INTERIM REPORT ON VA CLINICAL EVALUATION OF EXTERNALLY POWERED UPPER-LIMB PROSTHESES[a] (June 1971–June 1972)

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INTRODUCTION

The Veterans Administration's Prosthetic and Sensory Aids Service launched the Clinical Application Study of Externally Powered Upper-Extremity Prostheses with an orientation course, held in conjunction with Northwestern University Prosthetic-Orthotic Center, April 5–9, 1971, in Chicago, Illinois. The following systems to be evaluated were introduced at that time: The VA switch-controlled elbow, the VA switch-controlled hand, the VA/NU myoelectric hand, and the VA elbow/hand system.

SUBJECT DATA

The first patient was fitted in June 1971. As of June 30, 1972, 70 subjects from 18 participating stations (including two Army hospitals and Northwestern University) were in the process of being fitted with, or had been wearing, the experimental prostheses.

The 18 stations with Prosthetic Appliance Clinic Teams were:

VAH, Atlanta, Georgia
VAOPC, Boston, Massachusetts
VAH, Chicago (West Side), Illinois
VAH, Cleveland, Ohio
VAH, Dallas, Texas
VAH, Denver, Colorado
Fitzsimons General Hospital Denver, Colorado
VAH, Houston, Texas

[a] This clinical evaluation was authorized on October 26, 1970, by Circular 10–70–242 of the Department of Medicine and Surgery, U.S. Veterans Administration. Mr. William M. Bernstock was designated as Project Director, and Mr. Earl A. Lewis was designated as Associate Project Director. Data collection was begun in June 1971.

VAH, Los Angeles (Wadsworth), California
VAH, Miami, Florida
VAH, Nashville, Tennessee
Northwestern University, Chicago, Illinois
VAOPC, Philadelphia, Pennsylvania
VAH, St. Louis, Missouri
VAH, San Francisco, California
VAH, Seattle, Washington
Valley Forge General Hospital Phoenixville, Pennsylvania
VA Center, Wood, Wisconsin

Of the 70 subjects, 11 were shoulder-disarticulation amputees (5 right, 5 left, 1 bilateral); 36 were above-elbow amputees (22 right, 14 left); and 23 were below-elbow amputees (9 right, 13 left, 1 bilateral). (See Table 1.)

TABLE 1.—*Percent Stump Length and Level and Side of Amputation*

Amputation Level	Stump Length, %	Side R	Side L	Total	Range, %	Mean, %
ABOVE ELBOW						
S/D and forequarter	0	6 [a]	6 [a]			
Humeral neck	0–30	—	—			
Short	30–50	8	4			
Standard	50–80	9	6			
Elbow disarticulation	80–100	5	4	48 [b]	0–100.0	62.6
BELOW ELBOW						
Very short	0–35	2	5			
Short	35–55	2	6			
Long	55+	7 [a]	2 [a]	24 [b]	20.0–95.0	46.9

TOTALS: 68 Unilateral
2 Bilateral
70 Subjects
72 Amputations

[a] Includes 1 bilateral.
[b] Includes bilaterals.

The majority (52) of the patients were of the Vietnam era. Ages ranged from 18 to 58 years, with a mean age of 31.6 years. Average height was 70.5 in., ranging from 64 to 77 in., while average weight was 170.8 lb., ranging from 105 to 250 lb. Amount of education ranged from 8 to 22 years, averaging 12.7 years. (See Table 2.)

TABLE 2.—*Subject Data*

Amputee data	Years	Inches	Pounds	No. of subjects	Total	Range	Mean
Age	Under 20	—	—	2			
	20–29	—	—	40			
	30–39	—	—	7			
	40–49	—	—	15			
	50–59	—	—	6	70	18–58 yrs.	31.6 yrs.
Height	—	64–65	—	4			
	—	66–67	—	3			
	—	68–69	—	14			
	—	70–71	—	22			
	—	72–73	—	17			
	—	74–75	—	7			
		76–77	—	3	70	64–77 in.	70.5 in.
Weight	—	—	100–109	1			
	—	—	110–119	0			
	—	—	120–129	1			
	—	—	130–139	4			
	—	—	140–149	7			
	—	—	150–159	14			
	—	—	160–169	8			
	—	—	170–179	12			
	—	—	180–189	7			
	—	—	190–199	8			
	—	—	200+	8	70	105–250 lb.	170.8 lb.
Education	7–8	—	—	3			
	9–10	—	—	9			
	11–12	—	—	30			
	13–14	—	—	13			
	15–16	—	—	12			
	16+	—	—	3	70	8–22 yrs.	12.7 yrs.

Eleven subjects, 5 below-elbow and 6 above-elbow amputees, were non-previous prosthesis wearers. The mean length of wear of conventional prostheses was 8.1 years, ranging from 0 to 28 years. Subjects wearing conventional prostheses (previous prosthesis wearers) had worn their present prostheses for a mean of 3.3 years, ranging from 2 months to 20 years. (See Tables 3 and 4.)

