PART 4 PSYCHO-SOCIOLOGICAL EVALUATION IN FIELD TESTING

by

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4.1 Introduction

It is common and strong desire for the amputees to have better prostheses than now. Because its role and meaning is very important for them in life. For example, most of the prostheses for the upeer-extremity amputees in Japan, are cosmetic or functional artificial hand, providing that they are internally powered.

Therefore the newly developed prosthesis, an electric hand which is externally powered and both cosmetic and functional roles is considered to have a great influence of the way of their social life. The effective application of this will evoke a positive attitude on the patients'side. And it is expected that it will give a good influence on the physical and mental rehabilitation and will have the advantages in vocational rehabilitation.

For these reasons, it is expected to establish an evaluation method on the real efficiency of the powered fore-arm prosthesis from the psycho-sociological side (the humanistic point of view).

4.2 Methods

4.2.1 Purposes of the psycho-sociological evaluation

The purposes are to collect and analyse the references and the data on the psycho-sociological side, in order to be used for designing an powered fore-arm prosthesis, and to grasp quantatively and qualitatively how they are accepted by the amputees.

4.2.2 Methods and subjects of the psycho-sociological evaluation

This study consists of two investigations. Because we need the data for two different kinds of analysis(quantative analysis and qualitative one).

(1) Quantative investigation

subject: 451 below-elbow amputees who would be in need of the electric fore-arm prosthesis. The answers are 232 and the no answers are 219.

method: 451 candidates are surveyed by the mailing method.

a. their physical characteristics
b. comments on their present prostheses
c. their expectation of the new electric fore-arm prosthesis
d. comments of their applications of their electric fore-arm prostheses and problems to be solved

(2) Qualitative investigation

subject: 28 WIME HAND monitors who are below-elbow amputees. The effective answers are 20, the noneffective answers are 8.

method: 28WIME HAND users are surveyed by the interviewing methods in personal and in group.

a. their physical characteristics
b. their expectation to WIME HAND
c. comments on their application
d. problems and the prospect
e. personality inventory test

4.3 Outline of the result

4.3.1 Quantative investigation (mailing)

In this paper, the results are as followed.

(1) Sex

Out of 232 amputees, 76% are male, while 24% are female.

(2) Cause and stump length

Cause of the amputation	
Labour accident	.....36%
General accident	.....33%
Disease	.....16%
War	.....15%

The cause of the amputation is showed above. Most of the labour accident'amputees are working in the factory and operating the machine.

The stump length are classified into three, short, medium and long. The medium size takes share of 50%. Short and long one are occupied the rest equally.

(3) Acknowledgement of the roles of the artificial hand

27% of the amputees regard the artificial hand as only cosmetic , 48% of them evaluate its function and regard it as an assistant hand and 19% of them ask for both roles. The user of the cosmetic hand, only 35% of them regards it as a mere decoration, that is, more than 60% think it as assistant hand or both roles. 80% of them who have bilateral amputation acknowledge it as assistant.

(4) Knowledge of the electric fore-arm prosthesis
65% had already some informations of the electric fore-arm prosthesis, and 35% knew nothing about it. The bilateral upper-extremity amputees were much more interested in the electric fore-arm prosthesis than the unilateral upper-extremity amputees. Because 90% of bilateral amputees knew it. They knew the prosthesis through mass communication, such as T.V. and radio or through persons concerned. 7 persons(4.7%) had an experience to put on it.

4.3.2 Qualitative investigation (interviewing)
(1) Sex and age
As shown in the following, only one female had a WIME HAND out of the 20 monitors, and the half of them are young people.

Sex and age (N=20)

Sex	male	.....19 persons
	female	 1
Age	20s	10
	30s	 4
	40s	 5
	50s	 1

(2) Jobs before and after the amputation
Before amputation, 16 persons had been engaged in production line in the factory, and after amputation only 5 were same before. Others became clerk (6 persons) and guardmen (5 persons).

Jobs before and after the amputation

same as before	.....11 persons
changed	 4
quited	 2
had no job	 2
no answer	 1

(3) The age of amputation
The amputation occurred mainly to the producing-age people, twenty to fifty years old.

The age of amputation

10 - 19	..... 1 person
20 - 29	12
30 - 39	 3
40 - 49	 3
50 - 59	 1

(4) Years after the amputation
Half of them obtained WIME HAND within one to two years after the amputation.

Years after the amputation

1 year	.....5 persons
2 years	5
3 years	3
4 years	1
5 years	3
more than 5 years	...1

(5) Cause
18 persons are amputeed by labour accidents. 3 of them are amputeed by electric shock.

