Designing integrated testing for product development of prosthetic hand

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Abstract. In order to produce a standardized product, a series of product testing is needed from the beginning of the product design to the final product. The development of medical devices that are very rapid and demands excellent product quality needs to be accompanied by a very rigorous testing process because the use of the product is related to the user's physical and mental health condition. This study aims to summarize the ongoing testing carried out during product design to the use of the product by the user. The product in this case study is prosthetic hand made by CBIOM3S Diponegoro University. The research method used is based on research and direct surveys of designers, users and experts as well as literature review confirmation. The results showed a variety of stages and standardized starting from design testing, material testing, failure analysis and simulation, prototype testing for both the bionic and mechanical hands, usability and psychological testing by respondents and ended with medical confirmation.

1. Introduction

Human health conditions become an important part of the quality of human life. Parts of the body that are widely used in daily activities are the hands. If there is interference on the hand, then the patient will have difficulty to move. For patients with hand disorders who are forced to amputate their hands due to accidents or other causes, the health sector seeks in terms of mobility to aid in the form of assistive devices [1]. These aids can be in the form of prosthetic hands or robot hands. Before being used by people with disabilities, tools are needed to test the feasibility of an artificial hand, especially robots, both as a learning tool and as an aid to the adaptation process during using artificial hands.

With limitations in carrying out human daily activities, rehabilitation tools are needed to recover hand movements quickly and assistive devices in the form of prosthetic hands or robotic rehabilitation media as a substitute for previous hands. Before use, it will be very important to test the feasibility of a prosthetic hand or robot hand that will be used by patients or people with disabilities on the hands.

Recently, test of this product development is performed separately to encourage the speed of product design and testing. However, in terms of documentation and alignment of perception and mindset, it is necessary to consider integrated testing of products made. Although there are a variety of products made, basically the thinking framework refers to and is based on the similar pattern.

Several studies conducted related to prosthetic hand testing are based on experimental evaluations on 3D-printed prosthetic hand prototype [2], tests on appearance and functionality [3], mechanical testing methods [4], Anthropomorphic Hand Assessment Protocol (AHAP) [5] and various designs for artificial hands [6-20]. The aim of this study is integrating testing concept of the prosthetic hand to produce a standardized product based on literature and actual standard.

2. Methods

The method used in the design of this integrated test is a survey and interviews with users. This was accompanied by a literature review. In accordance with the initial stages in the product life cycle, product design begins with user need requirements [21], but to accommodate the speed of development of existing medical devices, the concept of product development is shifting from user needs based on
functionality and prototype development. The proposed product improvements refer to the ergonomic concept and product design.

The research method was carried out starting from mapping the stages traversed by prosthetic hand as products form Center for Bio Mechanics, Bio Material, Bio Mechatronics and Bio Signal Processing (CBIOM3S) Diponegoro University. At each stage, a defined testing is carried out to achieve product standards in accordance with technical and ergonomic standards. The integrated test results are intended for the construction of an integrated testing center.

Interviews were conducted with three product designer respondents from CBIOM3S, two persons with disabilities respondents and two product experts. Prototype trials and comments from respondents provide improvements that are used to build the next version of the product. The tested product is divided into two types namely bionic hands and mechanical hands.

3. Result and Discussion
The study results show testing is divided into several parts, namely testing in product design, material testing, running simulation testing, prototype testing and usability testing.

3.1. Design Testing
In design testing, there are several stages of testing that are accompanied by physical parameters. The stages in design testing can be seen in Figure 1.

Figure 1. Phase of design testing.

User needs specifications are obtained from interviews result with disabilities respondents. The initial specifications obtained are functional hands with relatively cheap prices, easy and comfortable, ergonomics size according to the user, strong durability, a human hand-like shape; easy and fast to use, high safety during adaptation process, simple, convenient, lightweight, intuitive actuation, can be produced with 3D printing and there are sensors at each finger. In addition, several previous studies also provide initial discussions related to user needs [21-27].

The technical specification phase provides the initial technical assumptions set by the product designer. Examples of assumptions are that the product is safe to use when carrying a 1.5 kg load, the weight of a light product (defined as having a weight of 300-500 grams), the use of sufficient and inexpensive quality materials such as PLA and resin [25] [26].

At the stage of making alternative concepts, the product is differentiated first for bionic and mechanical hand products. Definition of the alternatives is distinguished by sub-functions up to three levels. Sub-functions for bionic hands can be seen in Table 1, while sub-functions for mechanical hands can be seen in Table 2.