TABLE 3.—*Years of Prosthetic Wear*

Range, yrs.	No. of subjects
0	11
Less than 1 yr.	9
1–4	28
5–8	0
9–12	1
13–16	3
17–20	4
20+	14
	TOTAL 70

Range: 0–28 yrs.
Mean: 8.1 yrs.

TABLE 4.—*Length of Wear of Pre-Study (Conventional) Prosthesis*

Range, yrs.	No. of subjects
0	11
Less than 1 yr.	10
1–4	32
5–8	8
9–12	6
13–16	1
17–20	2
	TOTAL 70

Range: 0–20 yrs.
Mean: 3.3 yrs.

PROTOCOL OF STUDY

Each Clinic Team, upon selecting a subject for the study, submitted Form UE–IS (Selection and Prescription) to the Research and Development Division, PSAS. Decisions to accept or reject subjects were based upon criteria as published in the Manual for Clinical Application Study of Upper-Extremity Prostheses, April 1971. Once a subject was selected for participation in the study, the appropriate components and accessories were shipped to the designated prosthetic facility.

After the final fitting, Form UE–2P (Prosthetist's Fitting Report) was completed and forwarded to the R&D Division, PSAS. The patient was then trained by a qualified therapist, and the prosthesis was checked out by the Clinic Team and delivered to the patient. Form UE–3D (Delivery Report) and its Appendix A (Checkout) were completed and sent in. Fifteen days and again 1 month after the completion of training, the patient was interviewed by the Clinic Team and Form UE–4F (15-Day and One-Month Follow-up Reports) were submitted. The final evaluation was scheduled for 3 months after delivery; Form UE–6F (3-Month Follow-up Report) was used for this evaluation. Patient and Clinic Team comments were noted and analyzed. Malfunctioning, broken, failed, and lost or damaged components were replaced as soon as possible after being reported to R&D, and Form UE–5P (Malfunction Report) was completed and returned with the malfunctioned unit to the R&D Division. All returned units were carefully diagnosed as to cause, nature of failure, and possible conditions to which the component was subjected.

All information was recorded, and a monthly report was compiled for the use of the developers and appropriate "in-house" staff. Periodic recommendations and changes in the various systems were adopted. (See sections "Problems and Changes Made or Planned" for details.)

SYSTEMS

The VAPC Elbow System

The VAPC Electric Elbow (Fig. 1 b.) is essentially the same size and weight as the Hosmer E–400 elbow. It fits both the standard forearm and the elbow turntable. The device is powered by a small permanent magnet electric motor. The motor shaft is coupled directly to a planetary roller reduction harmonic drive wave generator, which forces the flexible spline of the harmonic drive to engage the rigid spline. The flexspline is fixed to the square output tang on the outside of the elbow which is adapted to engage a square hole in the forearm saddle. The rigid spline, which is also the elbow housing, acts as a reaction point in the gear reduction process. The high motor speed (11,000 r.p.m.) is reduced approximately 12:1 by the planetary wave generator. The harmonic drive achieves a ratio of exactly 80:1. The limits of flexion and extension are controlled by two microswitches and four diodes. Attempts to extend or flex the elbow past these limits activate the switches which shut down the power.

The VAPC Control System consists of a five-position switch, which is easily inserted into the front support strap (FSS) of the above-elbow Figure-8 harness. Shoulder extension, a motion formerly used to lock and unlock the conventional elbow, provides full control of the position of the VAPC powered elbow. The elbow is powered by a 25-volt nickel

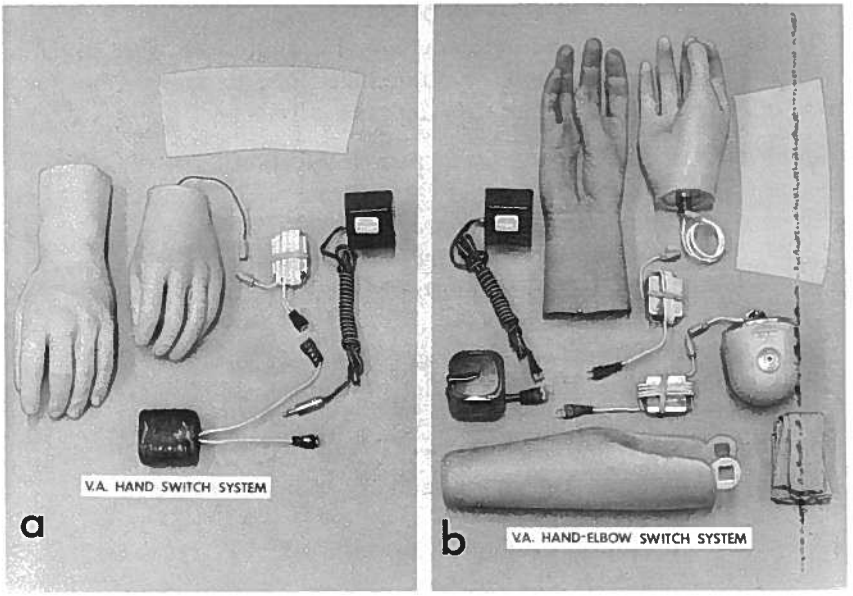

FIGURE 1.—a.The VAPC Switch-Controlled Hand System: plastic wrist fairing, cosmetic glove, VAPC hand and PVC shell, switch, charger, and 12-volt battery pack (with resistor); b. The VAPC Hand/Elbow System: charger, cosmetic glove, VAPC hand and control switch, plastic wrist fairing, 25-volt battery pack, control switch, VAPC elbow, soft foam forearm, and stockinet cosmetic cover.