Cause

War	..... 1 person
Labour accident	18
Other	 1

(6) Stump side and length
About their stump side, 12 persons are right below-elbow, 5 are left below-elbow and 3 are bilateral below-elbow amputation. The stump length is differnt but short stump'amputees are only three.

Stump side and length

Right	short	.....2 persons
	medium	6
	lower 1/3	1
	long	7
Left	short	1
	medium	4
	long	2

(7) Wearing hours per day
The shortest applicating time is less than an hour, and 16 hours is the largest.

Wearing hours per day

0 - 1 hour	.....4 persons
1 - 2 hours	3
2 - 3 hours	3
4 - 5 hours	1
5 - 6 hours	3
9 -10 hours	1
11 -12 hours	2
14 -15 hours	2
15 -16 hours	1

4.4 Consideration

4.4.1 Expectation toward WIME HAND (before use)

It is natural for a man to have some expectation and anxiety toward an unknown "tool", and the bigger the expectation, the greater the anxiety. Especially for those who have physical handicaps, they seems to be more serious in using the tool, for this tool is supposed to take place of their physical handicaps.

There are three kinds of anxiety about WIME HAND before its wearing. First, the anxiety against the mechanical things occurs to them; they are afraid of having some mechanical troubles. Second, against the operation of WIME HAND; they are not sure if the device would work as well as they wish,"What should I do if it stops?" And the last is its influence to their daily living; inspite of being eager to use it, they often say "Can I adapt it in my daily life as well as the present prosthesis?"

This is thought to be the fear to change the present way of life partly. Thus, some have the anxiety toward the mechanism, the operation and influence toward the daily life, but those who have seen a WIME HAND ever say, "I will not have any fear in wearing it especially. Because I have seen it used by others." They have some acknowledgement of its characteristics and a certain relationships with themselves objectly.

The expectation to WIME HAND could be categorized largely into two; its function and its cosmetic role. These expectation are not completely separated, but rather overlapped and combined. This means that they have certainly been disappointed at the prosthesis of old type; they were compelled to choose either fuctional role or cosmetic role. WIME HAND is expected as " similar to the natural hand", far from traditional conception of the prostheses.

The following is the analysis of the expectation to WIME HAND on its structure(mechanizm), functional and effectiveness in daily life.

(1) Structure

No special expectation to the structure is seen, since they think that it is only a machine after all. As far as the outlook is concerned, they had expected it to be more decorative or at least the same as the conventional type.

(2) Function

Some expect that they could get another new hand which can operate exactly in the same way as their lost hands; "I wish it would work as well as a natural hand! I can do everything." Some expect that it could cover the inconveniences they are presently facing; to press things or to carry a luggage. Thus, the expectation for WIME HAND is so big that it seems as if they are expecting to have their real hands again.

(3) Effectiveness in daily life

They strongly hope that it would work effectively in an situation where both hands are required, such as in operating agricultural tools or tying shoe laces. Also they hope to exploit it in their office work since the fingers move smoothly and precisely than a hook. They are, however, half in doubt about the difficulty in their daily living. Those who have left-hand prosthesis(right one for the left-handed) prefer the cosmetic role of the old type prosthesis to the effectiveness of the electric fore-arm prosthesis.

4.4.2 Actual usages of WIME HAND

The average of the applicating hours per day varies from 1 hour to 16 hours. The former is aimed for cosmetic role, the latter for its function role. Many use the conventional type and the electric fore-arm preostheses alternatively.

The content of their usages, 45% of them use decorative hand main and WIME HAND sub, 25% use hook type hand main and WIME HAND sub, and WIME HAND only are 10%. So the time of usage of WIME

HAND is more long than the traditional hand.

WIME HAND is used generally during their commutation, and nextly during their former jobs. WIME HAND is used also for driving, gardening, taking pictures, fishing and etc.. They are using effectively by making use of the characteristics of WIME HAND, both cosmetic and functional roles, as a part of their body. Other examples are making notes while phoning, or showing a ticket at a station with an umbrella in the other hand.

There are, however some problems in operation; the noise of the operating it and closing speed, weight, reducing electrodes's power because of the sweat, and the anxiety about the mismove.

The form of the hand, the cord of the battery, noticed in short sleeves, are other problems to be solved.

While these problems in their daily lives, its influence to the mental side cannot be overlooked. In consequence of the personality inventory test, that is one of these evaluation. It can bee seen that the acceptance of handicap and prosthesis has the great influence on the effective applience for amputees.

