt simple repairs), and 12 revealed actual defects in the battery mechanism (2 of these also due to prosthetist error).

Maintenance requirements of the battery packs were not a reason for rejection of the VA Elbow/Hand. Three subjects did, however, state that the practice of daily battery charging was inconvenient, and 3 others objected that the connectors were too loose. These were not reasons for rejection, but they did contribute to rejection of the powered units (especially the VA Elbow).

During the course of the Study, the 74 battery packs were used for a total of 25,160 man-days of wear, with a mean of 340 days per battery pack.

Chargers

Table 15 also shows the service record of the chargers that were issued with all systems. During the course of the study, 90 chargers were issued 109 times to 72 subjects. Use periods ranged from 1 day to 740 days, averaging 293.1 days. The failures were as follows:

Broken charger due to abuse or carelessness (7)
Charger plug incorrectly wired (1)

Of the 90 chargers issued during the Study, 8 were sent back twice, and 50 were returned once. Thirty-five were returned because of prosthesis rejection or subject withdrawal, 20 reported as malfunctions were found to be in good working order, and 6 actually failed. One charger was returned upon the death of a subject, 2 were judged obsolete (i.e., they were not compatible with newer systems), and 2 were lost by the subjects. Forty-five chargers are still in use; of these, 42 have not failed.

Maintenance requirements have not been a reason for rejection of any of the systems. As stated in the section Battery Packs, however, 3 subjects did note that the practice of charging was inconvenient.

During the course of the Study, the 90 chargers were used for a total of 31,294 man-days of wear, with a mean of 347.7 days per charger.

AMPUTEE AND CLINIC TEAM REACTIONS AND RESPONSES TO THE EXPERIMENTAL DEVICES

Amputee Reactions

Considered in this section are the responses of the 69 subjects who participated in the majority of the 3-month period. Two sub-

jects fitted with the VA elbow and conventional TD withdrew early in the Study and a forequarter amputee fitted with a VA Elbow/ Hand system died.

The VA Electric Elbow

Seventeen of the 40 subjects fitted with the VA Electric Elbow and a conventional terminal device elected to continue wearing the experimental prosthesis, while 21 did not. Two elected to continue wearing the VA Elbow on a part-time basis only and are therefore considered "partial acceptances." They chose to wear the VA Elbow at all times other than during working hours; one felt the noise distracted others at work, and the other was unable to use the VA Elbow because, in his occupation as a postal clerk, the flexspline continued to crack from the load of carrying heavy bags of mail. Both of these subjects liked their powered prostheses and did not wish to return them.

Of the 17 subjects who accepted the VA Elbow, plus the two subjects who "partially accepted" the device, the average period of wear was 9.5 hours per day, 5.9 days per week. In most cases, this reflected approximately the same amount of wear as with the Pre-Study prosthesis (except for the 2 "partial acceptances"). In one case of a shoulder-disarticulation amputee there was an increase of wear from 3 hours per day, 4 days per week, to 8 hours per day, 7 days per week.

The developer's claim that the VA Elbow reduces the amount of effort and excursion required to raise and lower the forearm appears to be confirmed by the test wearers' responses. Of the 40 subjects who used the VA Elbow, 21 stated that the reduced effort and excursion were definite advantages. This was especially true of 6 shoulder-disarticulation amputees and 1 bilateral shoulder-disarticulation amputee. The original assumption that the powered elbow would be indicated for very high level amputations is valid; however, prescription of the VA Elbow is not limited to these amputees. The remaining 14 subjects who thought that the reduced effort and excursion were advantageous, were above-elbow amputees, the majority of whom had midhumeral (8 in. +) stump lengths. One enthusiastic wearer was an elbow-disarticulation amputee. Sixteen subjects favored the reduced excursion because it allowed easier and increased terminal device operation. Other responses to the question of reduced effort and excursion included 8 subjects who felt that these factors were immaterial, and 9 who found them a disadvantage. These 9 gave the following reasons: 3 stated that there was not enough feedback to position the forearm; 7 felt that the VA Elbow required more mental effort ("too much concentration"); 5 main-

tained that the reduced excursion in particular was a disadvantage, because it caused inadvertent operation.