Alternative of the concepts are arranged in three concepts for example for alternative bionic hand concepts are as follows [26]:

- Concept 1: A1+B1+C1+D1+E1+F1+G1
- Concept 2: A1+B2+C2+D2+E2+F1+G1
- Concept 3: A1+B2+C2+D2+E2+F2+G2

Alternative of the concepts for mechanical hands are arranged as follows [25]:

- Concept 1: A1+B2+C2+D2+E1
- Concept 2: A1+B1+C3+D1+E1
- Concept 3: A1+B1+C1+D2+E1
| No | Sub-Function      | Sub-Function | Sub-sub-sub Function |
|----|-------------------|--------------|----------------------|
| 1  | Material selection | Polymer      | A1 PLA               |
| 2  | Index finger      | Mechanism    | B1 Gear              |
|    |                   |              | B2 Linkage           |
|    |                   | Motor        | C1 Servo MG995       |
|    |                   |              | C2 Micro servo MG90  |
| 3  | Middle finger     | Mechanism    | D1 Couple little finger |
|    |                   |              | D2 Linkage           |
| 4  | Thumb             | Mechanism    | E11 Degree of Freedom |
|    |                   | Motor        | E2 2 Degree of Freedom |
|    |                   |              | F1 Servo Mini Micro MG90 |
|    |                   |              | F2 Micro Gear motor DC N20 |
| 5  | Linkage           | Material     | G1 PLA               |
|    |                   |              | G2 Acrylic           |

| No | Sub-Function      | Sub-Function | Sub-sub-sub Function |
|----|-------------------|--------------|----------------------|
| 1  | Material selection | Polymer      | A1 PLA               |
| 2  | Fingers           | Material     | B1 PLA               |
|    |                   |              | B2 PLA and Flexible PLA |
| 3  | Linkage           | Material     | C1 PLA               |
|    |                   |              | C2 Flexible PLA      |
|    |                   |              | C3 Acrylic           |
| 4  | Spring            | Material     | D1 Metal             |
|    |                   |              | D2 Flexible PLA      |
| 5  | Rope              | Material     | E1 Fishing line      |

The basis of concept selection is determined based on the results of weighting and the highest criterion value of all alternative concepts. For example, designers of bionic and mechanical hand products decide to make products with Concept 3 which has the highest criterion value. Some assessment criteria that need to be considered are price, product weight, degree of freedom, grasping ability, ease of manufacture, ease of assembly, flexibility, ergonomic factors, ease of care, product shape, and ease of lifting [25] [26].

3.2. Material Testing
There are three tests on the material carried out namely tensile test, impact test and bending test. Tensile Test gives consideration of unit factors related to proportionality limit, elastic limit, yield point and yield strength, maximum tensile strength, breaking strength, ductility, modulus of elasticity, modulus of resilience, modulus of toughness, modulus of stress and strain engineering and actually. The test equipment used was Universal Testing Machine with ASTM D638-02 standard. Existing standards indicate the testing process by pulling a material until it breaks. The basic analysis used in the product is that the ductile material is preferred because it is generally more resilient and gives advance warning before damage occurs.

Impact testing considers unit factors related to temperature. Transition temperature is the temperature which indicates the change in fracture type of a material when tested at different temperatures. In testing with different temperatures, it will be seen that at high temperatures, the material will be ductile while at low temperatures the material will be brittle. Physical parameters show that a tough material can absorb more energy and lower the position h'. A material is said as a tough material if it has the ability to absorb large shock loads without cracking or deforming easily. The test equipment used was an impact testing machine with ASTM 32 standard, British Standard 4360 which states that the test of material...
strength is determined in the form of absorption of potential energy from a load that swings from a
certain height and mashing the test material so that deformation occurs.

The final stage in material testing is the bending test. Physical parameters used are a maximum crack
of 3 mm measured from all directions on the surface, a maximum crack of 10 mm from the sum of all
the biggest cracks between 1 - 3 mm, a maximum crack angle of 6 mm unless cracks originate from
several types of cracks, a maximum crack of 3 mm. Considerations of the most difficult factors include
tensile strength, chemical composition and microstructure, yield stress (yield). Test equipment that can
be used is AU-1016A stiffness tester (Taber Type) with ASTM D790-2 standard, ASME. In the standard
described testing does not require a testing machine to determine the quality of a material visually, to
measure the strength of the material due to loading and suppleness of the results of the connection.

3.3. Simulation Running

The simulation is used to analyze important parts of the components, especially the most potential
failures and critical pressures. There are two stages of testing, namely displacement and stress analysis
(Von Mises Stress).

Displacement analysis shows areas of stress concentration and deformation points. In addition, by
using maximum load, test can estimate almost tangible results to determine weak points in the design.
For simulation parameters, the force is assumed to be the main force broken into x, y and z components.
The unit factor considerations are unit displacement (URES) [28] with ANSYS/SolidWork software test
kits and finite element analysis standards. By using software-based testing, the impact of design changes
through simulation can be analyzed objectively. This analysis forms the basis and generates broad
assumptions, so that their values and displacements can be used for design purposes.

Another analysis is the stress analysis using Von Mises Stress. Material is said to begin to melt when
the Von Mises voltage reaches a critical value known as yield strength. Material is also determined as
in good level when the Von Mises Stress value is below the yield strength of the material. Unit factor
considerations related to the Von Mises Stress are switch, material yield stress and safety factor [28].
Test equipment used was ANSYS / SolidWork software and finite element analysis standard. Examples
of displacement analysis can be seen in Figure 2 (a), while the Von Mises Stress analysis can be seen in
Figure 2 (b).

