HAND PROSTHESES

AN EVALUATION PLAN FOR THE BEOGRAD HAND

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Summary

A plan for the evaluation of the Beograd hand was developed by the author in collaboration with personnel of the Center for Prosthetics and the Mihailo Pupin Institute.

The plan had two major aspects:

1. Engineering or mechanical testing, for which the Mihailo Pupin Institute was responsible, and
2. Functional testing of selected patients, which was the responsibility of the Center for Prosthetics. In this portion of the program the Beograd hand was to be compared with the Dorrance voluntary-opening and the APRL voluntary-closing devices. Below-elbow, above-elbow, and shoulder-disarticulation amputees are to be used.

The program of mechanical testing was based on "Tentative Design and Functional Standards," compiled jointly by representatives of Mihailo Pupin Institute, AMBRL, and the Committee on Prosthetics Research and Development, and supplemented by additional test items developed by Mihailo Pupin Institute.

The amputee functional testing program drew upon American experience in the evalution of mechanical hands. Test areas included two tests of "abstract" function — one involving grasp, transfer, and release of disparate objects; and the other requiring grasp and release of selected objects in various positional orientations. An additional test involved the performance of the daily living activities of significance to the individual amputee. These tasks were of the bimanual type.

The first phase of the study has been essentially completed. A second phase in which the Beograd hand will be compared with the Viennatone, MYOBOCK, and Russian hands has been initiated.

It was just about two years ago that I was invited by the Social and Rehabilitation Service of our Department of Health, Education, and Welfare in the United States to assist in the development of an evaluation program for the Beograd hand. An additional challenge was that the protocol developed might have application to other electromechanical terminal devices. At that time I know very little about electromechanical hands. However, I had had a very extensive experience in evaluation generally, including the evaluation of a number of mechanical hands, such as the original APRL 4C, APRL No. 1, and the Dorrance series. So, it was natural enough,

in approaching this new assignment, to draw heavily on our prior experience.

In the United States the principles and procedures governing the evaluation of prosthetic and orthotic items have become fairly well established over the years. They have shown little change since they were first presented in organized form by Fishman in 1954 [1]. Review of these principles and procedures served to identify the developmental status of the Beograd item and the required evaluation procedure.

The phases of evaluation as they have been recognized in the programs conducted in the United States are:

1. *Shakedown* (Prototype Model) *Testing* — 2 or 3 subjects
   To assure integrity of device
   To orient evaluation staff
   To develop test procedures
2. *Service* (Production Model) *Testing* — 12—15 subjects
   A controlled laboratory experiment
3. *Field Testing* — up to 100 subjects
   Transition of application to clinicians and industry — wide variety of patients, occupations, locations, climates

Consideration of the Beograd Hand in relation to these categories revealed that it did not fall neatly into any one of the standard pigeonholes. Lack of prior testing by an independent agency suggested the desirability of shakedown testing. However, the units available were production items. In view of this factor and to expedite the evaluation process a service-type testing program was decided upon with a limited number of models and patients.

The typical evaluation experiment for this so-called service testing phase consists of:

1. *Selection of Amputees*
   Medical, psychological, and prosthetic suitability
2. *Evaluation with Conventional Device*
   Medical factors
   Psychological considerations
   Performance
   Engineering criteria
3. *Experimental Fitting*
   Application of test item in accordance with developer's instructions
4. *Training*
   As necessary to develop proficient use
5. *Reevaluation*
   Reapplication of test procedures relative to test item

A list of typical participants in an evaluation experiment and a brief description of the functions or concerns of each follow:

1. *Physicians*
   Physical well-being of patients
   A. Occupational and Physical Therapists
      Training
      Ratings of performance
2. *Physical Scientists* (M.E., E.E., Physicists)
   Objective analysis of performance
   Design considerations
3. *Psychologists*
   Selection of patients
   Reactions in relation to psychological traits
4. *Prosthetists*
   Fitting considerations
5. *Patients*
   Acceptance

Prime criteria applied in the evaluation of a given prosthetics item are;

1. *Comfort*
   Pressures, shears, heat, perspiration
   Weight
   Energy cost
2. *Performance*
   Approach to normalcy
3. *Cosmesis or Factors Related to Obtrusiveness*
   Shape
   Bulk
   Color
   Noise
4. *Durability*
   Maintenance requirements
5. *Cost*
   Money
   Time

Types of items which are the subject of evaluation in prosthetics are components, techniques, and combinations. Some miscellaneous requirements related to the evaluation process are the independence of evaluators, training in application, and written description of the item or fabrication instructions.

With respect to "Types of Items for Evaluation," it should be noted that some items can be fitted or applied with a minimum of special skill; as for example, a cosmetic glove applied to an artificial hand. Other components require considerable technical skill in their application; for example, an alignment or transfer jig. The Beograd Hand fell somewhat into this latter category, particularly in harnessing for control of the device.