Regarding the automatic lock feature, 18 subjects stated it was an advantage, 7 felt it was immaterial, and 13 said it was a disadvantage. These 13 subjects complained that the automatic lock made the arm "stiff" in appearance and function, and that they missed the free-swinging elbow. Two of the 18 subjects who liked the automatic lock also mentioned that they missed the free swing.

Twenty-one of the subjects observed that they experienced less fatigue with the VA Elbow than with their conventional, Pre-Study prostheses. Five felt more fatigued with the experimental prosthesis, while 12 wearers did not mention any difference. Seven of this group of 12 had also indicated that the prosthesis required more effort to use. (All 7 rejected the VA Elbow.)

Each subject was asked if the noise that the VA Elbow produced was an advantage, disadvantage, or immaterial. No wearers of the elbow stated the noise was an advantage, while 17 found it a disadvantage. Twenty-one wearers felt that the noise was immaterial, even though they were "aware" of it.

Likewise, each subject was asked if the increased weight of the powered prosthesis was an advantage, disadvantage, or immaterial. Three felt the prosthesis was lighter, and one other stated it was an advantage in that the weight "balanced" his body (short above-elbow amputee). Three declared that the weight was a disadvantage, and 31 found the increased weight immaterial.

Regarding the speed of the elbow, two wearers maintained that it was too fast in extension; both wearers had long above-elbow stumps and the battery pack was in the forearm section. Fifteen subjects stated that the elbow was too slow in flexion for their needs. Twenty-one regarded the elbow speed as satisfactory. Two of these mentioned that they would like to see proportional control and variable speeds, and one found the elbow faster than his conventional arm.

Each subject was asked if the practice of recharging the batteries regularly was convenient, inconvenient, or immaterial. Five wearers felt that the charging was a convenient practice (all 5 were very enthusiastic subjects), while 8 found it inconvenient. Of these 8 subjects, all of whom rejected the experimental prosthesis, 2 stated that part of the problem was loose battery connectors. Twenty-five wearers stated that the practice was immaterial.

Responding to a question concerning the *Soft Endoskeletal Forearm* (answered by 13 subjects), 9 affirmed that the forearm was much lighter and more "natural." The developer's claims that the soft forearm is lighter, feels more natural, and does not make a

"clunking" noise when it strikes a hard surface, all appear to be verified. However, 4 wearers pointed out that the forearm was not as durable and soiled easily, and one thought the soft forearm felt heavier. Eleven of the 13 subjects liked the soft forearm, whether or not they accepted the VA Elbow. Of the 13 subjects fitted, 84.6 percent liked the soft forearm as opposed to 15.4 percent who did not. The 2 who did not like the soft forearm rejected the experimental prosthesis. Twenty-five subjects wore the crustacean-type forearm and therefore did not respond to this question. They were prescribed hard forearms, either because the soft unit had not yet become available, or because their long above-elbow stumps required battery pack placement in the forearm section. It should be noted that 10 of these people complained of the slowness of the elbow and/or the increased weight of the prosthesis.

Regarding harnessing, 4 subjects made the unsolicited comment that the harness was more comfortable with the experimental prosthesis. The most likely reason is that harnessing was needed for suspension only, and that tight or extra harnessing for elbow and terminal device control was not necessary.

Negative reactions centered on inadvertent operation, lack of free arm swing, noise, and inadequate lifting force. Twenty-one wearers reported inadvertent operation, especially while driving or reaching for an object. Two others had reported inadvertent operation early during the test wear period; they were then given on/off switches, in line with the battery and control switch. Of the 23 subjects who experienced inadvertent operation, 20 had reported difficulties with controls training or in harnessing. With respect to the absence of free swing, 15 subjects considered the lack a hindrance to their ability to dress (putting on shirt or coat was difficult) and/or to drive (prosthesis "got in the way"). Three of these subjects also mentioned that the lack of free swing made the arm "look stiff" and, therefore, affected cosmesis. Concerning noise, as stated previously, 17 wearers complained that the VA Elbow was unnecessarily noisy and was distracting to others. One subject, however, felt that the noise was a good feature in that it gave him some feedback and position sense.