cadmium, rechargeable battery. The elbow motor uses a nominal 24 volts for operation and it draws less than 300 ma. to bring a loaded elbow from 10 deg. of extension to full flexion (135 deg.) in less than 2 seconds. Forearm malalignment can significantly affect the efficiency of the system by continuously applying a frictional load on the elbow.

In December 1971, the soft (foam) endoskeletal forearm was introduced for use with the powered elbow. The forearm is lighter, puts less load on the elbow, is claimed to be more cosmetic, and may reduce damage to clothing and furniture when struck by the forearm. In cases where amputees have long above-elbow stumps, it is necessary to place the battery pack in the forearm section. The soft forearm does not make provision for battery-pack placement in the forearm. Therefore, at this time, the soft forearm may be used only by patients with short to mid-length stumps. Those amputees with long stumps who require location of the battery pack in the forearm must use the hard, crustacean-type forearm. As of June 30, 1972, no subjects had completed the 3-month wear period with the soft forearm and there is, therefore, no other information to report on at this time.

Malfunctions of the VAPC Elbow System

During the reporting period, 69 elbows for 47 subjects were issued or reissued. Thirty-seven elbows malfunctioned one or more times for a total of 56 failures, with the following causes:

13—Manufacturing error or poor fabrication.
- Specifically:
  - Limit switch not set properly (2)
  - Motor burn-outs (elbows with small motor shaft) (3)
  - Cold solder joint on printed circuit board to microswitch (1)
  - Forearm saddle malaligned (7)

16—Misuse, accident, or overload by subject.
- Specifically:
  - Flexspline cracked (16)

20—Prosthetist error in fitting, fabrication, or repairs.
- Specifically:
  - Assembled without thrust washer (7)
  - Lost parts (2)
  - Elbow installed backwards (2)
  - Improper installation, resulting in binding (3)
  - Operating from hand switch; wrong voltage (1)
  - Overtightened screw, jamming motor shaft (2)
  - Elbow off a gear tooth (1)
  - Excess dust, dirt, and foreign particles found inside housing (2)

7—Component failure, cause unknown:
- Limit switch bent or broken (2)
- Small motor shaft broken or showing excessive play (5) (on early model elbows)

Only three malfunctions of the battery packs occurred: One battery-cell failure, one due to prosthetist error (batteries partially discharged—field-repairable), and one with cause unknown. Only one charger malfunctioned, due to misuse (wires pulled out).

Problems with the VAPC Elbow and Changes Made or Planned

The VAPC powered elbow has shown an approximate 50 percent acceptance rate (7:8 ratio of conventional to powered elbows). The major problems, complaints, malfunctions, and/or failures have been as follows:

The VAPC elbow used in the beginning of the study utilized a *small motor shaft* which burned out easily. A larger motor shaft has been used in all units since the fall of 1971.

Flexspline failures constituted 30 percent of all elbow malfunctions

(17 out of 56). In the majority of these cases, the flexspline cracked when an overload (greater than 358 in.-lb.) was applied, or when a sudden shock load was applied, as in a fall. An improved version of this model elbow will contain a flexspline with additional fiber glass, which, according to laboratory tests, increases the strength of the elbow flexspline approximately by 80 percent.

The *motor* itself is not easily field-repairable in its present configuration. Design changes in the wave generator and planetary rollers should result in increased serviceability and easier motor replacement. This new elbow will have a quick disconnect (Fig. 2) to allow easier fabrication and access to the elbow, as well as fittings to longer stumps by elimination of the long stud. The same drive and motor system will be used until a new motor is available for a more sophisticated elbow contemplated for the future.

