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Clinical Evaluation of Externally Powered Prosthetic Elbows

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During the past few years, several externally powered prosthetic elbows have been developed and attention has been called to them in the news media. On October 21-23, 1968, the Panel on Upper-Extremity Prosthetics of the CPRD Subcommittee on Design and Development met to survey seven different elbows. Functional characteristics were examined, the elbows were demonstrated on amputees, and recommendations for future development and evaluation were made.

Based on the recommendations of the Subcommittee on Design and Development and subsequent discussion and approval by the CPRD Subcommittee on Evaluation at its meeting on May 27, 1969, a clinical evaluation program was undertaken on the following: (1) the American Institute for Prosthetics Research (AIPR) elbow, (2) the Army Medical Biomechanical Research Laboratory (AMBRL) elbow, and (3) the Boston elbow.

Because of the unavailability of the AIPR elbow, the Rancho Los Amigos Hospital elbow was later substituted for it. It was also decided that the elbows would be evaluated in the following six clinics: Jackson Memorial Hospital, New York University Prosthetics-Orthotics Studies, Northwestern University Prosthetics-Orthotics Center, Rancho Los Amigos Hospital, University of California at Los Angeles Prosthetics-Orthotics Program, and the Veterans Administration Prosthetics Center. To acquire additional clinical experience with the elbows, J. E. Hanger, Inc. of Georgia was later added to the list.

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DESCRIPTION OF ELBOWS

The AMBRL elbow (fig. 1) is a battery-powered, electrically driven unit, which is controlled by a pull switch in the shoulder harness. It has free swing when the elbow is positioned at full extension.

Fig. 1. The AMBRL elbow.

The Boston elbow (fig. 2) is a battery-powered, electrically driven unit, which is myoelectrically controlled by use of surface electrodes on the stump. It has a feedback system that maintains the speed of motion regardless of load.

The Rancho elbow (fig. 3) is a battery-powered, electrically driven unit, which is controlled by a pull switch in the shoulder harness. The McCulloch fast charger is used in conjunction with it.

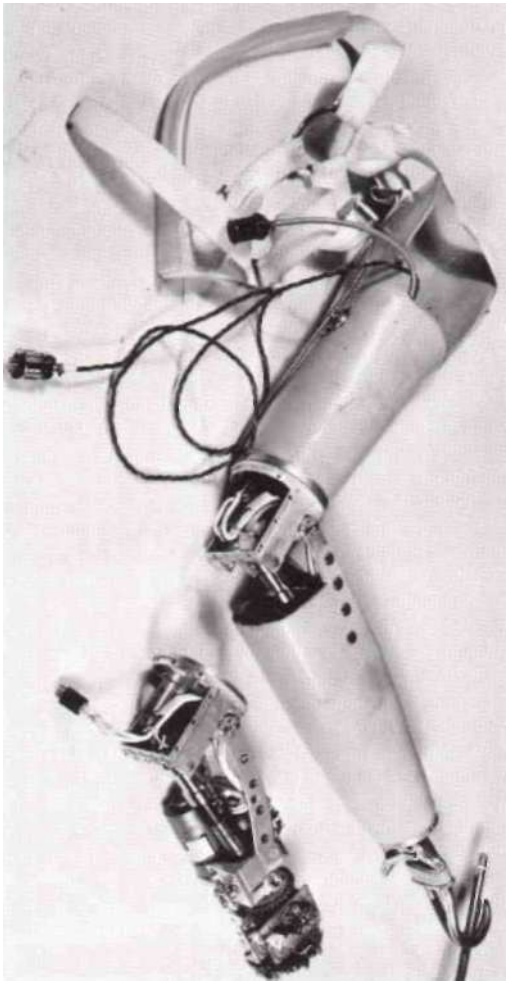


Fig. 2. The Boston elbow.

Fig. 3. The Rancho elbow.

PROCEDURE

ORIENTATION SESSION

An orientation session was held on October 21-23, 1969, for the developers to familiarize the clinic teams with the elbows and for CPRD to familiarize the clinic teams with the evaluation forms. The agenda and list of participants are attached as appendix A to the full report (E-4).