The inadequate lifting force appears to be the major negative feature of the elbow. Nineteen of the 38 wearers (50 percent) felt the unit was not strong enough for their needs, especially those who had heavy-duty jobs or who were very active wearers. Five of these 19 wearers accepted the experimental prosthesis in spite of this reported disadvantage; once they learned the lifting capacity of the elbow, they were able to function within that capacity.

The VA Switch-Controlled Hand

Six of the 10 subjects fitted with the VA Switch-Controlled Hand elected to continue wearing the experimental prosthesis on a regular basis, while one did not. Three others preferred to use it on a part-time basis and are therefore considered "partial acceptances." These three subjects had been using a temporary prosthesis incorporating a conventional hook prior to being fitted with the VA Hand. Their negative reactions all are based on hook versus hand bias; they all liked the power aspect but did not like the hand for reasons typical of hook/hand bias (too heavy, too bulky, too awkward, cannot use for fine work, etc.). All 3 of these wearers did elect to keep the powered hand, however, as it "has its place" and "is easy to use."

The one subject who rejected the VA Hand had a biceps cineplasty. The VA Switch-Control was operated by means of the cineplasty. Although this subject liked the hand, he rejected the experimental prosthesis because the switch control was "too fine" to be operated by cineplasty. He was later fitted with a VA/NU Myoelectric Hand, which he accepted.

For the 6 subjects who accepted the VA Hand, plus the 3 "partial acceptances," the mean period of wear was 10.8 hours per day, 6 days per week, ranging from 4 to 16 hours per day and 4 to 7 days per week. In most cases, this reflected approximately the same wear as with the Pre-Study prosthesis. All three "partial acceptances" increased their wear time approximately 2 hours per day and 1 day per week.

The claim that the VA Hand reduces the amount of effect and excursion required to open and/or close the terminal device appears to be verified by the test wearers' responses. Of the 10 subjects who used the VA Hand for the 3-month period, 8 stated that reduced effort and excursion were a definite advantage. The one who did not feel that this was a desirable feature was the cineplasty patient. Two subjects, one a "partial acceptance," felt that the use of the VA Hand required more effort, especially mental, in using the switch control because there was no feedback in determining hand position.

Regarding the speed of the VA Hand, no one thought it too fast, 1 indicated that it was too slow, and 9 found the speed satisfactory.

Each subject was asked if the noise level of the VA Hand was an advantage, a disadvantage, or immaterial. Two felt that the noise was an advantage in that it provided feedback, 1 stated the hand was too noisy, and 7 felt the noise level was immaterial.

In response to a question regarding the weight of the prosthesis, 1 wearer answered that the experimental prosthesis was lighter, 3

felt it was heavier, and 6 thought the increased weight was immaterial.

Each subject fitted with the VA Hand was also asked if the practice of regular battery recharging was convenient, inconvenient, or immaterial. All 10 subjects felt that this practice was immaterial.

Several unsolicited responses were noted as follows: Three wearers found the Northwestern University Self-Suspended Socket much more comfortable and 1 stated that the prosthesis was much easier to don. Three subjects noted that the "butterfly" type of harness was more comfortable and allowed more freedom of movement. Six of the 10 subjects specifically stated that the experimental prosthesis was considerably more cosmetic. Three noticed that they had more control over their terminal device, while 1 wearer missed his wrist flexion unit. Only 2 responses concerning the breakaway feature were reported; 1 subject stated that this feature was very important to him while another felt that is was undesirable. This veteran complained that he was unable to carry heavy objects and that he was insecure with the breakaway, not knowing when "it will give." One subject reported that the VA Hand was not as sturdy as his conventional hand (he had several malfunctions).

Inadvertent operation was a problem for 4 subjects, while 5 subjects complained that the switch control was too fine. All of these subjects had early complaints of either difficulty in learning the switch control or of a tight harness. (Note: Three prostheses incorporating the VA Hand were returned with the Figure-8 harness instead of the recommended "butterfly" harness.)

The VA Elbow/Hand System

Three of the 7 subjects fitted with the VA Switch-Controlled Elbow and the VA Switch-Controlled Hand elected to continue wearing the experimental prosthesis on a regular basis, while 1 did not. Two of the subjects elected to wear the VA Elbow/Hand System on a part-time basis and are therefore considered "partial acceptances." The 2 latter subjects liked the VA Elbow but not the VA Hand. One man liked both units but was unable to use the prosthesis at work (part-time dairy farmer).

