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Developing and testing of an electronic data collection system for the treatment of phantom limb pain

Master of Science Thesis in Biomedical Engineering

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CHALMERS UNIVERSITY OF TECHNOLOGY
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Abstract

Following an amputation, a phantom phenomenon is normally felt in the missing limb. This phenomenon can be of a painful nature, in which case it is known as phantom limb pain (PLP). PLP is reported by approximately 70% of all amputees and is extremely difficult to treat. Recent developments have introduced a new rehabilitation treatment based on the promotion of motor execution via Augmented Reality (AR) and gaming, while the source of control are phantom motions that are predicted using myoelectric pattern recognition (MPR).

Chronic PLP patients experience pain with great complexity, which cannot be evaluated in a single point in time due to the fluctuations on pain intensity over variable periods. Pain intensity, frequency, and location are key variables in chronic PLP that are rarely monitored together. Consequently, it is difficult to measure pain over time and evaluate if treatments are relieving it. To date, there is no validated pain questionnaire available for pain tracking and reporting that captures all the complexity of chronic PLP.

This thesis investigates and evaluates how pain is currently reported in order to develop a user friendly questionnaire that captures all different aspects of chronic PLP. A subject with PLP was treated with the new MPR/AR-VR/Gaming treatment. The treatment software was developed at Chalmers University of Technology, the Centre of Orthopaedic Osseointegration at Sahlgrenska University Hospital, and Integrum AB. The subject was treated approximately once a week and additionally answered the prototype questionnaire developed in this work for evaluation and feedback.

A new PLP tracking questionnaire was developed and tested using the feedback from the subject. This questionnaire will be used in a clinical trial for the new PLP treatment. The subject was able to answer the questionnaire without assistance both in English and Swedish with an approximate answering time of 20 minutes. The questionnaire was reported as easy to follow and understandable. Furthermore, stand-alone software was programmed in C# to visualize the pain tracking and reporting and to make it simple and user friendly for clinicians and patients. Future work will consist of testing the proposed questionnaire with other subjects and compare it with other validated pain measures to confirm its reliability and validity. A future goal is to combine the proposed PLP tracking software with the new MPR/AR-VR/Gaming software developed for treatment of PLP.

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Table of Contents

Abstract.....	i
Acknowledgements.....	ii
Table of Contents.....	iii
Abbreviations.....	v
1. Introduction.....	1
1.1 Aim.....	2
2. Background.....	3
2.1 Treatments.....	4
2.1.1 Virtual Reality, Augmented Reality and Gaming.....	5
2.1.1 BioPatRec.....	5
2.1.2 Neuromotus.....	6
2.2 Measures of Pain.....	6
2.3 State of The Art of Pain Reporting.....	6
3. Methodology.....	10
3.1 Pain Report Forms.....	10
3.2 Design Overview.....	10
3.3 Design Implementation.....	11
3.3.1 Question Design:.....	11
3.3.2 Study Limitation.....	12
3.3.3 Questionnaire Development.....	12
3.4 Prototype Testing.....	12
3.4.1 Subject.....	12
3.4.2 Treatment procedure.....	12
3.5 Clinical Trials.....	14
4. Results.....	15
4.1 Background Information.....	15
4.2 Pain Tracking.....	16
4.2.1 Pain Frequency.....	16
4.2.2 Pain Characteristics.....	16

4.2.3	Pain Intensity.....	17
4.2.4	Activity Interference	18
4.2.5	Pain Location.....	18
4.2.6	Medication changes and Prosthesis Use.....	19
4.2.7	Sleeping Patterns	20
4.2.8	Phantom Limb Sensation	21
4.2.9	Telescoping	21
4.2.10	Phantom Mapping	22
4.2.11	Phantom Movements.....	22
4.3	Pain Distribution	23
4.4	Stand-alone Software Implementation.....	25
5.	Discussion	31
5.1	The Development.....	31
5.1.1	Pain Distribution over Time.....	31
5.1.2	Limitations	31
5.2	Challenges in Current PLP Questionnaires	32
5.3	Future Work	32
6.	Conclusion.....	33
	References.....	34
	Appendix A.....	38
	Appendix B	39
	Appendix B	42
	Appendix C	46

