User-Centered Prosthetic Development: Comprehension of Amputees' Needs

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Abstract

The goal of user-centered development (UCD) is an active involvement of the user for a clear understanding of the users' needs. In the context of rehabilitation engineering it is essential to integrate the users' needs into the development methodology. In fact the use or disclaim of assistive device depends on good comfort and satisfaction during application. Especially prostheses are developed to improve amputees' quality of life up to live independently again. UCD can improve integrating the amputees' needs into the prosthesis' properties. For a more detailed view of the prosthesis-users' needs we developed a questionnaire and collected data from patients regarding their needs using lower limb prostheses. 88 items, describing satisfaction, usability, appearance, functionality and handling of the prosthesis in different motor situations, were generated. Among 65 participants, 29 transfemoral amputees and experienced prosthesis users completed the questionnaire. The results indicate a lack of satisfaction with the prosthesis shaft as well as with different motor functions. Furthermore, the majority feels socially restricted and is dissatisfied with their appearance in public. While the latter is significantly negative correlated with feelings of social restriction, problems during changing gait speed are significantly negative correlated with feelings of certainty and stability during spontaneous movements. Although prostheses are developed to help to improve amputees' quality of life, the lack in different motor- and social- issues are noticeable. This indicates that the enhancement of changing gait speed in prostheses may help amputees to feel more certain and natural during walking. From an amputee's point of view, this could be one important predictor for being more satisfied and a first step for being more independent in life in general. With this first step of UCD, important information for the design of prosthesis in future has been generated.

1 Introduction

In Germany approximately 50000 amputations were executed every year. 95% of those are applied to the lower limbs [3]. Also in the UK incredible high values of new referrals for lower limb prostheses are reported (over 90% according to [6]). The rehabilitation process after amputation is thus an important field because the bigger the areas of amputations, the higher the effect to the equivalent receptive fields in the central nervous system [8]. This is resulting in a wide time span (from 14 days to several years) to integrate a prosthesis in the body scheme [5]. In this time, also basic principles could be formed for the satisfaction of the prosthetic user.

Although there is a lot improvement in new lower limb prosthesis technologies, studies showed that some patients are unsatisfied with their prosthesis [4 , 2].Issues of importance were fit of the socket with the residual limb, the mechanical functioning of the prosthesis, non-mechanical qualities, and the advice about adaptation to life with prosthesis with support from others [2]. Newer studies show that although patients with above knee amputation report are benefitting from e.g. microprocessor-controlled prosthetic knee joints after one week of using them, this benefit is not reflected in their actual daily activity level [9]. Additionally, the epidemiology may have impact on the satisfaction during motor performance [1].Finally, the overcome of some motor situation is related to ones' perceived satisfaction of the appearance of the prosthesis during daily living [4].

It will be apparent, that the construct of satisfaction in prosthetics users seems to be evoked by a multi-causal background and to some extent an acceptance of dissatisfaction is noticeable. For now there is no data whether satisfaction is defined qualitatively or quantitatively in a different way between patients with different kind of amputation. We assume that the claim to be satisfied during the use of prosthesis is also dependent from the amputation type and hence a transfemoral amputation evokes much higher demands on the prosthesis than other types of amputation on lower levels.

Beside the satisfaction due to usability factors, acceptance of technology impacts also the satisfaction in rehabilitation. For this, user centered design cycles have been shown to enhance a rehabilitation process during virtual [11] or robot technology implementation [10]. While data for lower limb amputees are missing, the user centered develop-

ment (UCD) may also overcome difficulties in this patient group that result because of the mulifactorial structure of "satisfaction".

The goal of UCD is an active involvement of the user for a clear understanding of the users' needs. In the context of rehabilitation engineering it is essential to integrate the users' needs into the development methodology. In fact the use or disclaim of assistive device depends on good comfort and satisfaction during application. Especially prostheses are developed to improve amputees' quality of life up to live independently again. UCD can improve integrating the amputees' needs into the prosthesis' properties.

In this paper, items of a newly developed questionnaire are presented with the focus on transfemoral prosthetic users and their satisfaction in daily living. A correlation matrix may demonstrate the acceptance of dissatisfaction to some extent and the Prosthesis-User-in-the-Loop simulator [12, 13] concept may give ideas to overcome the issues related to non user centered development in the design of a rehabilitation process in lower limb amputees.

2 Methods

For a more detailed view of the prosthesis-users' needs the authors developed a questionnaire and collected data from patients regarding their needs using lower limb prostheses. 88 items, describing satisfaction, usability, appearance, functionality and handling of the prosthesis in different motor situations, were generated.

Among 65 participants (15 females, 50 males), 29 transfemoral amputees and experienced prosthesis users completed the questionnaire. The ages ranged from 15 to above 71 years, but a larger number of 49 participants were over 41years old. Among all participants the time span since a prosthesis first being used, ranged between 0 and 63 years.