Of the 5 subjects who accepted the VA Elbow/Hand System (including the 2 "partial acceptances"), the average wear time was 8 hours per day, 4 days per week, ranging from 2 to 16 hours per day and 3 to 7 days per week. This reflected a decreased wear period by approximately 2 hours per day and 1 day per week from their Pre-Study prostheses. One subject died.

The developer's claim that the VA Elbow/Hand System reduces effort and excursion in raising and lowering the forearm and in

opening and closing the terminal device appears to be confirmed by the wearers' responses. Of the 6 wearers, all felt that the reduced effort and excursion were definite advantages over their conventional prostheses.

With regard to the automatic locking feature, 2 subjects stated that it was an advantage; 2 stated that it was a disadvantage due to lack of free swing; and 2 stated that it was immaterial.

Only 1 wearer stated that the experimental prosthesis was less fatiguing than the conventional prosthesis. The other 5 did not respond to this query.

Three of the 6 subjects complained that the prosthesis was too noisy, while 1 thought that the noise was an advantage for feedback. Two stated that the noise factor was immaterial.

Each subject was also asked if the increased weight was an advantage, a disadvantage, or immaterial. Only 1 felt that the experimental prosthesis was too heavy; the remaining 5 felt that the weight was immaterial.

Concerning the speed of the powered devices, one wearer felt that the hand was too slow, 2 found that the elbow was too slow, and the remainder stated that the rate of speed was satisfactory.

In response to the question of recharging the batteries, only 1 subject had any complaints. He stated that the connectors were too loose fitting, but that the actual practice of recharging the batteries was not an inconvenience. In effect, all 6 subjects felt that this practice was immaterial.

Two subjects complained of inadvertent operation of the hand and 1 experienced trouble with the elbow. There had been previously reported problems in fitting; 2 had trouble with the harnessing and 1 had a switch with leads that were too short.

All 3 subjects wearing the soft, endoskeletal forearm liked this feature. The remaining 3 subjects were fitted with the hard forearm, since the soft forearm was at first unavailable. One of these subjects had the battery pack placed in the forearm section (unnecessary, as the subject was a short above-elbow amputee). He accepted the experimental prosthesis, but complained of the slowness of the elbow.

Two wearers stated that the elbow did not have adequate lifting force. One of these subjects had cracked many flexsplines and finally rejected the prosthesis.

Three subjects reported increased control of the terminal device. One reported that the increased grasping force of the VA Hand was a desirable feature. No other comments were noted.

Table 16 summarizes the amputees' responses to the experimental devices after completion of the 3-month wear period.

TABLE 16.—*Amputee Reactions to the Experimental Devices*

Reactions	(No. Subjects = 48) VA Elbow and Terminal Device	(No. Subjects = 10) VA Hand	(No. Subjects = 7) VA Elbow/Hand
Reduction of Effort and Excursion			
Advantage	21	8	6
Disadvantage	9	1	0
Immaterial	8	1	0
Total	38	10	6
Noise Factor			
Advantage	0	2	1
Disadvantage	17	1	3
Immaterial	21	7	2
Total	38	10	6
Fatigue			
More	5	2	–
Less	21	0	–
No difference	12	8	–
Total	38	10	–
Increased Weight			
Advantage	4	1	0
Disadvantage	3	3	1
Immaterial	31	6	5
Total	38	10	6
Speed			
Too fast	2	0	0
Too slow	15	1	3
Satisfactory	21	9	3
Total	38	10	6
Battery Recharging			
Convenient	5	0	–
Inconvenient	8	0	–
Immaterial	25	10	6
Total	38	10	6
Total Overall Acceptance			
Acceptance	17 (42.5%)	6 (60%)	3 (50%)
Partial acceptance	2 (5.0%)	3 (30%)	2 (33.3%)
Rejection	21 (52.5%)	1 (10%)	1 (16.7%)
Total	40	10	6 (1 Deceased)

The VA/NU Myoelectric Hand

Ten of the 15 subjects fitted with the VA/NU Myoelectric Hand System elected to continue wearing the experimental prosthesis. Two subjects preferred to use the system on a part-time basis and are therefore considered "partial acceptances."