Abbreviations

AR	Augmented Reality
CPGS	Chronic Pain Grade Scale
EMG	Electromyography
GQPAA	Groningen Questionnaire Problems after Arm Amputation
MES	Myoelectric Signals
MPI	Multidimensional pain Inventory
MPQ	McGill Pain Questionnaire
MPR	Myoelectric Pattern Recognition
NPSI	Neuropathic Pain Symptom Inventory
NRS	Numerical Rating Scale
PLP	Phantom Limb Pain
PLS	Phantom Limb Sensation
PM	Phantom Movement
Q-TFA	Questionnaire for Persons with a Transfemoral Amputation
Q-PLPT	Questionnaire for Phantom Limb Pain Tracking
SF-MPQ	Short Form McGill Pain Questionnaire
SP	Stump Pain
TAC	Target Achievement Control
UAT	User Acceptance Testing
VAS	Visual Analogue Scale
VR	Virtual Reality
WPD	Weighted Pain Distribution
XML	Extensible Markup Language

1. Introduction

Medical treatments are constantly improving, leading to an increased survival rate of patients. However, at the same time the amount of patients that need rehabilitation rises, and the demand for new rehabilitation technologies is increasing, giving more pressure to clinics and clinicians. Recent developments have given patients the ability to rehabilitate at home with more flexibility and requiring fewer visits to the clinic. Rehabilitation of amputees is affected by this development and new software systems are emerging. For instance a system that uses augmented and virtual reality (AR/VR) environments is currently being developed at Chalmers University of Technology (CTH), the Centre of Orthopaedic Osseointegration at Sahlgrenska University Hospital (COO-SUH), and Integrum AB. The main objective for rehabilitation after amputation is to reach the best possible quality of life for the amputee. Approximately 70% of individuals with amputation feel chronic pain in their absent limb [1], [2], which can developed into a significant problem. Rehabilitation helps amputees decrease their constrained functionality, improve their prosthetic use and relieve the stump pain (SP) and phantom limb pain (PLP).

To date, there exists no validated pain questionnaire available for pain tracking and reporting that captures all the complexity of chronic PLP. Therefore it is difficult to analyse the progress of PLP during rehabilitation except for a single point in time. There are standard pain assessment tools that have been used for many years such as visual analogue scale (VAS) and McGill pain questionnaire (MPQ). These assessment tools do not capture the fluctuating pain of amputees. This is creating a problem for clinicians and physical therapists when analysing the progress of their patients during the time of rehabilitation. Furthermore, this problem extends to rehabilitation at home since the collection of data is crucial to track the progress of the rehabilitation, and to provide clinicians an overview of the efficacy of the PLP treatment.

1.1 Aim

The aim of this thesis was to develop a user friendly questionnaire that captures all different aspects of chronic PLP by investigating and evaluating the way phantom limb pain is currently reported. This questionnaire was developed with prototyping and testing with a feedback from a PLP patient that is using the new MPR/AR-VR/Gaming software (Neuromotus). The objective was to analyse treatment impact on PLP, test the proposed questionnaires and check that the content covers relevant and important issues regarding pain reporting of individuals that have suffered an amputation. The purpose of the questionnaire is initially to be applied by clinicians during rehabilitation of amputees or for amputees rehabilitating at home, and secondly to be applied in a clinical trial regarding assessment of the new MPR/AR-VR/Gaming software. This clinical trial will be introduced in this report. It is important for the clinical trial that the questions are not ambiguous and that they are correctly interpreted by the patients. Also, the pain tracking progress must be easy for the patient to understand and visualize.

In this study, new software will be developed around the proposed questionnaire with a simple user interface. The benefits of having the questionnaire in software are that less time is needed to evaluate the result, and it would make it easier to filter out unnecessary raw data. Simple build-in graphs and tables can give a comprehensible overview of the pain progress.

The desired outcome of this thesis is that the questionnaire will be sufficiently tested in order to be applied in the clinical trial. This is important in order to analyse pain tracking for the new MPR/AR-VR/Gaming software for treating PLP. One aim of this software is to be widely available so PLP patient can conduct the rehabilitation at home and answer the questionnaire on their own in order to collect data, which will ultimately allow the patient and clinician to track the PLP progress.