The questionnaire was published in a German and an English version on different internet platforms regarding prosthetics. The items which included statements like "Are you satisfied/restricted…" , "How satisfied/restricted…", "Do you feel/have…" could be answered with a numeric rating scale (NRS) such as"1"=very satisfied, "2"=somewhat satisfied,"3"= dissatisfied, "4"= very dissatisfied. In case of interpretation, the value "1" was defined as being totally satisfied with the related issue. The values "2" to "4" were defined as a being not completely satisfied. No statement was coded with the value "5"(missing value).

First, the frequencies, median, mean values and standard deviation were calculated (for the discussion of using a NRS as a scale with ratio scale characteristics [7]). U-Mann tests were applied between lower leg and transfemoral amputees to test, whether there is are quantitative differences between the types of amputation. Other comparisons between groups were not tested because of their different N sizes.

Second, the authors excluded all subjects without transfemoral amputation from the correlation calculation, to show the specific relationship of satisfaction or the possible acceptance in dissatisfaction in patients with this particular type of amputation. All items that show significant correlations are presented.

The study was conducted from November 2010 to March 2012. In this period a majority of sixty participants used the German version. Table 1 summarizes that the activity classes of all prosthesis user ranged from AK3 to AK5.

	Categories				
Activation class	AK0	AK1	AK2	AK3	AK4
Frequencies	0	0	16	17	32

Table 1: Frequencies of activity classes of the sample

Furthermore microprocessor-supported (N =30) or mechanic prosthesis (N = 26) represented the most common types of prosthetic components (see table 2).

	Categories			
Type of prosthesis	active	microprocessor -supported	mechanic	other
Frequencies	2	30	26	7

Table 2: Types of prosthesis

Among all participants, there were 29transfemoralpatients (see table 3).

	Categories				
Level of amputation	hip disarticulation	thigh/femoral	knee exarticulation	lower leg	foot
Frequencies	2	29	10	21	3

Table 3: Levels of amputation

SPSS 17 and MS Excel 2007 were applied to calculate the values shown below.

3 Results

In Image 1 means and standard deviation of subjective satisfaction ratings are presented in subjects with different types of amputation (transfemoral/lower leg). No significant differences were found between the two groups. The median value was "2" in every condition. Frequency tables strengthened the observed tendency of prevalently dominance of the numbers "2" to "4".

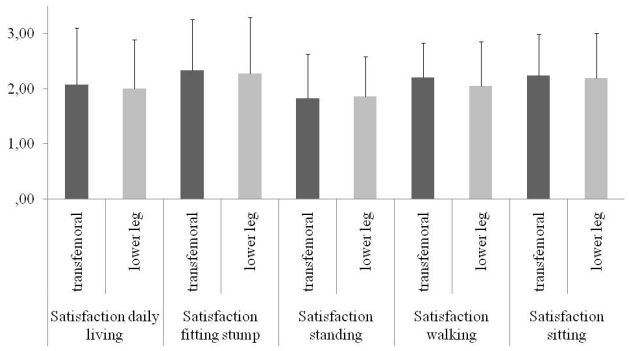

Image 1: Satisfaction ratings between two different groups N=29 transfermoral and N= 21 lower leg) of amputees:

The rating of item "Do you feel socially restricted?" which is not presented in image 1, showed that more subjects with transfemoral amputation felt restricted (1/3 to 2/3) than patients with lower levels of amputation (1/4 to 3/4) . Image 2 shows the items and their acronyms which showed significant correlations.

Acronym	Question
A	Are you satisfied with your prosthesis in everyday life?
B	Are you restricted in everyday life by the size of your prosthesis?
C	Do you feel socially restricted?
D	How many times a day do you have problems because of a swollen stump?
E	Are you satisfied with your appearance in public?
F	Do you think you have a natural gait pattern?
G	Would you prefer more mechanical/electronic aid during the extension of your prosthesis?
H	Do you feel comfortable when you cannot change your gait speed?
I	Do you have problems with your prosthesis while changing your gait speed?
J	Are you satisfied with the transition from standing to walking?
K	Do you feel uncertain with your prosthesis as a mechanical aid?
L	Do you feel certain and stable when you have to compensate the loss of balance? (e.g. to stabilize the body in the event of imbalance during a lunge/sidestep)
M	Would you prefer a foot prosthesis which adjusts to different heel levels?

Image 2: Items and acronyms with significant correlations

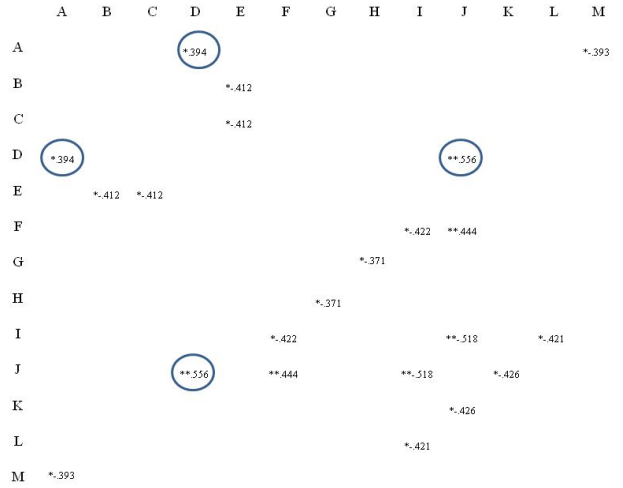

Image 3: Correlation matrix (N= 29 transfemoral amputees). Marked correlations may be defined as acceptance of dissatisfaction. * p< .05, ** p < .01.