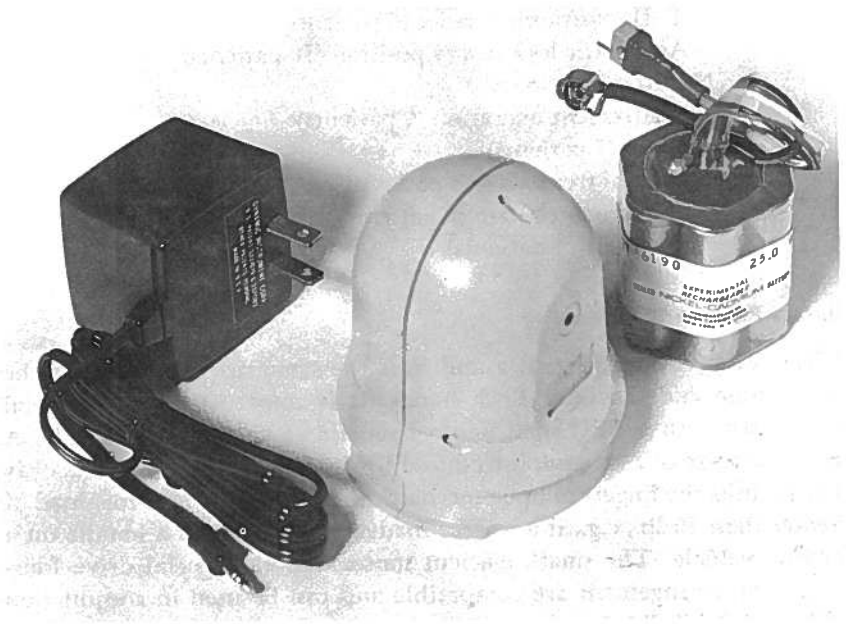

FIGURE 2.—The revised VAPC Elbow System: quick-charge battery charger, elbow, and battery pack (which has since been significantly reduced in size).

Prosthetists' and patients' complaints that the *battery pack* is bulky and difficult to place have resulted in a design change to make it smaller and lighter with a *quick-charge* (1 hour) feature, and a separate charging connection with a jack for easier accessibility.

Problems of *inadvertent operation* have indicated the need for a plug-in disconnect on/off switch. Such a switch is now available upon request.

This on/off switch is installed in line with the battery and control switch and will shut down the power when desired.

Because of the many difficulties in engineering and design, the major problems of *noise, limited load capability,* and *lack of free swing* have not produced immediate changes. However, working models of a more advanced elbow with EMG control will hopefully have significantly improved operating characteristics (by using high-energy magnets and other techniques), and will have free swing, decreased noise and weight, and an overload release (breakaway). These features, unfortunately, will result in higher cost.

User Reaction to the VAPC Elbow (comments from 15 patients)

Positive reactions:
- Ease of effort (9 patients)
- More natural control (6 patients)
- T. D. positioning easier (6 patients)
- Automatic lock in *any* position (10 patients)

Negative reactions:
- Inadvertent operation (9 patients)
- Noise (7 patients)
- Lack of free swing (8 patients)
- Not strong enough (8 patients)
- Too slow (4 patients)

The VAPC Hand System

The VAPC Hand (Fig. 1, a and b) is the same size and shape as the Viennatone and the Otto Bock hands. It is constructed on a skeletal framework with a PVC shell and a cosmetic glove over the outside. 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., e.g., if a wearer inadvertently grasped a handle on a moving vehicle. The small, efficient motor and the special drive four-stage gear arrangement are compatible and can be used in conjunction with the VAPC elbow.

The hand is controlled by the same type of five-position pull switch as used for the elbow. The switch is readily inserted into the control attachment strap (CAS) of a below-elbow "butterfly" harness or an above-elbow Figure-8 harness. If an above-elbow patient is fitted with a powered elbow *and* hand (Fig. 1b), the switches may be placed in the FSS (for the elbow) and the CAS (for the hand); they *may* be placed in series, with both switches in the CAS—varying tension (by the amount of rubber bands) will differentiate function. This latter configuration is not recommended.

The power pack consists of a rechargeable 12-volt (originally 18-volt) battery pack which is placed in the distal forearm section. If the hand is used with the powered elbow, it operates from the same 25-volt battery pack that is used for the elbow, using a tap to provide the required voltage.

Malfunctions of the VAPC Hand System

Twenty-seven switch-controlled *hands* were issued or reissued from June 1971 through June 1972. Fourteen hands malfunctioned one or more times (19 malfunctions), with the following causes:

5—Manufacturing error or poor fabrication.
Specifically:
Internal motor failure (2)
Back-lock mechanism failure (under-designed) (2)
Brushes worn due to small motor shaft (1)

3—Misuse or accident by subject.
Specifically:
Broken lead in hand (1)
Thumb bent (1)
Breakaway used excessively (1)

5—Prosthetist error in fitting, fabrication, or repairs.
Specifically:
Fingers not reset, or only partially reset, after breakaway used (1)
Polarity reversed (1)
Elbow switch used for hand (1)
Attachment screws loose (1)
Field-repairable failure not attempted (1)

2—Inadequate training by therapist.
Specifically:
Patient maintained tension on switch, creating thermal overload and burn-out of motor by keeping power "on" with hand in fully closed position (2)

4—Component failure, cause unknown.
Specifically:
Water damage (rust and corrosion) (1)
Broken leads (3)

Thirteen hands are still in use, and 13 hands had no malfunctions.

