# FUNCTIONAL AND HEALTH RELATED ANALYSIS IN THE DISCIPLINE OF PROSTHETICS

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## *ABSTRACT*

*The purpose of this investigation was to identify the determinants of patient satisfaction with outcome after a period of wearing prosthesis. The instruments demonstrate adequate internal consistency of average mean 2.39 for lower extremity functional status and average mean 3.44 for health related quality of life. Subjective variables associated with pain were independent predictors of patient satisfaction. Thus, in assessing patient satisfaction, importance of patient-derived subjective assessment of symptoms and function are emphasized. Documenting mechanical stability of the prosthesis is inadequate when reporting follow-up studies and a questionnaires assessing patient satisfaction should be added to provide a better picture of the outcome and results.*

## *KEYWORDS*

*Amputation, prosthesis, functional, stump, patient satisfaction*

## 1. INTRODUCTION

In order to identify changes in the profession related to the delivery of care, the components available and the technology in use today, many study centers and hospitals had performed practice analysis and validation studies recent years. The profession was resurveyed every year as planned to provide conceptual guidance regarding the conduct of the practice [1].

A human-machine interface, the prosthesis socket has to be designed properly to achieve satisfactory load transmission, stability and efficient control for mobility. The biomechanical understanding of the interaction between prosthetic socket and the residual limb is fundamental to such goals [2].

This study was focus on investigating the patients' satisfaction with orthotic and prosthetic devices in Malaysia in order to come out with a better and innovative solution for improving their life quality.

The literature reviews from previous study on the requirement of prosthetic design, the satisfaction of the used of prosthetic design in other countries and the current trend of prosthetic design provide conceptual guidance on developing suitable and good questionnaire for further development in the study.

This study is divided into six sections. The first section mainly introduces the whole study. It provides the general overview and a description of the purpose of the survey. The second section includes the objectives of this study, which describes the aims that needed to be achieved. The third section discusses the background information, literature review and the basic concept in this study. Section 4 discusses about the study implementation. A specification list of the data analysis, description of practice development and empirically derived test development will be discussed in section 5. Finally, the last section contains the conclusions, future developments and possible enhancement and improvement on this study. The framework of the system is shown in Figure 1 below. Beginning with defining the study problem, this study is carried out according to a proper and systematic flow with

reference to the steps in the study process model adapted from How to Plan and Implement a Successful Survey by Louis and Richard [3].