As shown in the following, 10 persons want to use WIME HAND continuously and 5 want it in addition to partial improvement.

The degrees of wish to use WIME HAND continuously

strongly hoped .....2 persons
as supplementary hand 8
adding improvement partly.....5
return 4
and others .....1 .

As shown in the following, the personality of these persons are emotional stability, social adjustment and active, that is 10 are D-type, 3 are A-type, and 4 are C-type by Y-G personality inventory test. It takes the share of 75%.

Monitors' personality characteristics

Characteristics \ Type	A	B	C	D	E
Emotional Stability	±	-	+	+	-
Activity	±	+	-	+	-
Social adjustment	±	+	+	+	-
Monitors' number	3	2	4	10	1

(+, ± and - mean the level of characteristics; +...good, ±...average, -...bad)

It is easily understood that the personality of amputees and acceptance of their prosthesis, have a great influence on the effective application of the electric fore-arm prosthesis and the usages it continuously.

4.5 Conclusion

For the psycho-sociological evaluation, it was made quantative analysis about the physical characteristics and the role of their prosthesis, to 232 below-elbow amputation who would be in need of the electric fore-arm prosthesis. And it was made qualitative analysis to 20 monitors of WIME HAND in field test regarding to their expectations and some problems.

As a result, it was understood that amputees have always strong desires for the natural outlooks as the substitution of their physical handicaps. WIME HAND is the first type of the electric fore-arm prosthesis in Japan which has cosmetic and functional role and it will have a great expectation for the amputee. On the functional aspect of this hand, it has been expressed their satisfaction, but there are some problems to be solved. It should be made an effort to improve the electric fore-arm proathesis and approach to their needs. Besides the level-up of these mechanism and the appropriate way of use and trainning, for the effective use of the electric hand.

CONCLUSION

The result of evaluation of WIME Hand taken as a case is synthesized as follows.

The man-machine evaluation in the Part 3 and the man system evaluation in the Part 4 are summerized in Table c-1.

In the man machine evaluation 15 people(50%) score more than two marks. They score 37 marks against 44marks of the total, so the degree of effectiveness is 73.3 %. On the other hand in the man system evaluation 10 people(50%) dare to use the hand continuously and moreover 5 people(25%) hope to keep it for themselves. So it can be said the men(75%) who total 15 use it closely contact with their life.

Combining the both evaluations into a whole, the total marks are nearly 75% and the degree of acceptance is high in conclude.

In putting the welfare related instruments into practical use, the results of thr evaluation itself is apt to be effected whom, when, how,and what.

This paper has proposed a concrete evaluation method about the evaluate system from a national point of view taking a powered arm prosthesis as a case. On the basis of the precious data from the field testing of WIME Hand for this three years,we have made clear the evaluate process for the developed welfare instruments.These process opens the way of effective application for the welfare instruments.

In the future, if this reseach study was applied broadly to the evaluation of the general welfare instrument and the idea of developing the instruments was established, the hadi-capped and the person of advanced age would find satisfaction at the will of participating in society and the will to work and establish himself stably in this matured society.

Table c-1 Synthetic evaluation (member of person)

man machine evaluation			man evaluation		
most suitable	7	15	strongly hoped	2	15
more suitable	8		as supplementary	8	
according to circumstance	7		adding improvement partly	5	
no adaptable	8		return	4	
			and others	1	

Appendix

Test Code for Performance of the WIME HAND

1. Scope

This standard defines matters concerning inspections to be carried out to clarify the characteristics of the WIME HAND.

2. Genaral Rules for Inspection

2.1 Inspections, as a rule, shall be carried out at IMASEN Electric Industrial Corp. Ltd., the manufacturer of the WIME HAND.

2.2 Inspections shall be carried out without fitting the WIME HAND on the person under test.

2.3 Inspections, as a rule, shall be carried out with the WIME HAND in the assembled condition.

2.4 The batteries, or power supply unit, to be used shall satisfy the specified output characteristics.

3. Method of Inspection

Inspection shall be carried out according to the following procedure and method.

3.1 Entry of General Items of Inspection List

Machine No. _______, Model No. _______
Date of Manufacture 19__, _____, _____
Date of Inspection 19__, _____, _____
Name of Measurer _______________

3.2 Specification Test

3.2.1 Size of WIME HAND (with inner glove)

Such major dimensions as the length, width and thickness of the hand with the fingers stretched out and closed shall be recorded in the general drawing.

3.2.2 Weight of WIME HAND

Weigh such parts as the prosthetic hand mechanism, inner glove, cosmetic cover, myoelectric amplifiers, electrodes, battery (with case), etc., first as a simplex and then as an assembled unit.