Nineteen *chargers for* switch-controlled hands were issued during the report period; of these, seven malfunctioned and 12 had no malfunctions. The malfunctions of the chargers were found to have been caused by the following:

1—Manufacturing error or poor fabrication.
Specifically:
Incorrectly wired charger plug (1)
2—Misuse or accident by subject.
Specifically:
Broken by patient's children (1)
Charger plug stepped on (1)
1—Prosthetist accident in fitting, fabrication, or repairs.
Specifically:
Prosthetist inadvertently pulled wires out (1)
2—Component failure, cause unknown.
Specifically:
Short in charger plug (1)
Broken charging jack (1)
3—Other.
Specifically:
Charger for myoelectric system used (not compatible with switch hand) (2)
Damaged in shipping (1)

Eighteen *battery* packs were issued for switch-controlled hands; of these, five malfunctioned one or more times (7 malfunctions), and 13 had no malfunctions. Thirteen battery packs are still in use. The malfunctions were attributed to:

4—Mistakes in fabrication, or manufacturing errors.
Specifically:
Battery incorrectly wired (1)
Bad cell in battery pack (1)
Dropping resistor too high (1)
Loose connectors (1)
2—Prosthetist errors in fitting, fabrication, or repairs.
Specifically:
Batteries partially discharged; needed charging only (1)
Batteries jammed into wrist section and crushed (1)
1—Component failure, cause unknown
Broken wire (1)

Problems with the VAPC Hand and Changes Made or Planned

Acceptance rate of the switch-controlled hand was 83 percent or a 6:1 ratio. One special case, a cineplasty wearer, was the only subject who rejected the switch-controlled hand on the basis that the switch control is too fine for use by cineplasty. [Note: This patient was later fitted with a myoelectric hand, and he continues to wear that system with much success.]

Originally, the hands operated from an 18-volt nickel-cadmium (nicad) battery pack. In order to permit charging from the same charger as for the elbow, the system was changed to operate from 12 volts, using a 470-ohm dropping resistor. This resistor proved to be too high and the batteries did not receive enough charge. The resistor was therefore changed to 220 ohms, which resulted in an increased charging rate and reduced *battery-pack failure.*

Several *shipping* errors occurred in "matching" chargers for switch-controlled hands versus chargers for myoelectric hands. This was corrected by the change from 18 volts to 12 volts by using the dropping resistor, by correct labeling of all chargers, and by changing the charger plug.

The *charger plug* was changed to a "tiny jack" for ease of plugging into the receptacle (on below-elbow systems only). It is therefore unnecessary to remove the battery leads from a "window" in the distal socket; it does, in fact, preclude the need to open or close the "window" for purposes other than for removing or replacing the battery pack.

Complaints of *slippage of grasp* were reduced when improved thumb pads were added to the skeletal "thumb."

Major problems of *noise, wearing of the "no-back" assembly,* and *slow speed* have resulted in the following design changes:

1. A new high-powered motor with heavy-duty brushes and armature, resulting in increased performance in speed and torque, was introduced in January 1972.
2. The newest model hand, to be introduced shortly, has had the following changes: An even more powerful motor, different materials for the gears, different ratio in the second stage of the gear train; an end-cap over the motor; and plastic instead of Oilite bearings. These changes have resulted in noticeably reduced noise and increased speed during lab tests (.94 seconds is the specification for maximum speed from full open to close. The average *testing* time has been .7 seconds).
3. A "no-back" assembly with a higher capacity and a reduced number of parts, which have eliminated the "click" or releasing noise upon opening from full close, has been introduced.
4. The above changes have also resulted in increased pinch force (17–18 lb. is the specification for prehension. Testing forces, however, have averaged 18–22 lb.). (For additional changes, see section under the VA/NU Myoelectric system.)

User Reaction to the VAPC Hand (comments from 6 patients).

Positive reactions:

Ease of effort (6 patients)

Improved cosmesis (3 patients)

Easier to don and doff (use of NU supracondylar, self-suspended socket with simple butterfly harness) (2 patients)
More comfortable harness (2 patients)
Noise feedback (2 patients)

Negative reactions:

Too fast (3 patients)
Inadvertent operation (1 patient)

The VAPC Switch-Control System

The switches themselves are discussed in this separate section, as the topic now is *control* (as opposed to component features). These switches, as described in the section on the VAPC Elbow, are basically the same for both the elbow and the hand, with the following exceptions: the hand switch has two male prongs for connection with the battery pack; the elbow switch has one male prong for this connection; voltages are different in that the elbow switch uses approximately 24 volts and the hand switch uses a nominal 12-volt circuit.

Malfunctions of the Switches

Eighty-three switches for VAPC Hand, VAPC Elbow, or VAPC Hand/Elbow Systems were issued during the report period. Eighteen of these malfunctioned one of more times (25 malfunctions); fifty are still in use, Sixty-five switches had no malfunctions.

The following causes were attributed to the malfunctioning of 18 switches (includes multiple causes):

9—Manufacturing error or poor fabrication.

Specifically:

Cold solder joints on printed circuit board (4)
Excess RTV interfering with switch function (2)
Casing cracked near Allen screw hole (1)
Loose connectors (1)
Leads too short to be mounted in harness (1)

1—Misuse or accident by subject.

