THE EVALUATION METHOD OF REHABILITATION DEVICES
---FIELD TESTING OF POWERED FORE-ARM PROSTHESIS,WIME HAND---

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Rehabilitation devices are generally designed individually by each designer who only thinks his own conditions. But in this way, it is difficult to reach the ideal devices because of the lack of thoughtfullness. So we consider it important to investigate thoroughly how they are used and to have an appropriate design guide. With regard to testing methods of rehabilitation devices, same kind of things should be considered to make standards for evaluation.

As an example, myoelectric fore-arm prosthesis "WIME Hand" are actually tested according to this method, so we also wish to show about these results.

In this papers we describe what performance a myoelectric arm prothesis must have and how it must be tested and evaluated technically. Opinions of patients,medical side, engineering side and socio-psychological side are refered to.

We made a study of concerning the acceptance of handicaps,the adjustmental problems of social and vocational life,the dynamics of handicaps' family and the level of the ADL etc. by the proposed method-----a group interview and a personality inventory test etc. .

This method will be applicable to the development and practical application of the other rehabilitation devices.

This contribution consists of the following 4 papers.

Part 1 Systemization of Field Testing
Part 2 Technical Evaliation in Field Testing
Part 3 ADL Evaluation in Field Testing
Part 4 Socio-psychological Evaluation in Field Testing

INTRODUCTION

Differently from ordinary industry appliances, inputting the *rehabilitation devices** for the handicapped to practical use, the products of development study should not be directly put on the market. A product, which has attained a prospect of its availability and practicability, should be first check in the field testing in which the handicapped takes part as a user. The result of evaluation should be used as a feedback for redesigning of devices before it is put to practical use.

Rehabilitation devices are usually used as if they were a part of the body itself to get over the handicap of the user. This is because the connection between the handicapped and rehabilitation devices is stronger than in the ordinary sense.

Therefore, in order to give the devices maneuverability and fitness, it needs to do the assessment including the psycho-physiological ajustment.

But in actuality such a system has not been established yet concerning how the process should be proceeded with and how the method should be.

So we have tried to establish such a system for the powered hand prosthesis, which is now being carried out the field testing in Japan aiming to its practical use.

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* Technical Aids and Instruments for the Handicapped

PART 1 THE EVALUATION METHOD OF REHABILITATION DEVICES

by

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1.1 What is the Field Testing?

The parts of rehabilitation devices produced in a factory should not be used by the handicapped without processing that a doctor prescribe for the handicapped, according to physique and the degree of handicap, occupation and living environment of the handicapped, then orders to the manufacturer, and inspects and ascertain the adaptability of the product. Furthermore the doctor should give a rehabilitation training to the handicapped to use it satisfactorily. Without such training, the devices would not be utilized to the full. Therefore the evaluation of the rehabilitation devices, must be carried out with participation of the handicapped concerning the following points:

1) the range of the handicaps to which they are medically applied
2) number of cases in which the devices are medically available
3) safety from the medical point of view
4) technological features
5) sociological features

For this purpose, it is the first requisite that a team consisting of doctors, engineers, manufactures, sociologists, psychologists should observe and judge as a whole the actual use of the devices by the handicapped. We call this actual testing and evaluation as a *field testing*.

1.2 Method of Field Testing

In the field testing it is desirable to carry out the following:

1) Machine test ;

2) Man-machine test ;
3) Psycho-sociological test.

As an example, myoelectric foream prosthesis "WIME Hand" are actually tested according to this method, so we wish to show about these results.

1.2.1 Machine test

This is a so called *machine test* based on the technical evaluation method to be mentioned in Part 2. When a prosthesis is tentatively manufactured in a factory, all its standard characteristics should be measured by the machine test before shipment. The same test should made again after the field testing and it should be checked which characteristic has changed most.

Even while the field testing is going on, it is desirable to make the machine test periodically. Instead of it, it is possible to substitute *simplified machinetest* to reduce the trouble of the handicapped who cooporates the test.

In order to know the reliability and life etc., these test have been put into practice according to the logarithmic schedule that is for a week, two weeks, four weeks, two months, three months,six months, one year, and two years.

1.2.2 Man-machine test

The aim and object of the rehabilitation devices is generally attained when it is fitted on the handicapped. So the change in the total characteristics of man-machine system should be examined by the field testing. The behavior of man-machine system changes very largely between the beginning and the end of the test, because the man has the learning and adaptation function while the machine has the change of characteristics after repeated use, for example wear and back-lash ets.. So in making the simplified machine test in the field testing the man and machine check should be carried out at the same time so that the behavior may be recorded. By comparing the both results, we can check the promotion of the remaining functions of the handicapped, and get necessary information for improving the devices.