Responsibilities

By arrangement, the evaluation responsibilities were divided between the two agencies concerned —the Center for Prosthetics and the Mihailo Pupin Institute. The Mihailo Pupin Institute was to be responsible for the socalled engineering or mechanical testing of the Beograd Hand, while the Center for Prosthetics was to be responsible for the selection, fitting, and functional evaluation of patients. However, to avoid a complete dichotomy in the testing program, an engineer from the Mihailo Pupin group was to work with the staff of the Center for Prosthetics, and an engineer from the Center was to be related to the mechanical testing at Mihailo Pupin.

Mechanical Testing

The author's initial contact with the Beograd hand was made during a visit to the United States of Professor Miodrag Rakic in 1967. At a meeting attended by Prof. Rakić, Dr. Leonard of the U.S. Army Biomechanical Research Laboratory and his staff, and the writer, an attempt was made to develop "Tentative Design and Functional Standards for Electromechanical Hands and Control Systems" [2]. Inevitably, this initial approach to the formulation of design and functional standards was influenced by the work that had been done previously with respect to mechanical hands. Other items were, of course, added but in some instances items were listed simply as tests to be performed with no values or standards assigned.

In planning the evaluation of the Beograd Hand, personnel at Mihailo Pupin Institute accepted the items described in the "Tentative Standards" document as a basis for the engineering or mechanical testing portion of the program. However, the Mihailo Pupin investigators were desirous of including many additional items in the test program and this was done.

These items and the results of the engineering testing are the subject of a separate paper by Dr. Jaksić so we will not discuss them further here. It is our hope that, on the basis of these results, the present "Tentative Standards" can be extended and made more authoritative. A revised document on this matter will be the subject of a later publication.

Amputee Fittings and Functional Testing

With regard to the amputee fitting and functional testing aspect of the evaluation, there was general agreement among the parties concerned that the program initially should be kept as simple as possible. Some of the mutually agreed upon deliminations were: 1) That the number of subjects should be confined to three

— one below-elbow, one above-elbow, and one shoulder- disarticulation amputee. However, this decision was eventually amended to add another amputee in each category as a "spare." 2) Only subjects with unilateral amputations would be used. 3) Of the various socalled "logics" that might be built into the Beograd Hand, initial study would be confined to what has been called the number one or alternating logic. 4) Of the various types of controls that might be used to activate the Beograd Hand, the initial study would be limited to control mode No. 1, which involved a pull-type potentiometer. 5) The functionality of the Beograd Hand would be compared to that of two mechanical hands, the Dorrance voluntary-opening, and the APRL voluntary-closing devices.

The initial design of the study, therefore, can be expressed in a simple chart as shown in Figure 1.

BASIC DESIGN FOR FUNCTIONAL TESTING

Subject	BEC # 1	Control mode # 1	Dorrance V.C.	APRL V.C.	Control mode # 2	BEO # 2
S/E	1	1	3	2		
S/A	2	2	1	3		
S/B	3	3	2	1		

BEC # 1 = Belgrade Hand with alternating logic
BEO # 2 = Belgrade Hand with x logic
Control Mode # 1 = Pull type potentiometer control
Control Mode # 2 = Switch type control

Fig. 1. Experimental design for initial phase of Beograd hand evaluation.

To effectuate this program then, personnel at the Center for Prosthetics began a recruitment, screening, and selection process to obtain suitable subjects for the study. The screening process involved medical, prosthetic, and psychological aspects which were conducted independently by the appropriate personnel. Selection of acceptable subjects was then done jointly by the members of the screening team.

This paper will not present any further detail concerning this selection process. Perhaps Dr. Kajganić may wish to add something more in her presentation.

Amputee fittings began with the below-elbow subjects and, in accordance with the established design, they began with the fitting of the Beograd Hand. N. Ivancević and other members of the Mihailo Pupin staff were in close attendance during the fitting and training of the subjects and the results will be reported in the paper by Dr. Kajganić.

Following fitting, the subjects were trained by the staff therapist at the Center for Prosthetics until it was determined that a plateau of performance had been reached. The subjects were then tested, using the three test sequences that had been adapted for the study. The subjects were then refitted with another type hand and the process continued.

Form Board Test

The first test used was of the so-called "abstract" type, that is, the functions tested were not related too directly to the performance of real-life tasks. Its purpose was to focus attention specifically on the grasp functions of the device being studied.

The test involves the transfer of objects sizes, weights, and consistencies from the table into appropriately shaped slots in a form board. It was scored on the basis of subjective ratings of performance by the physician and therapist members of the evaluation team, by time, and by count of errors. The general scheme of the test is shown in Figure 2. An amputee performing the test is shown in Figure 3.