Specifically:

Wires torn loose (1)

7—Prosthetist error in fitting, fabrication, or repairs.

Specifically:

Lead broken off printed circuit board (field-repairable) (5)
Mixed up switches for hand and elbow (1)
Prosthetist overtightened Allen screw (1)

8—Component failure, cause unknown:
Actuators bent (2)
Wires "mashed" (2)
Wires torn loose (3)
Wires cut (1)

Problems with the VAPC Control System and Changes Made or Planned

The *leads* were susceptible to strain and breaking off from the printed circuit board inside the switch. The introduction in November 1971 of room-temperature vulcanized rubber (RTV) for strain relief has resulted in a substantial reduction of this failure.

The *last "off" (fifth)* position has proven to be undesirable or unnecessary in many cases. A button stop to eliminate this fifth position was introduced in December 1971 and is available *only* upon request.

The *switch case* cracked very easily in the location near the setscrews, because the case was initially manufactured out of specification. The case has since been strengthened (made somewhat thicker) so as not to require as critical a specification. A smaller setscrew is also being used.

Problems of *inadvertent operation* had been shown to be almost always a harnessing problem. An on/off switch is suggested in these cases. (See section under VAPC Elbow System.)

Many of the returned switches had *cold solder joints* at the connection of the leads to the printed circuit board. This should be corrected by improving the quality control of fabrication.

User Reaction to the VAPC Control System (comments from 21 patients)

In almost every case, positive reactions were ease of effort (15 patients) and less excursion requirements, with only $5/16$ in. total excursion (11 patients). In above-elbow cases, this resulted in easier and/or better terminal device control and positioning; in below-elbow cases, this resulted in more natural-appearing control and lower energy requirements.

Negative reactions were mostly inadvertent operation (10 patients) and difficulty in finding switch positions (3 patients).

The VA/NU Myoelectric-Control System

The hand used in the VA/NU Myoelectric Control System (Fig. 3) is essentially similar in structure to the VAPC Switch-Controlled Hand. The end-plate of the hand has been reduced in diameter to fit the wrist unit which contains the 12-volt batteries, EMG amplifier, and leads.

Operation of the hand is controlled by the detection and amplification of the electrical activity of two stump muscle groups (flexors and extensors). The electrical activity, or myoelectric signals, are sensed by two stainless-steel button electrodes, connected to the input stage of the

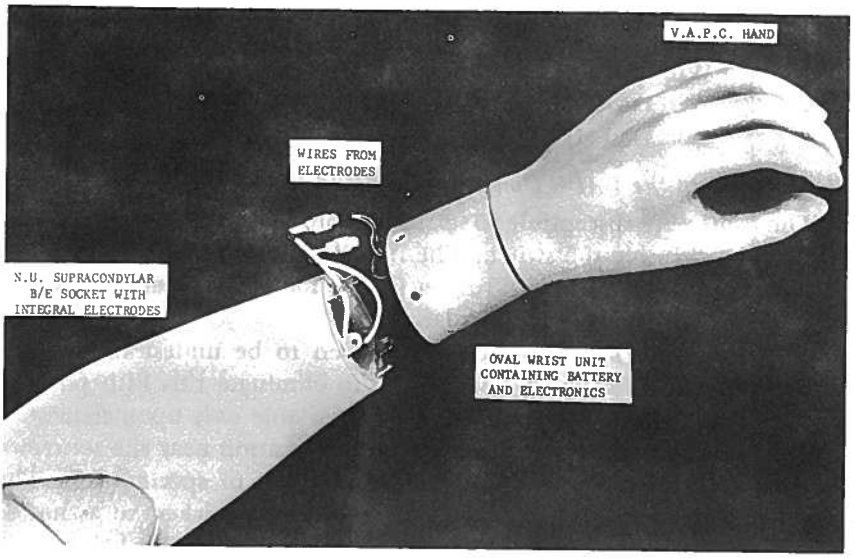

FIGURE 3.—The VA/Northwestern University Myoelectric System with self-suspended, self-contained supracondylar socket.

amplifier, amplified, and transmitted through the output stage 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.

The VA/NU Myoelectric System utilizes the NU self-contained, self-suspended supracondylar socket, which requires no harnessing. Use of this socket is not limited to externally powered prostheses.

Malfunctions of the VA/NU Myoelectric System

Thirty-six *myoelectric hands* were issued to 13 patients during the report period; of these, 28 malfunctioned one or more times (38 malfunctions) from the following causes:

10—Manufacturing error or poor fabrication.

Specifically:

Output power transistors blown (under-designed) (3)
Battery cells dead (1)
Cold solder joint (3)
Grease caked in back-lock mechanism (2)
Defective casting of wrist section (1)

7—Misuse or accident by subject.