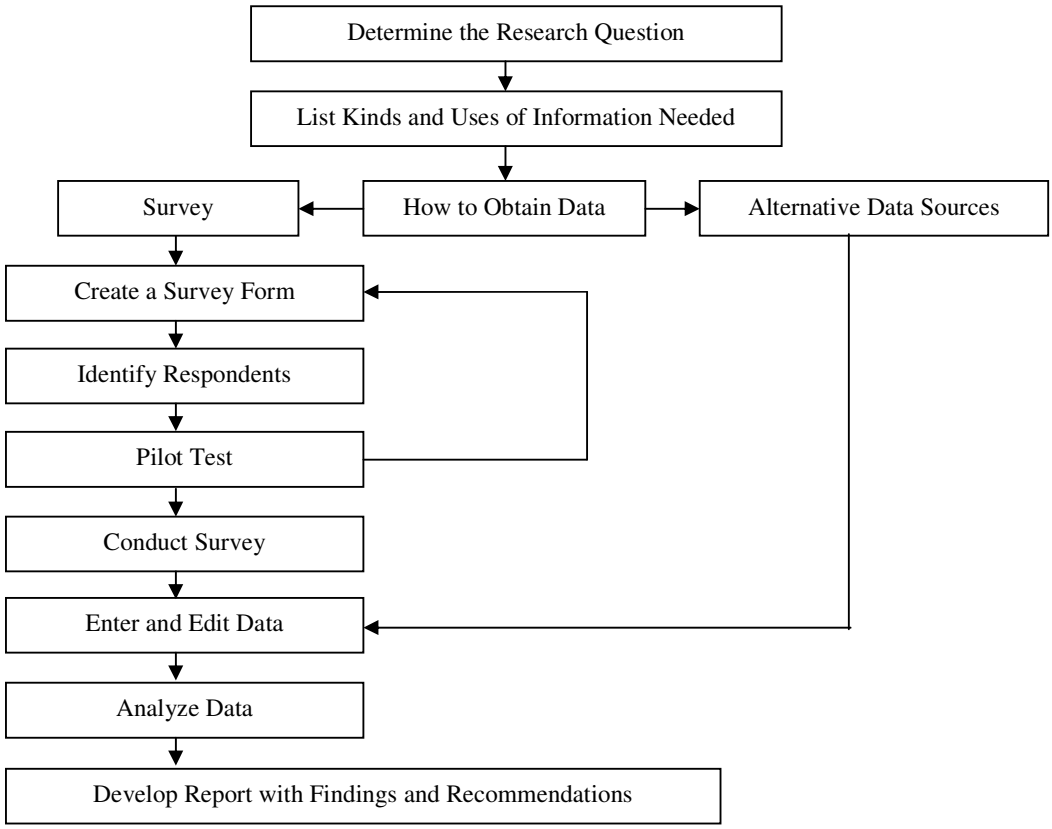


Figure 1. Data collection process flow

## 2. PROBLEM FORMULATION

The hypothesized function of this study is to provide the studier with information about what the subjects are feeling and do they satisfy with the prostheses in order to deliver useful information about their thinking with connection to the theory of mechanical movement of amputation leg.
The subjective experience of wearing prosthesis is simple hypothesized as the feedback from throughout their daily life. In this study, the practice item of measurement was focused on limb impairments. This study included some features prosthetic services and rehabilitation training.
The objectives of the fundamental studies are as follows:

- To investigate the patients' satisfaction with the orthotic and prosthetic devices in Malaysia.
- To make recommendation based on the study outcomes for the designer in order to improve their design.

Counterbalancing should be instituted to control for order effects and efforts made to ensure that all subjects complete tasks. New task need to be developed drawing on the best features of existing tasks.
In this study, an effective of patients' satisfaction with devices is presented. Several aspects for example the age, gender, year of amputation of the subject are considered while the assessment is being done. This study does not only serves patients' satisfaction as assessment, but also important in managing the subject data effectively and providing scientific information about prosthetic care.

## 3. LITERATURE REVIEW

### 3.1. Introduction

Traditional outcomes assessment measures include condition-specific measures, generic measures and measures of patient satisfaction [4]. In the past decade, patient satisfaction as a component of health

care outcomes assessment has achieved a critical role in the assessment of outcome after treatment. Moreover, the assessment of patient satisfaction may be used for various purposes, including evaluation of health care delivery systems, comparison of treatment methods, development of patient care models, facilitation of quality improvement and validation of quality of care [5, 6, 7]. As health care provision has shifted toward a market model, patient satisfaction has become increasingly important, with patients as consumers now playing pivotal roles in determining how and where their health care is delivered.

### 3.2. Prosthetic Replacement

Prosthetic replacements where incredibly realistic designed to not only are identical, but functional to the organ lost. Capable of being tailored to numerous species, prostheses ranged from not only hands, arms, and legs, but also eyes, ears, hearts, and lungs [8]. Additionally, many times the prostheses themselves could be upgraded, enabling the prosthetic to function far more effectively than the organ lost.

Limb replacement involves using some type of prosthetic to take the place of a part of the body that was amputated or lost due to injury or illness. With advances in technology and with a better understanding of how the brain controls movement, limb replacements are becoming more sophisticated and lifelike [9].

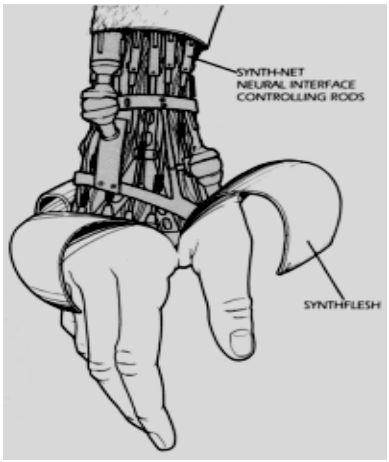


Figure 2. The reciprocating-gait orthosis, normally worn under the clothing, with structural components produced from 3D CAD.

### 3.3. Satisfaction of Patients with Prosthetic

Surveys have shown that amputees complain about their prosthesis being uncomfortable [10, 11]. It is not uncommon for amputees to develop skin problems on the residual limb, such as blisters, cysts, edema, skin irritation, and dermatitis. Discomfort and skin problems are usually attributed to a poor socket fit. Further improvement of prosthetic fitting is required to maximize amputee's comfort and acceptance of the prosthesis. The socket, as a human-device interface, should be designed properly to achieve satisfactory load transmission, stability, and efficient control for mobility. Some early designs of the prosthetic socket, such as the "plug-fit," took the form of a simple cone shape, with very little rationale for the design. Previous development shows that biomechanical understanding of the interaction between the prosthetic socket and the residual limb is fundamental to the improvement of socket design [12].