2. Background

Amputation or denervation of a body part can occur after traumatic injury, diabetes mellitus and vascular disease [3]. Following an amputation of a body part, a phantom phenomenon is felt in the missing limb. This feeling can be non-painful or painful [4]. Most amputees [5] experience awareness of their phantom limb, such as size and position and phantom limb sensation (PLS) which refers to a specific feeling of sensory stimulations of the missing limb, such as feeling of warmth or cold [6]. However approximately 70% [1] of patients experience a painful sensation in their absent limb, so called phantom limb pain (PLP) [7]. Phantom pain can be constant or occurring in short periods with presence of painful symptoms such as burning, stabbing, cramping, gnawing and more [8]. Additionally, PLP can be perceived immediately or it can occur many years after amputation [5], [8], [9]. Some amputees also experience a feeling that the fingers are locked in a painful clenched position like the nails are forced into the palm [10]. The perception of PLP can be affected by external factors such as touching the stump, rehabilitation and use of prosthesis [11]. PLP has an effect on mobility and makes a simple activity impossible to do, like dressing and showering [1]. Individuals that have amputated body parts can have painful sensation on the adjacent area to the amputated body part called residual limb pain or stump pain (SP) [8]. SP is in most cases positively associated with PLP [8]. Studies have showed that prosthesis use, stump pain, phantom sensation, pain before amputation, cause of amputation and time since amputation are risk factors that may have effect on phantom pain [1], [12]. Moreover, many amputees experience telescoping, which is the feeling that the phantom limb is retracting towards the stump and they frequently feel like their phantom part disappears into the stump [8]. Recent evidence suggest that telescoping is related with more phantom pain [13].

PLP is a complex phenomenon that is not fully understood and the exact cause is yet unknown [14]. There have been proposed three potential principal mechanisms underlying phantom pain: peripheral factors, spinal factors and central brain changes which seem to be the major determinant of PLP [8], [15]. Studies have shown that following an amputation, an extensive reorganization in the primary sensorimotor cortex occurs [16]. Furthermore, studies have shown a correlation between the amount of cortical sensorimotor reorganization and the occurrence of PLP [16], [17]. According to these studies, new methods have been proposed in order to reverse the cortical reorganization [16]. Figure 1 shows an illustration of the motor and sensory cortex. The motor cortex is responsible for planning, controlling and executing voluntary motor movements while the somatosensory cortex identifies the region being stimulated, receives input from sensory receptors and proprioceptors in order to sense touch [18]. The cortical representation of the hand and face are quite large compared to other parts of the body. If the hand is amputated, reorganization in the synaptic connections occurs and other adjacent parts of the body representation expand, thus taking over the forearm representation [10]. This phenomenon is called phantom mapping, where touching certain parts of the face or other body parts results in a sensation in the phantom hand [10]. It is

believed that the more extensive the reorganization is, the greater is the phantom pain intensity [10].

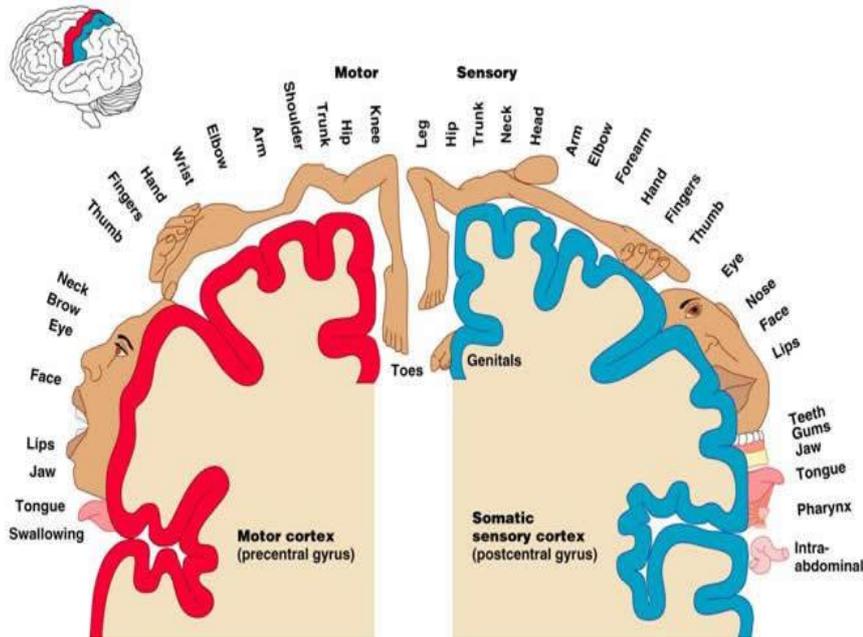


Figure 1: Mapping of the motor cortex (left) is responsible for planning and execution of movements. The mapping of the somatory sensory cortex (right) is responsible for sense of touch. Used with permission from [44] (cc) BY-SA