Specifically:

Broken by patient's children (1)

Breakaway excessively used and worn (4)
Wrist unit broken from shock load (2)

8—Prosthetist error in fitting, fabrication, or repairs.
Specifically:
Breakaway activated and not, or only partially, reset (2)
Batteries discharged, requiring recharge only (2)
Stops damaged by metal screwdriver used to adjust gain (1)
Broken leads, etc., from prosthetist's attempt to tighten wrist unit (1)
Securing tape removed, damaging electronics (2)

2—Inadequate training by therapist.
Specifically:
Thermal overload and burn-out of motor and/or amplifier—muscle contracting when hand fully closed, creating continuous muscle signals (2)

6—Component failure, cause unknown.
Specifically:
Interference from high frequencies (1)
Lead on printed circuit board burned out (1)
Battery damaged (1)
Lead broken (1)
Batteries shorted (1)
Teeth on plastic spur gear of back-lock mechanism broken (1)

5—Other
Poor electrode contact due to loose socket or poor socket fit (5)

Fourteen myoelectric hands are still in use. Eight myoelectric hands had no malfunctions.

Twenty-one *chargers* for the myoelectric hand were issued. Fourteen are still in use, and 19 had no malfunctions. Three chargers malfunctioned from the following causes:

1—Manufacturing error or poor fabrication.
Specifically:
Short in charger plug (1)

1—Misuse or accident by subject.
Specifically:
Broken by veteran's children (1)

1—Prosthetist error.
Specifically:
Prosthetist pulled wires out (1)

Problems with the VA/NU Myoelectric System and Changes Made or Planned

In spite of the high number of malfunctions, the acceptance rate of the myoelectric hand is 100 percent.

The same problems of *noise, speed,* and *wearing of the back-lock assembly* (as with the switch hand) occurred with the myoelectric hand. The same changes have been made in the myoelectric hand in an attempt to reduce noise, to increase speed and strength of grasp, and to produce a higher capacity of the back-lock. (See section under VAPC Hand.)

Problems with *EMG "burn-outs"* (short circuit on printed circuit board) and EMG amplifier failures have been attributed to extraneous noise entering the input stage of the amplifier. Extraneous noise may be caused by two things: a *poor-fitting socket,* in which case the skin acts as an antenna and extraneous signals are introduced; or, most important, *poor training,* in that the amputee has not been taught to relax the muscle; therefore, a myoelectric signal is introduced when the hand is fully closed, resulting in motor or amplifier burn-out. The new myoelectric hands (Fig. 4) have a simplified EMG circuit (less componentry), which should be less susceptible to noise and extraneous signals. Clinic

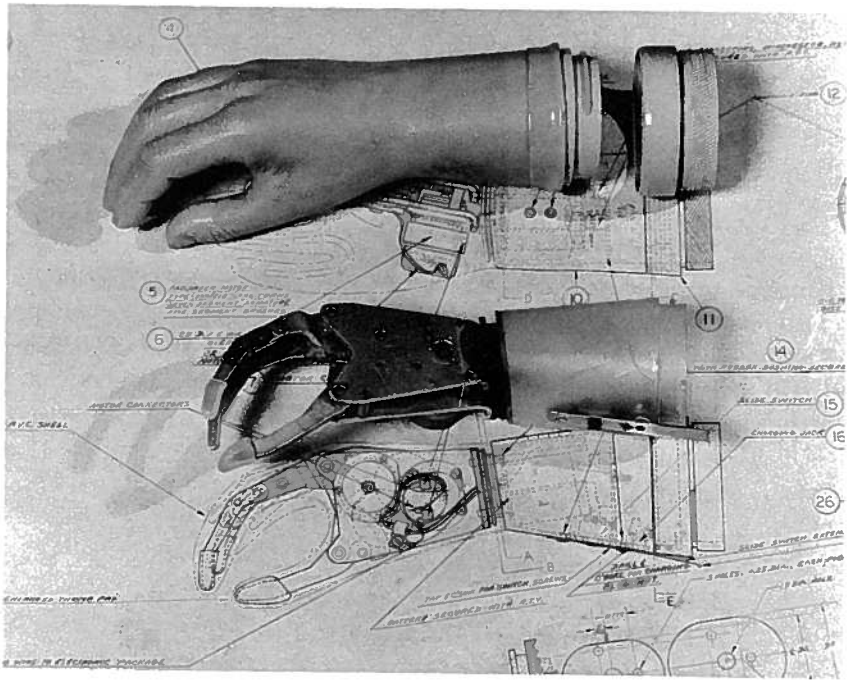

FIGURE 4.—The revised model of the VA/NU Myoelectric Hand with quick-disconnect feature and sealed-off electronics in wrist portion.

Teams have been notified of the importance of an intimate socket fit and the relaxation of the flexor muscles when the hand is fully closed or closed on an object (the back-lock is designed to prevent inadvertent opening).

Complaints of *early discharge of the batteries,* especially with active prosthesis users, have resulted in a change of battery type. Union Carbide 12-volt (225 ma./hr.) batteries are now being used instead of the General Electric 12-volt (180 ma./hr.) batteries.