The basic principles for socket design vary from either distributing most of the load over specific load-bearing areas or more uniformly distributing the load over the entire limb. No matter what kind of design, designers are interested in understanding the load-transfer pattern. This will help designers to evaluate the quality of fitting and to enhance their understanding of the underlying biomechanical rationale. Many studies have been conducted to evaluate and quantify the load distribution on the residuum by either clinical measurements or computational modeling [13].

## 4. METHODOLOGIES

In this section, the procedure and the methods used for assessment will be described.
The method of data collection chosen will be closely related to the study design. Concerns about reliability and validity are always important, but more so with an experimental or quasi-experimental design. A less-controlled study design, such as correlation or descriptive, will have less-strict requirements.

### 4.1. Study Design and Population

Study design closely related to the method of data collection chosen in the study. Interview and questionnaire were structured with consist of multiple choices and open-ended questions to demonstrate a change in a patients' condition after an intervention.
A comprehensive assessment of the patient was performed to obtain an understanding of the patient's prosthetic needs. Then formulation of the treatment plan by analyzing and integrating information from patient assessment to create a comprehensive prosthetic treatment plan to meet the needs and goals of the patient. A periodic evaluation was conducted to assure, maintain and document the optimal fit and function of the prosthesis after a continuing patient care.
Structured responses making them attractive for a large-scale study because of the characteristic of easier to score and analyze. Open-ended questions are particularly useful when study cannot anticipate the range of responses in advance nor need in-depth information relevant to opinions, ideas or attitudes.

### 4.2. Data Acquisition and Management

There are few scopes to ensure the study is conducted within the boundary set, and heading to the right direction to achieve the intended objectives.
In order to elicit pertinent information regarding patients' perceptions, lower extremity functional status and health related quality of life; a relevant questionnaire survey was designed. The questionnaires were distributed by prosthetist to 16 consecutive patients with amputations who attended the Medic Prosthetic Orthotic Centre and Sarawak General Hospital from January 2011 until April 2011. The prosthetist offered to read the questionnaires and explain the intent of questions in case any patients were illiterate, had vision problem or did not grasp the meaning of the questions. Questionnaires were completed at the clinic visit and the prosthetist collected them.

### 4.3. Statistical Analysis

Statistical Package for the Social Sciences (SPSS) was used to store, verify and analyze the information obtained from questionnaires. Although 16 questionnaires were returned, not every subject answered every item, and therefore some items have fewer than 16 responses.
The survey respondents have provided a great service to the profession. It is imperative that as professionals and providers of patients care, practitioners recognize the importance of studies such as this that provide vital information to standard setting organizations [14].

### 4.4. Instrument Revision

The preliminary set of outcome measures consisted of separate modules – demographic data, descriptive statistics for lower extremity functional status and descriptive statistics for health related quality of life.
Standardized answer options are provided in five Likert boxes and each question is scored from 1 to 5. There are two categories of assessment, each of which has five grades: very easy, easy, slightly difficult, very difficult and cannot perform for the functional part and health related part has grades: not at all, slightly, somewhat, quite a bit and extremely. Each category assesses different clinical information including subjective self-assessment of preinjury and current activity level, symptoms, devices perception and compartmental findings [15, 16, 17].
English version only was available at the beginning of this study. The questionnaire was translated into Bahasa Malaysia with reference of MedlinePlus Medical Dictionary and Kudoz Open Glossary.

Table 1. Descriptive statistics for demographic data

| Variable | Mean | Frequency (%) |
|---|---|---|
| Gender | | |
| Male | | (14) 87.50 |
| Female | | (2) 12.50 |
| Age | 49.4 | |
| Family burden | 2.19 | |
| Years of amputee | 2.06 | |
| Affected limb(s) | | |
| Left leg | | (5) 31.25 |
| Right leg | | (11) 68.75 |
| Reason for assistive devices | | |
| Accident | | (6) 37.50 |
| Disease like diabetes | | (10) 62.50 |
| Prosthesis wearing (hour) | 11.17 | |
| Employment | | |
| Full time | | (13) 81.25 |
| Part time | | (2) 12.50 |
| Not employed | | (1) 6.25 |