The Pigeon-Hole Test

The second test used was also of the so-called "abstract" type and focused attention on ability to grasp and release objects at the level of the amputee's mouth, chest, waist, and knees, as well as diretly in front of him and to his right and left. Figure 4 shows the general sheme of this test, and an amputee performing the test is shown in Figure 5. Again, scoring was on the basis of subjective ratings in relation to so-called "normal" performance, time, and error count.

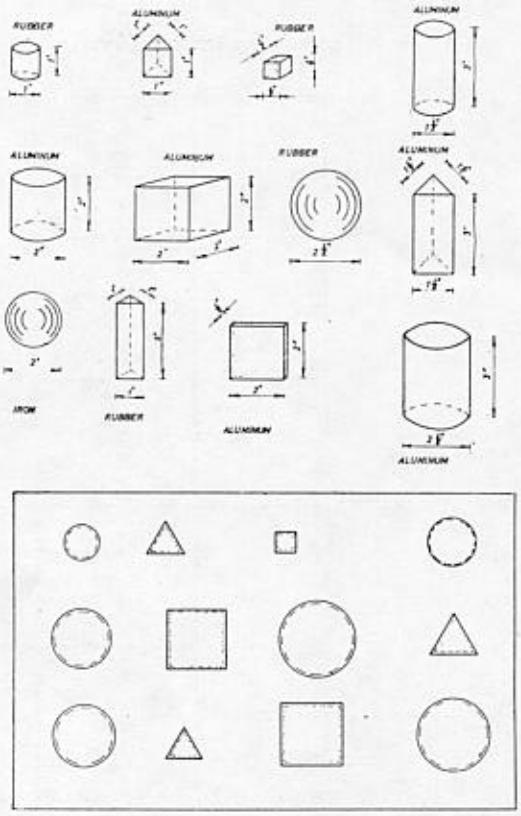


Fig. 2. Board and materials for Form Board test.

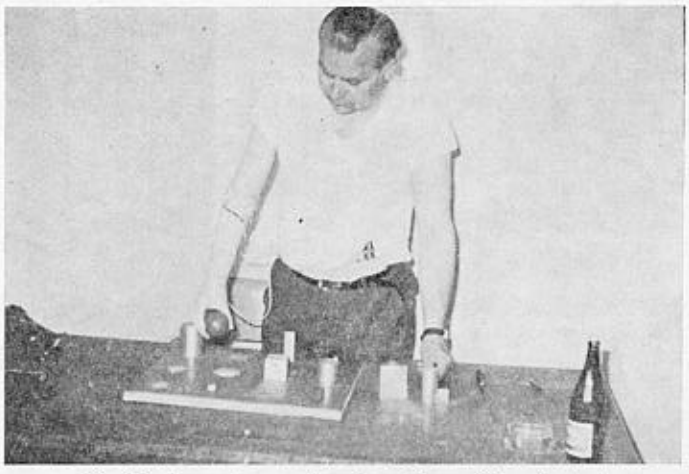


Fig. 3. Amputee performing Form Board test.

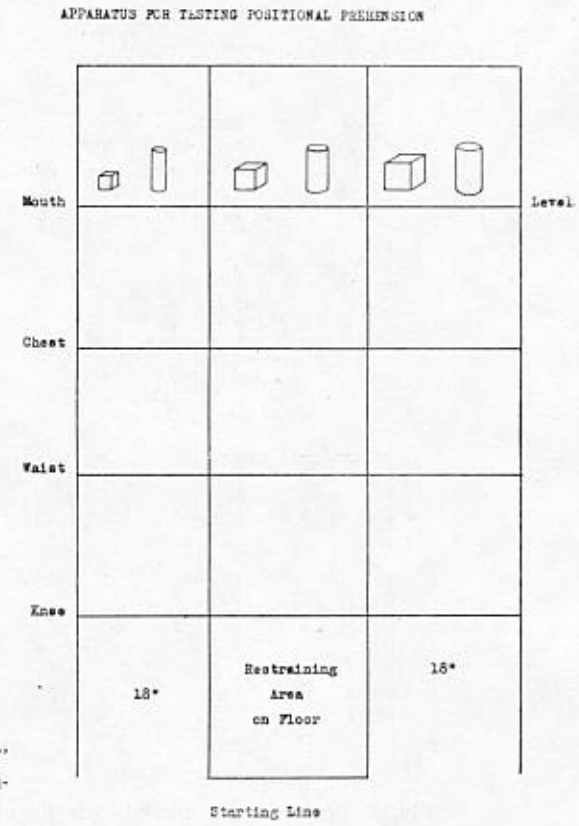


Fig. 4. "Pigeon holes" and objects for positioning test.