2.1 Treatments

Treatments for PLP can be categorized as medical, non-medical and surgical [11]. Treatments that are surgical or particularly pharmacological have showed slight effect to decrease PLP, while physical, psychological and behavioural treatments have shown greater effect in decreasing PLP [15].

Behavioural treatments frequently used are mirror visual feedback, movement imagery training, prosthesis use and training [15]. Lotze *et al.* [19] discovered that increased use of myoelectric prosthesis correlates to less phantom limb pain as well as cortical reorganization, which previously claimed, is one of the possible mechanisms responsible for phantom limb pain.

The mirror box therapy introduced by Ramachandran [20], is one of the most effective therapy for alleviating PLP. The therapy consists of a mirror box that is placed vertically on the table and the patient places his/her intact limb in the box and looks through the mirror and the patient is asked to execute motions with both limbs. The visual information of the intact limb creates an illusion for the patient that the amputated arm is

still there [20]. The illusion aims to induce a normalisation of the cortical hand/arm representation, and thus PLP alleviation [10]. In a study done by Ramachandran [20], six patients were tested and as a result when the intact limb was moved, the phantom limb was perceived to move as well, and a feeling of kinaesthetic sensation was experienced in the phantom limb [20].

However, there are some drawbacks to this method. A bilateral mirror-symmetric movements of the arms are required and therefore is restricted to unilateral amputees, and limited numbers of reflected movements are possible [21]. Furthermore this technique seems to be not inspirational and amusing enough for the amputee's to train for a longer period of time.

2.1.1 Virtual Reality, Augmented Reality and Gaming

Virtual reality (VR) applications have been developed using computers, video capture technology, desktop monitors, interfaces and real-time motion tracking devices [22]. In recent years, VR applications have been used as a therapy for motor rehabilitation and pain management [21]. The effectiveness of VR applications seems to fluctuate from one patient to another [16]. In VR applications, a virtual environment is created to replace the mirror for PLP therapy, and the movement of the virtual limb is made possible by a instrumented glove in the contralateral limb [21]. These applications can provide automated feedback about the user performance in the virtual reality and the user can be motivated by use of gaming challenges that can be implemented and modified as desired [21]. Despite the advantage of VR over normal mirror therapy, it is also restricted to unilateral amputees because instrumented gloves are employed as the source of control [14]. Furthermore, it is not sure that the amputee is making any real work to produce the phantom motion since it depends on producing the same motor execution in both limbs, thus there is no direct voluntary control of the virtual limb representation [14].

Augmented reality (AR) with the use of myoelectric signals at the stump to predict motions has been suggested to be a more promising method for treatment of PLP [14]. Raffin *et al.* [23] stated that amputees can distinguish between motor imagery and real motor execution with their phantom limb. Moreover, they could perceive that the position of their phantom was changing when a movement was performed but could not perceive the phantom changing when they imagined the movements. Raffin *et al.* [23] also discovered that chronic pain levels are independent to the ability to imagine phantom limb movements. The visual feedback “tricks” the brain into believing that there is a limb responding to motor commands and myoelectric signals and real movements helps with exercising stump musculature [14]. The use of myoelectric signals and AR environments may thus be a better alternative for a treatment of PLP.

2.1.1 BioPatRec

Open source software for the treatment of PLP named BioPatRec has been developed at CTH, COO-SUH, and Integrum AB. The system was created in Matlab and was initially

used for analysis and pattern recognition of bioelectric signals in order to improve controllability of prosthetic devices [24]. Myoelectric signals (MES) are produced during muscle contractions, then recorded with bipolar electrodes and the related movement is predicted with the use of pattern recognition algorithms. These predicted movements are then used as inputs for AR-VR environments and a racing game [14], [25]. This system gives patients the benefit of visualizing themselves in real-time, doing movements with their virtual arm superimposed on the stump while exercising their stump musculature [14]. Visual stimulus and motor execution produce positive results in pain relief and increase motor control over the phantom [26]. It has been hypothesized that this combination prompts plastic changes in the cortical representation of the amputated limb, phenomena associated with pain alleviation [26].