ALLOCATION OF ELBOWS

The final allocation of the elbows to the clinics is given in Table 2.

MECHANICAL TESTING

All the elbows were tested to ensure that they operated satisfactorily and conformed to the mechanical specifications before being sent to the clinics for fitting. Some of the units had to be returned to the developers for additional work before being sent to the clinics.

SELECTION OF PATIENTS

Unilateral above-elbow amputees were selected as subjects for the evaluation because: (1) most of the elbows and their control systems had been designed for use on AE amputees, (2) the unilateral above-elbow-amputee population is much larger than the shoulder or bilateral upper-extremity-amputee population, and (3) it was necessary to have a common base for comparative purposes. Further, the subjects were selected on the basis of having been previous wearers of a conventional, bodily powered, above-elbow prosthesis, because it is now the standard.

TABLE 1. SPECIFICATIONS OF THREE EXTERNALLY POWERED ELBOWS

	Acceptable Specifications	AMBRL Elbow	Boston Elbow	Rancho Elbow
Dimensions (in)				
Width at axis inside saddle	2¼	2¼	2⅝	2⁵⁄₁₆
Minimum distance, axis to stump end	2	5¼	1⅞	2⅛
Total length in full extension	3³⁄₁₆	6¹³⁄₁₆	3⁹⁄₁₆	3⅜
Weight (oz)				
Elbow unit only	12	15.6	33.7	18.5
All additional equipment worn	40.0	12.3	60.0	27.0
Range of motion (deg) (flexion-extension)	10–135	0–125	10–135	0–135
Speed (sec) (flexion)				
No load	2.0	2.0	1.0	2.5
With 12 in-lb load	2.0	2.6	1.0	3.5
Maximum lift (in-lb)	100	72	84	36
Resistance to load (in-lb)	600	192	600	unknown
Noise level at 12 in. (db)	<68	64	65	60
Standard turntable interchangeable	Yes	No	No	Yes
Standard forearm interchangeable	Yes	Yes	No	Yes

Adapted from Report of Sixth Workshop Panel on Upper-Extremity Prosthetic Components of the Subcommittee on Design and Development, October 21–23, 1968, Santa Monica, Calif.

The candidates for the AMBRL elbow were further restricted to AE amputees with relatively short stumps, because the elbow unit protrudes about five inches above the elbow center of rotation. For the Boston elbow, AE amputee subjects had to demonstrate sufficient biceps and triceps EMG activity to operate the control system. The Rancho elbow fitted most AE amputees because it protrudes only about two inches above the elbow center of rotation.

TABLE 2. ALLOCATION OF ELBOWS

Organization	Number of Elbows			Total
	AMBRL	Boston	Rancho	
New York Univ.	2	1	2	5
Northwestern U.	2	2	2	6
U. Calif., LA	2	2	2	6
Rancho Los Amigos	2	2	0	4
Jackson Mem. Hosp.	2	0	1	3
Vet. Adm. Pros. Ctr.	2	0	1	3
J. E. Hanger, Atlanta	0	1	2	3
Total	12	8	10	30

EVALUATION FORMS

Amputee subjects were properly fitted and trained by the clinic teams and were asked to wear each externally powered elbow for a month. Evaluation forms completed before and after the trial-wear period have provided information for considering the results of the evaluation. These forms are attached as appendix B to the full report.

MEETINGS

There was a meeting of the clinics, developers, and Subcommittee on Evaluation on May 12-13, 1970, to consider the preliminary results of the evaluation. The agenda and list of participants are attached as appendix C to the full report.

A second meeting of the clinics, developers, and subcommittee on November 9, 1970, considered the final results of the evaluation. The agenda and list of participants are attached as appendix D to the full report.