3.2.3 Dimensions of Each Part

Measure such dimensions as the length between the joints of each finger, the dimensions of palm (thickness, width and length), the outside diameter of the wrist section, and dimensions of the fitting section of the hand. Record the measurements into the drawing.

3.2.4 Backlash of Each Finger

With the fingers in a fully stretched out condition and a half-stretched condition (starting with the fingers in a fully stretched out condition, gradually close the fingers until the thumb reaches a position where the distance between it and other fingers will be about 5 mm), the measurer will apply a slight force (about 50 g) within each finger's motion surface (two directions), and then within a surface perpendicular to it, and shall measure with a dial gauge the maximum play that occurs in each direction. This measurement is to be carried out with the cosmetic cover and inner glove removed.

3.2.5 Rigidity of Each Finger

With the fingers fully stretched out, apply a force in the same manner as in 3.2.4 to the thumb and forefinger in each rotary direction and lateral direction. The force should be gradually increased from 0 kg up to +P kg, and then gradually decreased to 0 kg and further to -P kg, and again it should be brought back to 0 kg. Apply this load cycle several times and seek the displacements of each finger in both directions.

NOTE) The value of P is to be determined by referring to the design value.

3.2.6 Constrained Torque of Wrist Section

Tighten the adjust screw of the wrist section with various torques, and measure the static friction torque and dynamic friction torque for each case.

3.2.7 Noise

With a microphone set apart from the prosthetic hand at a 15 cm distance, measure the approximate values of noise that is generated in connection with stretching-out and closing of fingers, using an indicator-type noise meter, or a simplified noise meter.

3.2.8 Vibration (omitted)

3.3 Function Test

3.3.1 Pinching Function

(1) Maximum pinching force

After pinching up the finger-pressure converter using the thumb and forefinger, keep holding it with the fingers closed for a while. Record the gripping force on an electromagnetic oscillograph (or a pen-writing oscillograph), and seek the maximum gripping force. Measurements are to be taken 5 times. The mean value is adopted as the measured value.

(2) Pinching force

In (1), when the pinching force exceeds a certain fixed value, the current limiter will be actuated, thereby causing the current to the motor to be cut off (the ammeter's reading will become zero). At this point read the pinching force from the electromagnetic oscillograph. Repeat this measurement 5 times. Use the mean value as the measured value.

(3) Smallest object that can be pinched up

With the measurer holding the WIME HAND, input signals are applied to cause the hand to pick up objects of various configurations placed on a smooth surface to see how small an object the hand is capable of pinching up.

(a) square rod (d × d × 50 mm, aluminum material)
(b) round rod (ϕd × 50 mm, aluminum material)
(c) sphere (ϕd, copper material)

NOTES 1) "Capable of pinching up", in this context, implies that the hand can pick up the object in a secure manner at least 3 times per minute.

2) The value of "d" as a rule shall be changed 1 mm at a time.

(4) Largest object that can be pinched up

With the measurer holding the WIME HAND, input signals are applied to cause the hand to pick up a round aluminum rod d mm in diameter and 100 mm long to seek the maximum diameter of an object the hand is capable of pinching up.

(5) Maximum weight that can be lifted by two fingers (omitted)

(6) Pinching speed

Measure the time of one "stretching out - closing" cycle of fingers by applying signals to the input terminals of the WIME HAND.

3.3.2 Gripping Functions

(1) Maximum gripping force

Grip the finger-pressure converter for a physical capacity measuring device, holding it at the position shown in the drawing (omitted). Seek the maximum gripping force in a manner similar to that described in 3.3.1.

NOTES (omitted)

(2) Gripping force

Measure in the same manner as described in 3.3.1-(2).

(3) Maximum cylinder diameter that can be gripped (omitted)

(4) Security against pull

Have the hand grip a round rod 40 mm in diameter, and confirm that the round rod will not slip out when it is pulled by a force of 20 kg in the extended direction of forearm.

NOTE) Imagine the case when one holds on to a pole in a train.

3.3.3 Lifting Functions

With all the fingers except the thumb half-stretched, apply a load (P = 20 kg) to them in the extended direction of the forearm and confirm that the load will not slip off.

NOTE) Imagining the case when holding a strap of a train, the value of P is set to 20 kg. Supposing the case of holding a briefcase, it could be set to about 3 kg.

3.3.4 Twistiong Functions

With a door knob attached to the grip section of the arm-turning-force converter for a physical capacity measuring device, measure the maximum value of the twisting force with the hand in the grasp condition.