Table 2. Descriptive statistics for lower extremity functional status

| Variable | Mean | SD |
|---|---|---|
| Walk indoors | 1.94 | 0.734 |
| Balance while standing | 2.0 | 0.63 |
| Stand one-half hour | 2.0 | 0.63 |
| Dress lower body | 2.06 | 0.617 |
| Get on and off escalator | 2.06 | 0.617 |
| Carry a plate of food while walking | 2.06 | 0.617 |
| Put on and off prosthesis | 2.06 | 0.617 |
| Pick up an object from floor while standing | 2.13 | 0.604 |
| Get up from a chair | 2.25 | 0.576 |
| Walk up to 2 hours | 2.31 | 0.562 |
| Walk outdoors on uneven ground | 2.38 | 0.651 |
| Get into and out of tub or shower | 2.63 | 0.599 |
| Get into and out of a car | 2.63 | 0.599 |
| Get on and off toilet | 3.0 | 0.37 |
| Get up from floor | 3.0 | 0.37 |
| Walk up steep ramp | 3.06 | 0.496 |
| Walk outdoors in bad weather (eg. rain, wind) | 3.13 | 0.595 |

Table 3. Descriptive statistics for health related quality of life

| Variable | Mean | SD |
|---|---|---|
| To what extent are you insulted by the attitudes of other people towards your physical condition? | 2.0 | 0.63 |
| How much do you keep to yourself to avoid the reactions of others to your use of prosthesis? | 2.75 | 0.449 |
| Have you felt so down in the dumps that nothing could cheer you up? | 2.94 | 0.391 |
| How much does pain interfere with your activities (including both work outside the home and household duties)? | 3.0 | |
| Did you feel full of life? | 3.0 | 0.37 |
| Did you have a lot of energy? | 3.0 | 0.37 |

| | | |
|---|---|---|
| Have you felt downhearted and depressed? | 3.0 | 0.37 |
| Did you worn out? | 3.0 | 0.37 |
| Did you feel tired? | 3.06 | 0.37 |
| Have you been nervous? | 3.25 | 0.496 |
| To what extent are you prevented from doing what you would like to do because of social attitudes, the law or environmental barriers? | 3.375 | 0.756 |
| Were you easily bothered or upset? | 3.81 | 1.245 |
| Have you been happy? | 3.94 | 1.330 |
| To what extent have you cut down on work or other activities because of emotional problems? | 4.0 | 1.415 |
| Have you felt calm and peaceful? | 4.0 | 1.37 |
| Did you have difficulty concentrating or playing attention? | 4.0 | 1.37 |
| How much does your physical condition restrict your ability to do chores? | 4.06 | 1.453 |
| To what extent have you cut down on work or other activities because of your physical condition? | 4.88 | 2.269 |
| To what extent do you accomplish less than you would like because of your emotional problems? | 4.94 | 2.320 |
| To what extent do you accomplish less than you would like because of your physical condition? | 4.94 | 2.320 |
| How much does your physical condition restrict your ability to run errands? | 5.0 | 2.37 |
| How much does your physical condition restrict your ability to pursue a hobby? | 5.0 | 2.37 |
| How much does your physical condition restrict your ability to do paid work? | 5.0 | 2.37 |

## 5. RESULT

### 5.1. Analysis Result from Table 1

Sixteen patients were completed the questionnaire (14 males, 2 female). It is based on personal follow-up examinations, replies to questionnaires and data obtained from record cards kept on the amputees. The mean patient age was 49.4 and the age distribution was skewed more towards the younger population than expected.

There were 5 Malay, 3 Chinese, 7 Iban and a Bidayuh patients. Thirteen subjects had undergone amputation for less than 2 years. Causes of amputation included a significant incidence of disease like diabetes and road accident. Amputation included 5 left leg and 11 right leg.

The social situation of patients was not unusual. The largest percentage was married and has children (81.25%), 6.25% has no children and 12.5% never married.

Most patients were employed. At the period of collecting data, 13 were employed fully, 2 were employed part-time and 1 was unemployed.

### 5.2. Analysis Result from Table 2

Table II presents the results of the criticality rating scales for ability of performing tasks associated with implementation of the treatment.

Rating scale analysis of the functional status responses yields desirable person and item separation statistics. By default, the mean item difficulty is 1 with easier items and more difficult items in the higher range.