RESULTS

SUMMARY

Total number of elbows	30
Number of elbows not evaluated due to inadequate subjects or insu	9
Total number of elbows evaluated	21

Number of amputees preferring conventional elbow	17
Number of amputees preferring externally powered elbow	3
Undecided	1

To begin with, all the amputee subjects were asked what they liked and disliked about their conventional elbows. Most of them cited the positive lock as the best feature, and the control motion and cable needed for the lock as the most undesirable feature.

CLINICAL FITTINGS OF THE AMBRL ELBOW

Total number of elbows	12
Number of elbows not evaluated due to inadequate subjects or insufficient trial wear	4
Total number of elbows evaluated	8

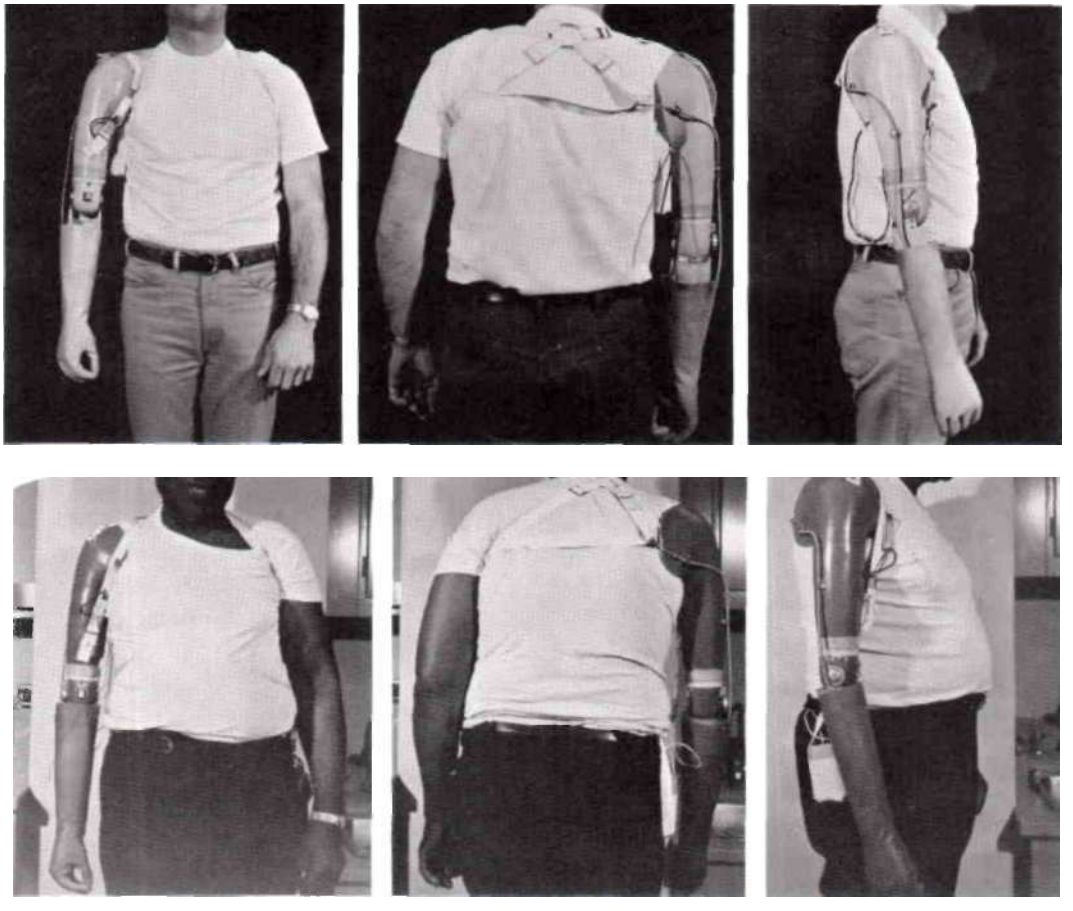
Number of amputees preferring conventional elbow	6
Number of amputees preferring AMBRL elbow	1
Undecided	1

The best features were ease of flexion and free swing.