2.1.2 Neuromotus

Myoelectrically controlled augmented reality environment called Neuromotus is the new standalone system currently being developed from BioPatRec. This system is simpler and more user friendly with the purpose that clinicians at rehabilitation centres and individuals that have suffered an amputation can use it independently. However, there is no questionnaire included in the system to analyse the pain tracking of patients for their PLP treatment. The proposed questionnaire will be introduced in chapter 3. Throughout this thesis, the new standalone system Neuromotus will be used to describe the new MPR/AR-VR/Gaming software used to treat the PLP patient.

2.2 Measures of Pain

Pain is experienced differently between individuals and is difficult to measure. All individuals have experienced some condition of physical discomfort or unpleasant feeling and some individuals suffer from excruciating chronic pain on daily basis. Individuals cannot fully understand pain other than their own since being in pain is difficult for others to understand, despite the individuals effort of explaining their pain [27]. Report forms for pain are complicated to establish and a great effort and time is required when developing a user friendly self-report questionnaire with the aim to understand patient's pain and to track the pain changes in time. After decades of studying pain in various forms, most scientist agree that pain is a multidimensional experience including sensory-discriminative, affective-motivational and cognitive mechanisms [28].

2.3 State of The Art of Pain Reporting

There are multiple questionnaire forms currently available to assess pain. First, there are simple measures for pain intensity such as single point visual analogue scale for pain (VAS Pain) and Numeric pain intensity scale for pain (NRS pain). The VAS for pain is a simple self-administered questionnaire that takes less than a minute to finish. This is a 100 mm scale where the respondent is supposed to draw a line perpendicular to the scale that best describes their pain intensity [29]. The result is normally measured with a use of pencil and a ruler on a piece of paper. The pain intensity is followed by observing the

changes in time. Many studies today use VAS for PLS, PLP and SP tracking in time. However, VAS is not suitable when doing questionnaire in a digital form which is important for the technology today. Numeric pain intensity scale for pain (NRS Pain) is on the other hand more appropriate scale to use for a digital form. The NRS is a single 11-point numerical scale where 0 represents no pain and 10 represents the worst possible pain [29]. NRS is easy to use, the pain tracking is straightforward and it is fairly simple to adjust VAS into NRS. However, the disadvantage is that chronic PLP patients have more complex pain profile than a single point in time pain level since their pain varies between measurements. Thus, the NRS alone is not sufficient to analyse the pain [29].

In order to develop a questionnaire to analyse the multidimensional complexity of pain, the McGill pain questionnaire (MPQ) was developed. The length of MPQ was a major limitation for daily use in clinics [28] and therefore two shorter versions of the McGill pain Questionnaire (SF-MPQ/SF-MPQ2) were created. The SF-MPQ has been successfully used [28] in many clinical studies where the goal is to understand better the sensory and affective measure of perceived pain in general and to evaluate reaction of different symptoms to treatment [2], [29]. In many of those studies, the sensory and affective pain scores were strongly correlated [28]. The MQ and SF-MPQ were designed to be generic and applicable for any type of pain. However, studies have shown that this type of questionnaire does not capture specific clinical situations such as neuropathic pain [28]. Therefore, to overcome this limitation, a new version (SF-MPQ2) was created. Additional words related to neuropathic pain were added to the SF-MPQ2 form, where a NRS form was used for each word to describe the pain intensity during the past 7 days. However, the reliability of the SF-MPQ2 was highly questionable due to factors such as classification of patients into neuropathic and non-neuropathic pain groups on the base of self-diagnosis via web survey [28]. Additionally, it has been claimed that the validation should be considered and thus further studies are required [28]. In addition, Hawker *et al.* claim that no standardized instruction for patient completion has been published for this questionnaire and it has been reported that the written instructions are unclear and descriptors are unfamiliar for the SF-MPQ [29].