In Image 3 the correlations between the items listed in image 2 are presented. The correlations marked with a black circle may show inconsistent content and therefore may be interpreted as acceptance of dissatisfaction (see conclusion).

4 Conclusion

Regarding the authors criteria of satisfaction, the results indicate a lack of satisfaction in daily living, the prosthesis shaft /fitting stump, satisfaction during standing, walking and sitting. This seems to be in accordance with [4] and [2]. No correlation was found regarding different epidemiological background [1]

The assumption that patients with a transfemoral amputation have much higher demands on the prosthesis satisfaction than patientswith other types of amputation is shown to be wrong. For now it seems that there is no difference.

Ratings of socially restrictions showed a higher (non significant) trend in subjects with transfemoral amputation. Additionally, higher values in the satisfaction with the appearance in the public ratings are significantly negative correlated with feelings of social restriction. Problems during changing gait speed are significantly negative correlated with feelings of certainty and stability during spontaneous movements. Beside those congruent or "sense-making" correlations, "incongruent" correlations in the sense acceptance of dissatisfaction were found. Why should a patient state that he is satisfied with the prosthesis in everyday life, if he experiences problems due to a swollen stump on more times a day? Why should a patient state that he is satisfied with the transition from standing to walking, while he indicates to have problems because of a swollen stump at multiple times a day? Does he accept the problem and the consequences of a swollen stump? Is it a kind of resignation? Literature supports some kind of incongruence between statements and behavioral data [9]. Maybe this describes an intra-psychological minus development which also affects the rehabilitation process.

Besides this psychological mal-adaption, it is important to prevent the consolidation of pain in the stump as a consequence of repetitive noxious stimulation that may cause swelling. This may interfere with the integration of the prosthesis in the body scheme, which could be prolonged [5]. The nervous system is very sensitive, also years after the amputation [8]

Regarding the authors' data, it is apparent that each particular patient has to be treated individually. It has been shown, that in some rehabilitation domains the user centered development or design may help to prevent incongruence and mal-adaptation due to a nomothetic paradigm [11, 10]

To provide a holistic user-centered design methodology, user experience and assessment should be considered during all steps of a prosthetic development. Until now, this is only possible by questionnaires to survey the user's requirements in the beginning of the development and for an

evaluation of prototypes in clinical evaluations in the end of this process. The Prosthesis-User-in-the-Loop simulator concept proposed by the authors [12, 13], aims at supporting user-centered prosthetic design by integrating the users to the development process. Therefore, it provides simulations of the biomechanical behavior of prostheses for the user in several gait scenarios. To complete the illusion of walking with the prosthesis simulated in hardware, a visual simulation is given.

A main functional unit of the simulator concept is the biodynamic simulation unit. This is attached to the stump of the participant's harmed leg and represented by an actuated and instrumented robotic device. By providing, a simulation of the biomechanical interactions between the users' body and the investigated prosthesis directly to the stump, the mechanical part of the illusion is set up. At the same time, the intact leg of the participant walks on a unit simulating the environment – e.g., a treadmill. The illusion of walking with the simulated prosthesis is completed, by the visual simulation unit - e.g., screens or projectors - and the concealment of the biodynamical feedback in a blackbox. A possible practical implementation of the simulator concept is given in Image 4.

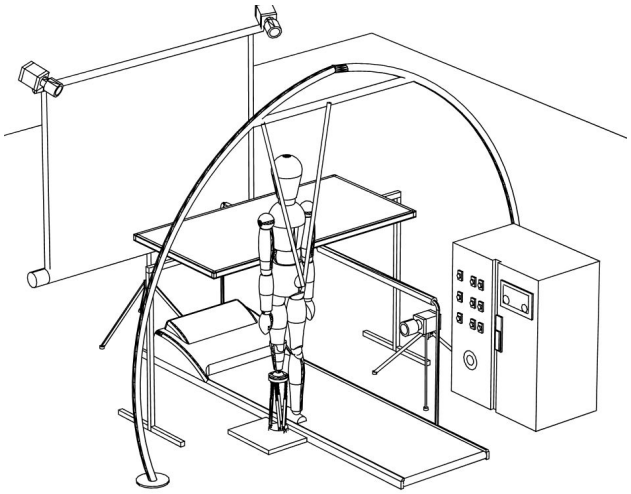

Image 4: The Prosthesis-User-in-the-Loop simulator concept

With this holistic illusion, the experience of physical integrity can be provided and changed during the examinations to assess its influence and the real behavior of the investigated prosthesis in this virtual reality. Thus, an isolation of prosthesis' functionality from other possibly correlated factors is possible and might support an objective assessment by the user. During the experiments the users are secured in a user safeguarding unit – e.g. a climbing harness. Further studies will proof, whether this concept is able to prevent incongruence and resignation. Beyond this, those studies will help to comprehend amputees' needs and will contribute in the rehabilitation of a growing number of patients [3, 6].

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