Sixty-seven percent of the subjects continue to wear the prosthesis on a regular basis, 13.3 percent on a part-time basis, and 20 percent rejected the device completely.

Of the 12 subjects (including the 2 "partial acceptances") who accepted the VA/NU Myoelectric Hands, the average wear time was 12.7 hours per day, 6.96 days per week, ranging from 4 to 18 hours per day and 6.5 to 7 days per week.

The developer's claims that the VA/NU Myoelectric Hand reduces the amount of effort required to operate the hand, supplies more natural control, and is more comfortable and "more natural" because of the Northwestern University self-suspended, self-contained socket, appeared to be verified by the subjects' responses. Six subjects claimed that the myoelectric hand required less effort to operate, and 6 said it was easier to don. Four observed that the terminal device was easier to position and control, 7 thought the prosthesis had more natural control, 2 found the socket more natural, and 11 said they appreciated the absence of a harness. Eight subjects said they liked the cosmesis of the prosthesis, while 1 said he thought the experimental hand felt light in weight.

However, 7 complained of inadvertent operation of the device, while only 1 stated that the myoelectric prosthesis was more reliable. Despite this, most subjects preferred to continue wearing the myoelectric hand.

Six subjects complained that hand operation was too slow, while 1 said it was satisfactory; the others did not comment on the speed of hand function.

Two subjects found the device noisy, 2 felt the hand was not strong enough and had limited lifting power, and 1 thought the prosthesis was too heavy.

Two subjects found the hand too cumbersome (versus the hook); yet another, who had never worn a conventional device before said he "likes" it.

The following figures summarize the overall acceptance/rejection of the 15 subjects fitted: 10 acceptances, 2 partial acceptances, and 3 rejections.

Clinic Team Reactions

The responses of the Clinic Teams were so varied that it was difficult in some instances to find any features that were liked or

disliked by a majority. Some contrasting reactions were almost identical in number for a particular feature; for example, the speed of the VA Elbow was considered satisfactory by 7 teams, but too slow to 8 others. Generally, however, the teams reinforced the reactions of the test subjects, while expressing some interesting opinions of their own.

To simplify analysis of the Clinic Teams' reactions the following discussion is separated into three sections: the first analyzes the teams' opinions of the devices, the second discusses their reactions to the control method; and the last contains a general discussion of training, batteries, chargers, and prescription considerations.

The VA Elbow

The reactions of the Clinic Teams to the devices are summarized in Table 17. Some definite conclusions can be made about the fact

TABLE 17.—*Clinic Team Reactions to VA Elbow and VA/NU Hand*

Feature	No. of teams	
	VA Elbow	VA/NU Hand
Reliable	8	6
Unreliable	3	2
Reliable but too many breakdowns	—	1
Not strong enough	16	—
Speed satisfactory	7	7
Too slow	8	4
Noise satisfactory	1	6
Too noisy	11	5
Not enough free swing	5	—
Good for SD or short AE	5	—
Less strenuous to use	4	—
Allows more function	2	—
Lifting force adequate	1	—
Better use of TD	1	—
Lessens activities	1	—
Allows natural motions	2	—
Hindrance in driving	1	—
Cosmesis is good	—	4
Too heavy	—	2
Prehension force good	—	4
Powered hook needed	—	2
Can perform more activities	—	1
Instant response	—	1
Less tiring	—	1
Prefer myoelectric hand	—	1
Wires subject to breakage	—	1
Myoelectric placement critical	—	1
Cosmetic glove soils	—	1
Myoelectric hand has natural control	—	1

that 16 of the 18 teams found the elbow insufficient in strength, while 11 teams commented on the noise level as too noisy. Eight teams found the device reliable, while 3 found it unreliable. Five teams were in agreement that the elbow did not allow enough free swing. Four teams considered the device less strenuous to use, and 5 emphasized that it was especially good for shoulder-disarticulation and short above-elbow amputees because of the reduced excursion and effort.