Thirdly, a chronic pain grade scale (CPGS) was made by Von Korff *et al.* and is not as commonly used as the MPQ [30]. The multidimensional measure, CPGS measures the overall chronic pain severity, pain intensity and disabilities related to pain in the past 3-6 months. These subscale scores are used to grade subjects into 1 of 5 pain severity grades (Grade 0-5) [29]. Hawker *et al.* claim that CPGS has a complex scoring that limits its use for valuation of pain at point of care. CPGS not only assesses the pain itself but also the impact of the pain on daily activities, both in social life and work [29].

The above mentioned questionnaires only assess pain in general, thus a new questionnaire was created and published the year 2004 to evaluate different symptoms of neuropathic pain named Neuropathic Pain Symptom Inventory (NPSI). NPSI includes 10 descriptors used to characterize subgroups of neuropathic pain patients and discriminate relevant

dimensions of neuropathic pain syndromes that are sensitive to treatment and can thus be good to use in studies to verify whether treatments or drugs have any effect.

Furthermore, there are other questionnaires available regarding amputation, such as the Groningen Questionnaire Problems after Arm Amputation (GQPAA), which assesses the current use of prosthesis, complaints occurring after amputation and the barrier involved with PLS, PLP and stump pain [31],[32]. This is a straightforward and simple questionnaire with a lot of background information involved.

There are not only general amputation questionnaire available but also distinctive for individuals with amputation at certain location. Hagberg *et al.* developed a questionnaire for persons with a transfemoral amputation (Q-TFA) which includes measures reflecting current prosthetic use, mobility, problems and health and has 70 questions with completion time of approximately 20 minutes [33]. The purpose of this questionnaire was to evaluate the quality of life after osseointegration in lower limbs.

In addition to English written questionnaires, there are many countries that create a questionnaire in their own language that have not been published in English. Lundqvist K. and Ragnö C. from the BräckeDiakoni Rehab centre Sfären (previously The Red Cross Hospital), in Stockholm, Sweden, created a questionnaire form for PLP in Swedish. This questionnaire has a study specific questions that have been developed and used for many years by clinicians and physical therapists and their chronic PLP patients. This questionnaire measures both PLP and SP frequency and intensity with addition to other important questions.

Kerns *et al.* [34] developed a questionnaire for PLP named Multidimensional pain Inventory (MPI). A new version was developed to learn more about PLP and how it affects amputees' life. Three sections were developed in order to reflect level of impairment, social support and activity. The first section of the questionnaire includes 21 questions about PLP impairment using the NRS with intensity levels from 0 to 6. The questions involve pain severity, interference, pain control, affective distress and support [35]. Section 2 is regarding how the significant other responses to the amputee when in pain during various circumstances where each answer has 4 levels. Section 3 has 15 questions regarding daily activities and how often those activities are done and has scale of 4 as well. MPI is valid, reliable and easily accessible self-report questionnaire for chronic pain. However, McKillop *et al.* claim that this questionnaire may lack sufficient stability and is therefore not good to use in either treatment comparisons or measurement of treatment outcome [35]. That is because studies have found that approximately one-third of respondents may unexpectedly change their classification in a short time interval which leads to unstable results [35]. McKillop *et al.* thus decided to develop a summary scale and test the MPI questionnaire by using patients suffering from fibromyalgia syndrome (FME). Their result indicates that summary scales might enhance usefulness of MPI results.

To conclude, it is widely seen that the most common tools of assessment of SP, PLP and PLS in studies are the McGill pain questionnaire and the visual analogue scale (VAS) [2], [16], [19], [36]. However, the author believes that a great need exist for a more integral questionnaire to monitor PLP during rehabilitation.

The second and third phases are combined where the prototype template is tested and evaluated to further develop and improve the questions. The complete results of the evaluated template prototype will be used in the clinical trial to treat amputees with PLP later this year. Furthermore, the results will be used as a reference for the *software prototype* developed in phase four.

The *Software Prototype* will be developed with the aim to be combined with Neuromotus. The decision for what software to use was simple to decide since Neuromotus was programmed in C# with Visual studio 2012. Therefore, to be compatible with the rehabilitation system, the questionnaire software was developed with the same programming language. When developing software, the usability and functionality of the system are great quality attributes that need to be considered. Usability is defined as how easy it is for the user to perform certain task. Functionality is the ability of the system to execute the tasks that it was intended to do [39].