Some patients have been either *overcharging* (which reduces battery life) or *undercharging batteries.* The newer batteries are of a different capacity with a quick-charge feature (1 hour to complete charge) and an automatic shut-down (giving a "trickle" charge) of the charger. We recommend that future chargers have an indicator light to show when the batteries have been fully charged.

Prosthetists have not been using the *plastic wrist fairing,* which is designed to allow easier rotation of the hand. The new model hands will have a wrist unit which has a quick-disconnect. This will eliminate the need for a plastic fairing, and it will close off the electronics from outside tampering and damage.

Other design changes that have been incorporated into the revised model are: The on/off switch was made smaller to avoid "catching" on clothing and inadvertent switching "on"; new thumb and finger pads have improved the grasp and have provided for easier assembly and disassembly of the hand by facilitating removal of the PVC shell; the undercut (lip) on the button electrodes was eliminated for easier manufacturing.

These newer-model myoelectric hands have two bypass capacitors on the motor leads and motor case ground, resulting in the decreased possibility of interfering with radio frequencies during hand operation, e.g., in an airplane. Changes in the motor and gear train will increase the grasp from 12 lb. to 16–18 lb. (or 20 + lb. *pulsing* signal) and will increase speed (.94 sec., spec.; .7 sec. test). Proper (oval) setscrews in the finger breakaway should increase the life of the breakaway, requiring less frequent resetting of the mechanism.

User Reactions to the VA/NU Myoelectric System (comments from eight patients who completed 3 months (or more) of wear by June 30, 1972)

Positive reactions:

More natural and easier control (7 patients)

Lack of harness (8 patients)

Improved cosmesis (because of lack of harness) (7 patients)

Easier to don and doff (5 patients)

Negative reactions:
Too slow (2)
Noisy (2)

Additional Information on the VA/NU Myoelectric System

The following additional information on the VA/NU Myoelectric System is of interest:

1. Five socket refittings were necessary, due to either poor fit or stump shrinkage. The socket *must* be of an intimate fit with the stump, or ambient noise, poor control, and "jerky" hand motion will occur.
2. One case was fitted immediately postoperatively (first in VA to be fitted IPOP with a myoelectric hand). The procedure was an outstanding success. The very nature of the myoelectric system lends itself readily to immediate fit with excellent results.
3. Two cases have reported that the muscles have hypertrophied markedly and the optimum myoelectric signal sites have changed from the initial locations. These cases have also required socket refittings in order to maintain the gains in a middle range of amplification. Prior to their refittings, the gains were set extremely high (to detect the now "distant" signals), resulting in increased susceptibility to ambient noise and, thus, motor or amplifier burn-outs.

DISCUSSION AND CONCLUSION

Although the study is far from completed, some inferences and suggestions can be made at this time:

1. In most cases, myoelectric control is preferred over switch control.
2. Myoelectric control lends readily to application by immediate postoperative fit. This procedure should be further investigated.
3. The VAPC elbow is presently contraindicated for patients who are extremely abusive users, putting excessive loads on the elbow, or who have heavy-duty occupations.
4. The soft (foam, endoskeletal) forearm cannot be used for patients with long above-elbow stumps. Patients with long stumps require battery-pack placement in the forearm; there is no present provision in the soft forearm for a battery pack. Therefore, above-elbow amputees with long stumps must use the hard, crustacean-type forearm at this time.
5. At least ⅓ to ½ of all malfunctions can be attributed to prosthetist error. The implications are for more thorough, intense, specialized education in the field of external power, a centralized fabrication facility, and/or modular components that are readily interchangeable and easily field-repairable. We recommend that the components be prescribed by a qualified physician who has been

trained in the application of external power. These components should be centrally procured, and major repairs should not be attempted in the field. The components must be fitted by a VA-Qualified prosthetist who has taken an approved course in external power. Finally, the patient should be trained by a therapist who has a thorough, working knowledge of externally powered devices and their applications. In summary, the *entire* Clinic Team should be completely familiar with and thoroughly educated in the use of external power.

6. Patients should be taught *all* aspects of the externally powered components they are wearing. Many malfunctions due to misuse could have been avoided if the patients had been made more aware of the limitations and capabilities of these devices (e.g., one patient *manually* flexed the forearm of a VAPC elbow and cracked the flexspline).
7. The Clinic Team should be the major focal point for selection of patients and prescription of devices. As with any other prosthetic device, external power is not meant for every amputee. Each patient should be carefully screened as to occupation, motivation, prosthesis *use* (as opposed to wear), ability to learn and follow through with instructions (donning and doffing the NU socket, charging the batteries each day, etc.), and, most importantly, to determine the benefits of external power for *that* particular individual.

Other components will be introduced into the study in the future. Included will be a powered hook, above-elbow myoelectric control, a powered wrist rotator, and externally powered devices other than the VAPC and VA/NU systems described in this report.

This study has demonstrated that external power is entering the armamentarium of components for the upper-limb amputee. Improved technology and future data obtained from this and other studies should result in compatible, beneficial, relatively maintenance-free components controlled by external power, giving the upper-limb amputee a more natural-appearing, almost effortless prosthesis.