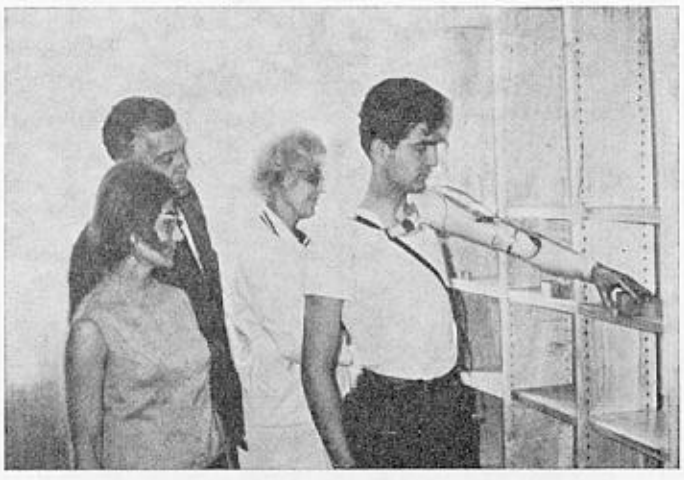
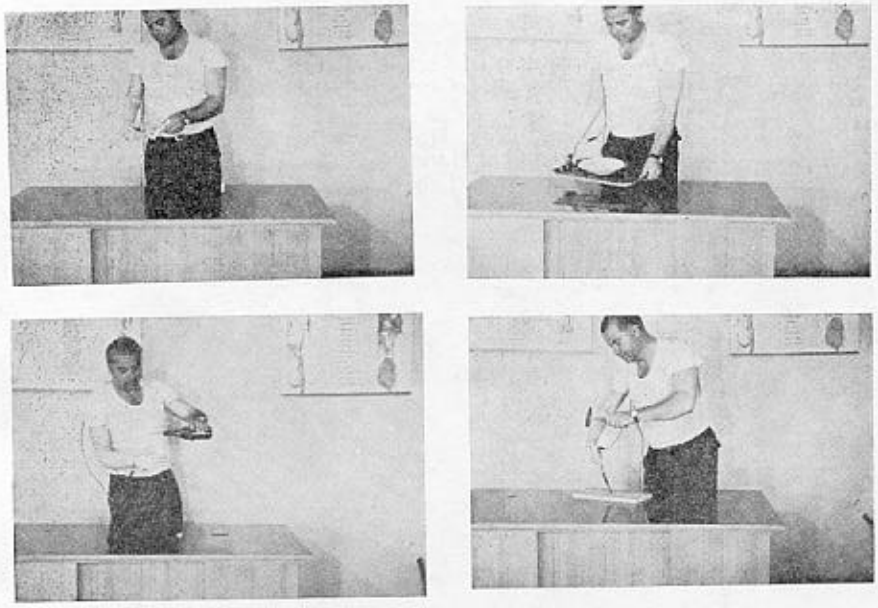


Fig. 5. Amputee performing "pigeon-hole" test.

Practical Activities

The third area of functional testing involved activities of daily living. From a list of 25 bimanual activities representative of eating, dressing, work, and recreation, ten of prime significance to the individual subject were developed and performance again evaluated on the basis of subjective ratings, time, and count of errors. Figures 6 through 9 show an amputee performing some of the tests.



Figs. 6—9. Amputee performing bimanual test activities.

Selection and testing procedures as described were applied to two below-elbow and two above-elbow amputees. Suitable shoulder-disarticulation subjects were not located. Comparisons of functionality were made between the Beograd, APRL, and Dorrance hands. The results are to be reported in a separate paper.

A second phase of the study involving comparisons between the Beograd, the Viennatone, and the Montreal version of the Russian hands was commenced. A different method of control was introduced in this phase. Models of the Montreal hand could not be obtained and the MYOBOCK and Russian hand will be substituted. A preliminary report on this phase of the study will be made.

Conclusion

In a development of a plan for the evaluation of the Beograd hand it was hoped that the procedures used would not only provide

useful data concerning the item under study, but would also be applicable to the evaluation of other electromechanical hands. The extent to which the first objective was achieved will be indicated in some degree by the subsequent paper by Dr. Kajganić. Time alone will tell whether the second goal was realized.

REFERENCES

1. Fishman, S., "The Principles of Artificial Limb Evaluation", *Human Limbs and Their Substitutes*, McGraw Hill Book Company, Inc., New York, 1954, pp. 775—793.
2. Leonard, F., Rakić, M., and Kay, H., "Tentative Design and Functional Standards for Electromechanical Hands and Control Systems," U.S. Army Medical Biomechanical Research Laboratory, Washington, D.C., June 1, 1967.