The table shows that the easiest items are “walk indoors”, “balance while standing” and “stand one-half hour”. Items of average difficulty include “walk outdoors on uneven ground” and “walk up to 2 hours”. The most difficult items are “walk outdoors in bad weather”, “walk up steep ramp”, “get on and off toilet” and “get up from floor”. All of the items are retained because they are both clinically relevant and constitute a measure spanning a wide range of ability. The items are well-targeted to the

sample as indicated by a total mean measure of 2.39, as the sample performed slightly above the average of slightly difficult in Likert scale.
The prosthesis has been used in the performances of fishing, gardening and agricultural work, meeting friend, gathering, heavy labor and while outdoors in cold or rainy weather.

### 5.3. Analysis Result from Table 3

Rating scale for health related quality of life analysis responses also yields desirable person and item separation statistics. The items table for this scale depicts the item hierarchy with smaller value indicates a higher quality of life. The item shows that positive items to endorse are "to what extent are you insulted by the attitudes of other people towards your physical condition" and "how much do you keep to yourself to avoid the reactions of others to your use of prosthesis." The average items are "have you been nervous" and "to what extent are you prevented from doing what you would like to do because of social attitudes, the law or environmental barrier." The negative items to endorse are "how much does your physical condition restrict your ability to run errands", "how much does your physical condition restrict your ability to pursue a hobby" and "how much does your physical condition restrict your ability to do paid work." The set of items are reasonably targeted to the sample as indicated by total mean measure of 3.44 as a whole performed a bit below of the normal quality of life.

## 6. DISCUSSION

As an integral aspect of the so-called third revolution in medical care, outcomes study has increasingly become fundamental in the evaluation of accountability and assessment [18, 19].
The overall survey return rate was 32%. The return rate was derived by taking the number of completed surveys received and dividing it by the number of surveys eligible to be completed. For an overall return rate of 32%, this response rate is very acceptable when compared with studies of other professions wherein potential respondents were required to respond to a detailed and comprehensive survey such as that used in the present study.
The patients were not unusual regarding etiology, site of amputation, gender, race or employment status. Most of patients were employed and this means that patients will not lose their jobs because of amputation. Most felt they had little choice regarding their amputation or selection of prosthesis yet most of them wore their prosthesis ten or more hours per day.
Some of the problems of the patients did not relate to the principle of the socket and would have occurred with other designs.
The gentle, alternating, positive and negative pressure afforded by the socket to the patient as he walks improves the circulation of the stump and constitutes one of the socket's main advantages.
This study assesses clinically relevant items of patient experience that should help clinicians and therapists provide high quality care. For example, outcomes be able to compare across facilities in a multi-facility database which using the same instrument. Implementation of corrective action can be done for the facilities with low levels of patient satisfaction or functional gains. Identification easily being done for patients with atypical response patterns like feel hard to perform certain items that are easy for most of the patient and thus follow by follow-up evaluation with questioned in greater detail about their unique need or the environment that makes their experience unique. Finally, prosthetist could follow-up with patients who are not satisfied with one or more aspects of their services for further evaluation.

## 7. CONCLUSION

These rating systems in general include subjective domains (functional status, activities of daily living) and objective domains (motion, strength, stability, mobility); the relative contributions of each vary by the scoring system used. Moreover, patient satisfaction is often a major component of the assessment and has relatively high impact on overall scoring. In the last decade, patient satisfaction has assumed a critical role in the evaluation of the quality of health care provision, the effectiveness of allocation of health care resources, the improvement of patient care delivery models and overall societal health status [20].

Most of our patients were recent amputees. Apparently, more experienced amputees have learned to obtain access to prosthetic devices without attending prosthetic clinics. Our review suggests patients are more depressed acutely following their amputation than when assessed months or years later. It may be that amputee patients require a period of mourning for their loss before they can get on with the daily business of prosthetic wear.

One potential limitation of the study is the 32% response rate among participants, however, this study demonstrated no difference in responders and non-responders in terms of age, gender or baseline medical comorbidity, and authors believe that the conclusions remain valid.

The domains in the study, lower extremity functional status and health related quality of life provide clinicians with promising tools to evaluate individual client and programme outcomes. The authors realise that this study has several limitations which are subjects were selected from only general hospital and rehabilitation center. It is possible that patients referred for prosthetic services in other settings might report a narrower or broader range of responses. The sample is sufficient to estimate item difficulties confidently, but it is not large enough to discern differences of sub-groups such as prosthetics and orthotics, adults and children. The new sample will reflect the characteristics of a larger patient population and allow the evaluation of sensitivity to change over the time.

All the patients were presented with appropriate levels of expectations and subsequently demonstrated high levels of satisfaction with the devices. Future work should be directed toward understanding the pathway by which patients with high expectations achieve greater pain relief such as self-efficacy or participation in rehabilitation.

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