3.4 Electrical Test

3.4.1 Myoelectric Amplifier

(1) Maximum gain

With one of the electrodes grounded and the other connected to an oscillator which generates sinusoidal wave of 10 µV rms at frequencies of 50, 200, 500, 2000 and 4000 Hz, measure the output voltage of the amplifier. In this case the gain controller of the amplifier should be set to the maximum position.

(2) Output voltage

By following the method (1), measure the amplifier's output voltage, varying the voltage of the input sinusoidal wave at 500 Hz to 5, 20, 40, 80, 120 and 200 µV. The gain controller should be set to the maximum position.

(3) Common mode rejection ratio

With the two electrodes connected to each other, apply the sinusoidal wave of 150 μV rms at 50 Hz to them. Measure the output voltage of the amplifier. The gain controller should be set to the maximum position.

(4) Current consumption

With the two electrodes grounded, measure the current that flows from the power source to the amplifier.

(5) Residual noise

Ground the two electrodes by means of 1 MΩ resistors and measure the AC portion of the output voltage. The gain controller should be set to the maximum position.

3.4.2 Myoelectric Processor Circuit, Driving Power Circuit and Motor

(1) Operating sensitivity

After connecting an oscillator to the input terminal of the myoelectric processor circuit, gradually increase the voltage of sinusoidal wave input at 500 Hz, and measure the input voltage at the time the prosthetic hand starts to operate.

(2) Response time

Apply a signal to the input terminal of the myoelectric processor circuit by way of an amplifier having characteristics similar to those of the myoelectric amplifier's output stage, and measure the delay time for the start of finger operation. Also measure the delay time for stop by discontinuing application of the signal. The signal shall be a sinusoidal wave at 500 Hz and 2 V rms when not connected to the myoelectric processor circuit.

(3) Current consumption

Apply a 500 Hz 1.5 V sinusoidal wave to the input terminal of the myoelectric processor circuit and measure the current consumption when the fingers are moving, and then discontinue application of the input signal and measure the current consumption when the fingers are still.

(4) Operation of current detector (Limiter)

With the fingers of the WIME HAND fixed at a position where the stroke-end limit switch does not work, apply the finger movement input signal and gradually raise the power supply voltage. This will cause the current consumption to increase. But at a certain point, the current detector will operate and will cut off the current flow to the motor. Measure the current value immediately before the cut-off.

3.5 Reliability

3.5.1 Operating Durability

Repeat finger movement of "fully stretched out - fully closed - fully stretched out" 10^5 times at a rate of 6 times per minute and confirm proper operation of each section.

3.5.2 Biting

Have the WIME HAND grip a bar until the current limiter is activated. Then apply the signal that will make the fingers move further toward the closing direction 5 times, and then stretch out the fingers. Repeat this gripping and stretching-out operation 2×10^5 times and confirm that each section operates properly without biting or any other abnormality.

3.5.3 Durability against Repetitive Load

With the fingers in the half-stretched condition, apply a tensile load of approximately 4.5 kg in the extended direction of forearm and then remove the load. Repeat this operation 5×10^4 times and confirm proper operation of each section.

3.5.4 Durability of Wrist Unit

Turn the wrist unit in a reciprocating manner over an angle range of approximately 100° at a rate of about 3.5 times per minute. Repeat this operation 10^5 times and confirm that there is no abnormality such as drop in torque.

3.5.5 Vibration Resistance

Mount the WIME HAND on a vibration table having a frequency of 20 Hz and an amplitude of 1 mm. With the fingers repeating stretching-out and closing movement, apply vibration for 2 hours each in the vertical, longitudinal and lateral directions. Confirm normal operation of both the mechanical and electrical sections.

3.5.6 Shock Resistance

Fabricate an arm whose upper arm and forearm form a straight line. Attach the WIME HAND to this arm. After raising the arm (with the shoulder serving as the center of rotation) to a point that forms a 30° angle with the vertical axis, drop it causing it to collide with a wooden post. Check for any abnormality in the functions. Let the hand collide with the post 5 times each at the 4 positions of the wrist (turned 90° each). (Acceleration of 23.5 g is applied to the WIME HAND in this test.)

3.5.7 Temperature Resistance

Leave the hand section of the WIME HAND for 30 minutes in the air at a temperature of -10°C, then leave it for another 30 minutes in +30°C air, and again leave it for 30 minutes in -10°C air. After each temperature exposure, apply "stretching out" and "closing" signals and confirm that the hand section can be operated smoothly at that temperature.