The VA Hand

Reactions to the VA Hand were without trends. Probably the only significant reaction is that 6 teams found the hand reliable as contrasted with 2 that did not and 1 that found it partially reliable. Three teams thought the cosmesis was good. The balance of the reactions is shown in Table 17. Generally the Clinic Teams liked the hand but were concerned with the number of breakdowns.

The VA Switch Control

The Clinic Teams held definite opinions about the switch control of the elbow and the hand. Five found the switch to be unreliable, of which 2 claimed frequent breakage and 3 complained of inadvertent operation. Four thought the switch was too difficult to use. Most significantly, the majority of Clinic Teams agreed that they would not prescribe the switch unless it was improved; most referred to its lack of reliability.

The Myoelectric Control

The Clinic Team reactions to the myoelectric control system were overwhelmingly favorable, based in part on positive subject response: some veterans expressed enthusiasm for the control, others liked the ease of functional use with this method, and 4 veterans were pleased that no harness was necessary. For prescription purposes most teams said they would select the prosthesis even though there were numerous breakdowns; they felt that the various good features outweighed this disadvantage. Some Clinic Teams felt that eventually these breakdowns would be reduced to a minimum, making the device even more desirable.

General Reactions from the Clinic Teams

Training

The most significant factor is that practically all teams considered the training information provided as adequate. Two teams felt that

nonprevious prosthesis wearers needed less training, and 1 team felt that the training was satisfactory for this group.

Battery and Charger

Most teams thought that the batteries and chargers were adequate. Two teams stated that the batteries had bad connectors, and one complained of a short battery life. There were no complaints about the charger.

Prescription

In general, the teams would not prescribe the switch control, but would prescribe the myoelectric control. However, each decision was usually qualified with "would not prescribe switch unless improved," or similar statements, or "would prescribe the myoelectric control but would prefer fewer breakdowns."

INCOMPLETE CASES

Sixty-nine subjects wore the experimental units for the complete test period. Fifteen subjects discontinued wearing the devices for the following reasons:

1. Three rejected the VA Elbow for reasons of general unit function.
2. One, because of a medical-surgical condition not related to his amputation.
3. Three, because of uncooperative attitudes.
4. Four, because they were unable to spend the necessary time for training and followup.
5. One, a forequarter amputee, died.
6. One moved.
7. Two, because the system was contraindicated.

SUMMARY AND CONCLUSIONS

The results have been presented of a 2-year survey designed to determine whether external power systems offer a significant contribution to the needs of the upper-limb amputee or whether they represent novelties duplicating the functions of conventional mechanical components. The following conclusions have been drawn:

1. External power does offer advantages to the arm amputee. Myoelectric control, especially combined with a self-suspending socket, offers an otherwise normal partial forearm amputee better function without the necessity of a harness. External power,

especially for the short partial or total arm amputee and others with limited excursion, brings increased function with less effort. For these patients the advantages of such components as the electric elbow outweigh the recent disadvantages.

2. The components evaluated in this Study are not without limitations. Maintenance requirements of the VA Elbow were excessive. The VA Elbow should not be prescribed for patients who do heavy work with their prostheses because the flexspline may break. Regarding such concerns as lack of sensory feedback, noise, weight, and flexion/extension speed, the advantages of each unit must be weighed against the disadvantages with preference to the individual amputee.

3. The endoskeletal forearm with soft cover is an advantage because of its lightness and cosmesis.

4. Because of the many malfunctions attributed to prosthetist errors, the need is evident for thorough specialized education in the field of external power. A few centralized fabrication facilities may be desirable as opposed to fabrication by many facilities with limited experience. Modular components that are interchangeable and field repairable would be desirable. The systems should be fitted, installed and repaired only by trained prosthetists who have successfully completed a course in externally powered upper-limb prostheses. All members of the Clinic Team should be thoroughly educated in external power as it is related to prosthetics.

5. Many malfunctions were due to patient misuse. Patients, too, after careful selection must be given thorough training in the care and use of externally powered components, including the limitations and capabilities of these devices.

6. Finally, and most important, the Clinic Team must be recognized as the focal point for the selection of patients and prescription of devices. Each patient must be carefully screened for information such as occupation, motivation, prosthesis use (as opposed to wear), ability to learn and follow through with instructions (charging batteries, etc.), and most importantly, the benefits that external power can offer.

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