The fourth and fifth phases are combined where the testing, modification and evaluation of the program takes place. It is essential that requirements of the system are fulfilled for the intended purpose of use. In this step of the development, it is essential to have a possible client do user acceptance testing (UAT) on the system. The future clients using the system are physical therapists working in rehabilitation centres and amputees' rehabilitating at home, thus the system needs to be user friendly and functionally reliable.

3.3 Design Implementation

3.3.1 Question Design:

In this thesis, the current state of the art of pain report forms were analysed in order to develop a simple and user friendly questionnaire for PLP. Phantom pain and other essential variables need to be understood and outcome measures analysed before designing a question.

Outcomes of interest:

- PLP intensity, frequency, interference and characteristics
- Stump pain intensity, frequency, interference and characteristics
- Phantom sensation
- Prosthesis use
- Medication intake
- Sleeping patterns
- Telescoping
- Phantom mapping
- Phantom movements

The proposed questions in this thesis are mainly based on the validated SF-MPQ questionnaire [40] and the study specific questionnaire developed from BräckeDiakoni rehabilitation centre, Sfären in Stockholm, Sweden.

3.3.2 Study Limitation

One limitation of this study is that it will only be tested with one patient. Furthermore, this thesis will not address the validation of the resulting questionnaire, which will be performed in future work.

3.3.3 Questionnaire Development

The questionnaire administration is twofold; Interview based when used for the clinical trial and secondly, the stand-alone version that will be self-administered for future home use. The language of each question was carefully reviewed in order to be understood correctly and to decrease the risk of misinterpretation, which would result in unreliable answers. Most of the questions are developed as closed questions where respondents are given possible answers to select. This was done because open questions increase the analysis time without necessarily produce better information[37].

3.4 Prototype Testing

3.4.1 Subject

The subject (male, 72 years old) was amputated at the elbow joint in 1965 due to trauma [14]. The subject wears an arm prosthesis 16 hours per/day, and has had chronic PLP since the amputation despite trying a variety of PLP treatments over the years. The subject started the MPR/AR/Gaming treatment and his PLP has decreased gradually since he started the rehabilitation [14]. The subject met the author approximately once a week for his treatment along with answering the proposed questionnaire (Q-PLPT).

3.4.2 Treatment procedure

Four self-adhesive bipolar electrodes (Ag/AgCl) and a fiduciary marker are placed on the subject's stump before starting the treatment. The locations of the electrodes are defined by asking the patient to perform eight movements (hand open/close, wrist flexion/extension, wrist pronation/supination, elbow flexion/extension) and the quality of the EMG signals are verified by short real-time myoelectric recordings [14], [24]. The subject sits in front of a computer with a web camera that captures the patient and his environment with the virtual arm visualised due to the fiduciary marker on the stump. This can be seen on figure 3a. The subject is asked to perform the eight movements "as if he still had the missing limb" [14]. The Phantom motions are predicted with the use of myoelectric pattern recognition (MPR) [14]. This allows the patient to move his virtual arm with the use of AR (figure 3b), drive a racing car with his phantom limb motions where, for example, pronation/supination is for turning left/right and open/close hand is for acceleration/breaking the racing car (figure 3c). Figure 3d shows the patient conducting a target achievement control (TAC) test in a VR environment, where a target

position is displaced and the subject is required to match that position. The AR, TAC test and the racing game allow the patient to enjoy the treatment while relieving PLP. This technology makes rehabilitation more engaging and entertaining. Before each treatment session, which takes approximately 1.5 hours, the patient conducts the proposed questionnaire to measure information such as PLP intensity, location and frequency to track the pain changes over time.