In the medical field, ADL (Activity in Daily Life) *test* is widely adopted for the functional evaluation of the handicapped, so in the final test we have decided to analyse the practicability in connection with ADL in order to compare with the man-machine check.

Comparing these data, it is desirable to evaluate the change in the man and the characteristics of the machine in the field test.

1.2.3 Psycho-sociollgical test

The final evaluation of rehabilitation devices cannot be made only with the machine test, man machine test and ADL test stated above. Considering the time when the handicapped returns to the society, there needs to be the evaluation of the change concering the relation between the handicapped and his environment.

Therefore, in this test we have introduced a psycho-sociological approaching method. The testers personally interviewed to the handicapped and his family to ask for their answers and views about the relation between the devices, the environments and the handicapped himself.

This test has been put in practice three times; at the beginning of the field testing, three months after and the end of the testing. Each time we put the same questions to examine minutely the change in the psyhcological evaluation of the subject.

We have dared to add this test which takes the greatest labor and considerable cost, judging that we could not truly evaluate the rehabilitation devices if we did not make a well-proportioned evaluation from the view point of medicine, technology, and sociology.

1.3 Project of WIME Hand field testing

1.3.1 Outline of WIME Hand

The object of this field testing is WIME (WASEDA IMASEN Myoelectric) hand* (Fig.1.1) which is the hand shaped powered prosthesis for a forearm amputee. It uses rechargeable battery (12 [v] NiCd) for a power source and a small d.c. motor for the driver. Each finger driven by the motor has two joints and acts as if it were a natural one. In the drive mechanism of the thumb a mechanical flip flop is incorporated, and by using this, three points pinching and a powered grip can be selected. The motion of the motor is controlled by the myoelectric potential.

When the muscle is contracted, there occurs a feeble electric potential about 1[mv]. This feeble electric potential is amplified and cotrols the rotational direction of the motor, namely, the hand grip and release through the processing circuit or relayunit.

So the amputee selects the control muscles properly, he can move the prosthesis as if it were a lost hand master the handling rapidly. The main specifiaction of this is shown in table 1.1.

1.3.2 Test organization

At the time when the field testing is put into practice, there need an organization to carry out each of medical, technological, and sociological tests.

As the organization which fulfills this conditions a specialized research institute for the prosthesis and the orthosis seems to be most suitable.

At present such institutes for specialized researches in Japan are: Prosthetic research laboratory national rehabilitation cenetr for the handicapped; Tokyo metropolitan prosthetic and orthotic research institute; The labor accident prosthetic and

* WIME Hand is the improved model of WASEDA Hand-4P (The reader may refer to Proc. of 3rd ETAN Symp. pp.155-170 1969)

orthotics center; Kanagawa rehabilitation center.These institutes have a fairly satisfactory staff of doctors, engineers, and socilogists and are regionally decentralized.

In this field testing, 4 institutes except for Kanagawa undertook the numan machine and the sociological test, while Mechanical engineering laboratory of MITI, Japan bicycle technical center, and Imasen electric industrial co. ltd. made the machine test.

In order to coordinate all the studies, *(the Committee for the Promotion of Practical Application of WIME Hand)* was organized, centering around Waseda University.

1.3.3 Test period

We made a two year plan for this field testing. At the beginning following conditions were fixed on:

1) never to make any considerable change in design of the original prototype model;
2) to make small scale changes of the design not exceeding two times.

Ater all, the test period took three years.

As a matter of fact, if we took much more time, it would only disappoint the handicapped.

1.3.4 The amputee

The necessary number of the cases should be fixed on considering the number of the handicapped who need a myoelectric prosthesis and reliability expected of it. But in this study, we decided upon 25 cases in view of the stuff of the project team and the budget. Finally we put into practice for 30 amputee.

The field testing is made by the planner who aims at the practical application, so it is indispensable to pay rewards such as daily allowance and traffic fees to the handicapped taking part in the test and to ask for his views at same time and comments. In order to make the machine test after the test is finished, all the devices should be withdrawn, but if the cooperator wants to use them longer, it is desirable him the substitute of the same type as a reward.

As an all round evaluation method for the field testing, it is very useful to take into account whether the cooperator wants to use the device longer or not. So it is desirable to include this consideration in the budget.

1.3.5 Test manual

It is desirable that the field testing should be an objective test as far as possible. The prosthesis and orthosis are directly put on the body, so the fitness of the man-machine interface must be emphasized. Moreover all the patients differ from one anther, and the interface is produced by handmaking. The skill of the prosthetic manufacturer directly affects the man-machine system, so the importanceof this process of making the