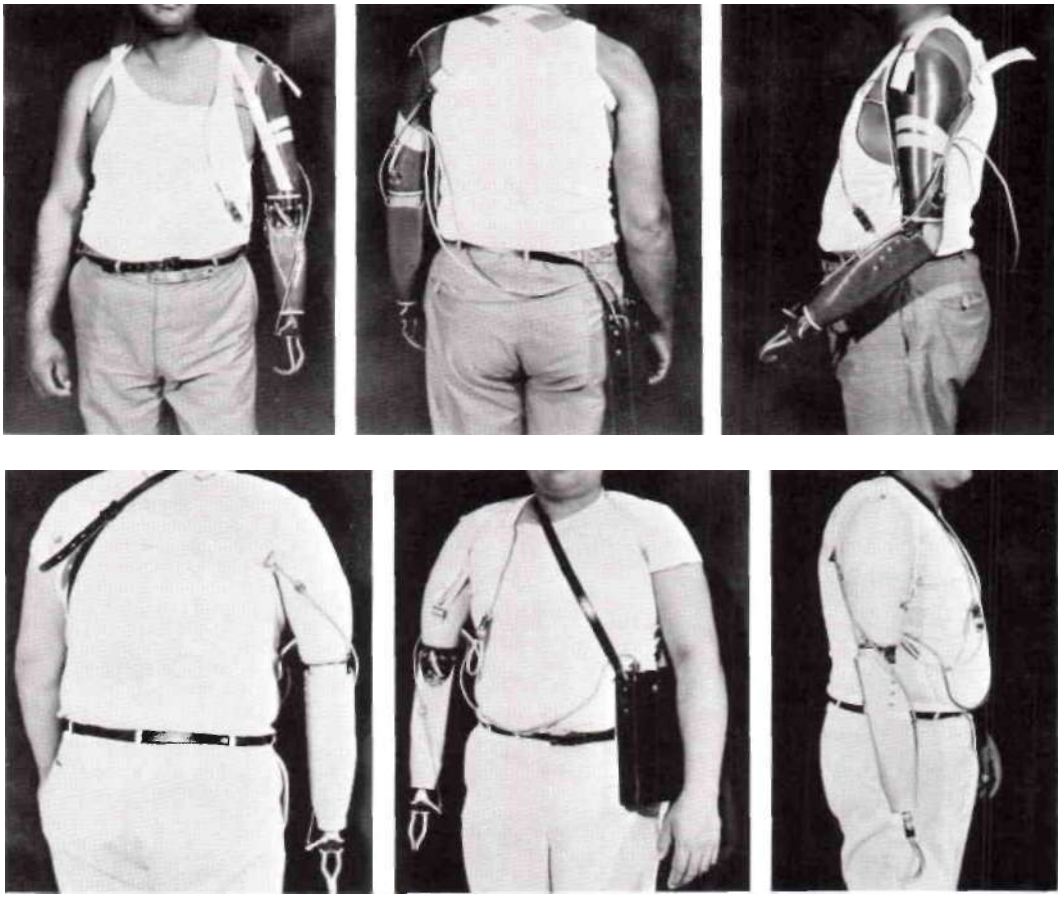
The most undesirable features were: weight, speed, noise, bulkiness, inadvertent operation of switch, lack of positive elbow lock, and size of unit proximal to the elbow joint.

CLINICAL FITTINGS OF THE BOSTON ELBOW

Total number of elbows	8
Number of elbows not evaluated due to inadequate subjects or insufficient trial wear	3
Total number of elbows evaluated	5



Figs. 4 and 5. Amputees fitted at UCLA with the AMBRL elbow.



Figs. 6 and 7. Amputees fitted at UCLA with the Boston elbow.

Number of amputees preferring conventional elbow	4
Number of amputees preferring Boston elbow	1

The best features were ease of flexion and independent elbow flexion and TD operation (not accomplished by all subjects, however).

The most undesirable features were: weight, speed, noise, bulkiness, donning of electrodes, need for tight harnessing, and lack of cosmesis.