![Displacement analysis](image1)
![Von Mises stress analysis](image2)

(a) Displacement analysis  (b) Von Mises stress analysis

**Figure 2.** Simulation running test.

3.4. Prototype Testing

Prototype testing is distinguished by the type of prosthetic hand, namely the bionic hand or mechanical
hand. Bionic hand testing refers to various types of grips such as precision grip, power grip/cylindrical
grasp, key grip/lateral pinch, ball grasp, open palm grasp and index point as shown in Figure 3 [28].
Testing is performed based on functionality aspect only by the designer.
Figure 3. Prototype testing for bionic hand [28].

Mechanical hand testing is only carried out using a hand tester and a suspended system. In the use of a testing hand, if the bag load can be maintained in the air for about 10 seconds without falling, a higher weight needs to be tested on the prosthetic hand until the weight can no longer be maintained. Consideration of related factors is the power generated on the dynamometer and the weight of the load that can be lifted. Tests carried out can vary with weightlifting tests on bag loads containing loads 2, 3, 5, and 10 lb. or 0.91 kg, 1.36, 2, 27 and 4.53 kg. When the maximum load generated in the final configuration setting on the prosthetic hand is the same as the power output on the dynamometer, the hand must then be assembled into a new configuration and the test needs to be repeated. Examples of tests can be seen in Figure 4.

Suspended system testing is almost similar to previous tests. The difference lies in the utilization of the PVC pipe segment to provide force on the pipe surface. The examiner also must determine whether the hand can support the weight for 10 seconds or the weighted iron handle will fall. If it fails to maintain grip for 10 seconds, then the test will be repeated to ensure that the weight is above the holding capacity. Test equipment used in mechanical hand testing is a dynamometer as shown in Figure 5 [29].

By utilizing the strength of the grip from outside the prosthetic hand, it is expected that the larger muscle groups in the arms can be used and it is possible to load the hands with higher weights. This test emphasizes the optimal angle bending that can be done to support the highest possible weight. The examiner also must determine whether the hand can support the weight for 10 seconds or the weighted iron handle will fall. If it fails to maintain grip for 10 seconds, then the test will be repeated to ensure that the weight is above the holding capacity.

Figure 4. Prototype testing for mechanic hand based on tester hand [29].
3.5. Usability Testing

Usability testing has been investigated for respondents [22] [23] [24] [29] [30]. In general, the testing phase includes measuring the time to complete the activity and filling out the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire. The respondents are given time for adaptation and learning to complete the given activities. Time measurement and questionnaire filling were conducted after completing each activity to obtain ISO 9241-11 criteria data, namely effectiveness, efficiency and satisfaction. The time calculation starts with instructions from the moderator as the stopwatch holder and ends when the respondent's hand is lifted off the object as a sign that the activity is said to have been completed. Completion of the activity was carried out several times to get at least 5 times the activity was successfully carried out [22] after repeating the type of activity given, respondents were given a USE questionnaire to find out the level of satisfaction of using prosthetic hands in completing that type of activity [31].

During the, moderators are encouraged to write small notes related to things that happened during the respondent trying to complete the activity. This can be in the form of obstacles experienced by respondents, complaints that are expressed related to the use of prosthetic hands, restrictions on the function of prosthetic hands that are found when unsuccessful in completing an activity and things that are considered important to be incident diaries when respondents respond.

Test results are documented for each usability criteria. The testing equipment used is a test kit that is continuously improved to accommodate daily activities as well as hand activity therapy [22].

3.6. Emotional Testing

Product evaluation was also carried out by means of product emotional assessment by respondents consisting of persons with disabilities and the community at large. The test tool used in this study was Premo Tool. The advantage of Premo Tool is the respondent giving emotional product does not have to see the physical/direct product to be assessed so as to facilitate filling out the questionnaire by focusing on product design. Stages in taking product emotional data is done by distributing questionnaires and showing product images to respondents. Then respondents were asked to fill in scores for 14 types of emotions that were felt after seeing the product [32]. The final stage is then a brief interview between the moderator and the respondent to find out the reason for choosing the most dominant emotional product. This product emotional assessment focuses on the achievement of research objectives so that the number of respondents is not a primary consideration in retrieving product emotional data. An example of the form of analysis for one prosthetic hand is shown in Figure 6.

Figure 5. Prototype testing for mechanic hand based on suspended system testing [29].
4. Conclusion
The results showed several stages of integrated testing for prosthetic hand products ranging from product design, material testing, running simulation, prototype testing and testing by respondents. Differentiation of products based on characteristics and functions needs to be done in each test to produce products in accordance with user needs and standards set. The final stage that needs to be done in subsequent research there is medical confirmation related to the results of this study. In addition, the development of the test can be done for other medical devices with similar models such as prosthetic foot or stroke therapy aid.

Acknowledgments
This research was financially supported by Diponegoro University in RPP (Riset Pengembangan dan Penerapan) 2020.

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