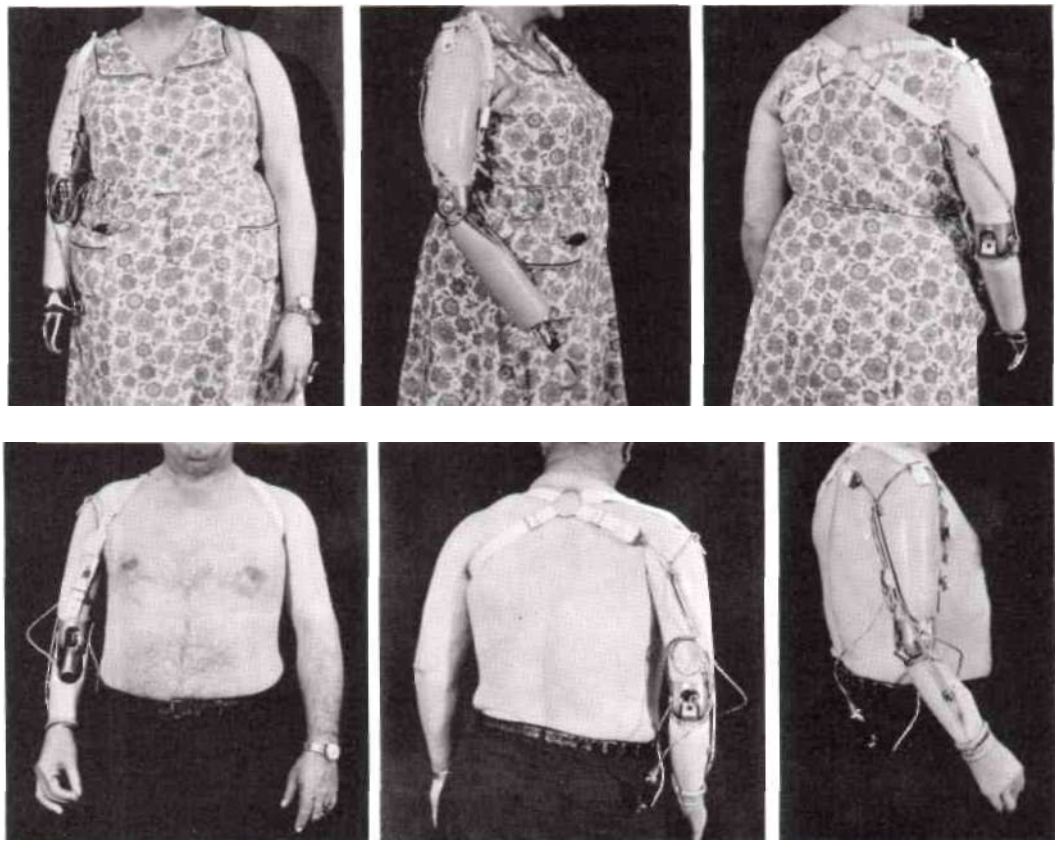
The Rehabilitation Clinic of the Liberty Mutual Insurance Company (one of the developers of the Boston elbow) also fitted two amputees with the Boston elbow during the evaluation period. One preferred the Boston elbow, and one preferred his conventional elbow. Both offered comments which substantiate the relative merits listed above.

CLINICAL FITTINGS OF THE RANCHO ELBOW

Total number of elbows	10
Number of elbows not evaluated due to in adequate subjects or insuf	2
Total number of elbows evaluated	8
Number of amputees preferring conventional elbow	7
Number of amputees preferring Rancho elbow	1

The best features were ease of flexion and the McCulloch quick charger.

The most undesirable features were: weight, speed, noise, bulkiness, inadvertent operation of switch, lack of positive elbow



Figs. 8 and 9. Amputees fitted at UCLA with the Rancho elbow.

lock, lack of control in positioning elbow (override), and lack of full range of motion.

OTHER CONSIDERATIONS

Because of the difficulty in finding AE amputee subjects with suitably short stumps, the protocol was modified to permit the clinics to fit some of the AMBRL elbows to unilateral shoulder amputees as well. Therefore, of the eight AMBRL elbows evaluated, six were fitted on "short" AE amputees and two were fitted on shoulder amputees.

Because the clinics had difficulty finding suitable subjects for all the elbows, they fitted the following amputees (who did not conform to the original selection criteria) on the premise that it was better to get some evaluation than none at all: (1) a new amputee with a unilateral shoulder disarticulation; (2) a new amputee with a unilateral AE amputation following brachial-plexus injury, with a fused shoulder on the amputated side; (3) a bilateral AE amputee who was a previous wearer; and (4) a relatively new AE amputee who had worn a conventional prosthesis for seven months.

Of the three amputees who stated a preference for the externally powered elbow, their specific reasons were as follows:

1. The subject who had positive comments about the AMBRL elbow was the new, unilateral, AE amputee with brachial-plexus injury and fused shoulder. He liked it because it allowed him to flex his elbow without using his sound arm.

2. The subject who preferred the Boston elbow was the relatively new AE am-

putee. He liked it primarily because it made elbow flexion easier.

3. The unilateral AE amputee who preferred the Rancho elbow liked it because of the ease of flexion and because it eliminated the elbow-lock-control motion.

For information, the bilateral AE amputee preferred his conventional elbow because he had inadvertent operation with the AMBRL elbow. The new shoulder amputee elected not to keep the AMBRL elbow, and was listed as "undecided" because of no experience with a conventional prosthesis for comparison.

Most of the amputees said that their main uses of the conventional and externally powered elbows are to hold objects with the elbow flexed and to carry objects with the elbow flexed or extended.

A few of the amputees expressed a liking for the "live lift" feature of the externally powered elbows, but none said it was a functional requirement.

Most of the amputees said there was nothing or little they could do with the externally powered elbows that they could not do with their conventional elbows.

RECOMMENDATIONS

It was obvious that the externally powered elbows that were evaluated are not yet ready for routine patient usage. This is understandable since most are first-generation units on amputee subjects. It was decided, therefore, that the best way in which the Subcommittee on Evaluation could help in the further development of powered elbows would be to offer recommendations for standards for future work. The standards listed below, which are based on the discussions by the participants and which directly reflect the clinical evaluation on amputee subjects, are therefore recommended for externally powered elbows.

Speed

The elbow should operate from full extension to full flexion in *one second or less* with the terminal device and forearm loaded or unloaded. (The range of motion from full extension to full flexion is considered to be 0 deg. to 135 deg.)

Control

1. Operation of the elbow should be independent of the operation of the terminal device.

2. For the amputee to satisfactorily position the elbow at the speed specified above, *voluntary variable control* may be necessary. This should be determined by separate study.

3. If myoelectric control is used, the electrodes should be incorporated within the socket.

Torque

The elbow should produce at least 3 1/2 foot-pounds of torque. This represents 1 1/2 foot-pounds for the weight of the terminal device and forearm and 2 foot-pounds for lifting objects.

Lock

The elbow should have a lock capable of withstanding at least 25 foot-pounds of resistance in any position (except free swing) for carrying objects, etc.

Weight

The total weight of the elbow, including the unit itself, the power source, and any other auxiliary equipment, should not exceed *18 ounces.* The use of lightweight battery packages, and more frequent charging using recently developed fast chargers, is recommended to keep the weight as low as possible when using electrical systems.

Noise

A noise level of 60 db or more is emphatically too high. *The lower the noise level the better.* A separate study is recommended to determine a realistic standard for noise level and means to measure it.

Cosmesis

It is obvious that improvement in the appearance of the elbow is needed. Amputees understandably object to wires showing, mechanical parts protruding, the necessity of wearing equipment on the waist, etc. It is strongly recommended that the elbow and its related parts be *self-contained* within the prosthesis, with *cosmetic improvement of the exterior surface.*

Free Swing

Free swing is a desirable feature and should be included in the elbow.