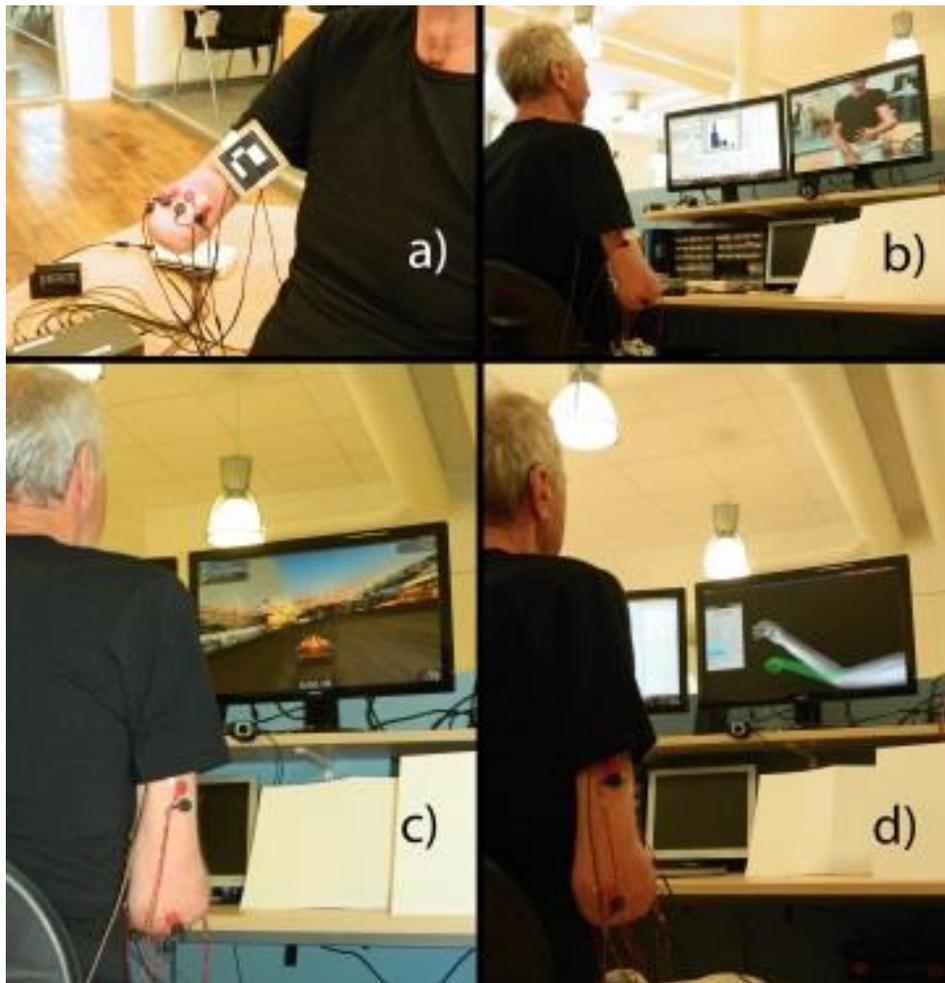


Figure 3: a) Surface electrodes and fiduciary marker placed on subjects stump. b) Augmented reality where patient can do desired motions which are displayed by the virtual arm on the screen. c) Subject playing a racing game using his phantom motions. d) Target achievement control (TAC) test used by the subject. The subject is supposed to mimic the movement of the green hand. Used with permission from [14]

3.5 Clinical Trials

As mentioned in previous chapter, the MPR/AR-VR/Gaming treatment has been tested as a case study, where pain decrease was achieved and therefore, a clinical trial will be established this year. It is thus essential to have integral questionnaires to track pain changes and its influence in quality of life. A clinical investigation plan needs to be written with all important details regarding the treatment background, procedures and evaluations in addition with case report forms, which needs to be filled in by the investigator to keep track of the overall treatment and any adverse events that may occur for each patient. There must be primary and secondary objectives established and a defined protocol to follow. The general objective of the clinical trial is to evaluate the performance of the proposed treatment for chronic PLP sufferers for whom other treatments have not been successful. One of the criteria required to participate in the study is that subjects need to have tried other treatments for PLP, which did not work for them. Additionally, their drug intake needs to be stable for one month before starting the treatment since it is not possible to ask subjects to stop their medication intake. All this will be monitored with the use of the questionnaires resulting from this thesis.

4. Results

The resulting PLP report form, named Questionnaire for Phantom Limb Pain Tracking (Q-PLPT), consists of three parts; Background information, PLP Tracking and Pain Distribution. This questionnaire has been developed and tested for 20 weeks in order to capture the complexity of PLP and other important variables during rehabilitation. The results of each part of the Q-PLPT will be discussed below.

4.1 Background Information

To gather all essential information of each patient prior to treatment, background information was created in Microsoft Excel. Basic information included in the background form was age, gender, weight, height, date of amputation, reason of amputation and location of amputation. Moreover, previous PLP treatments and medications were added to the questionnaire as can be seen in appendix A. It is extremely important to fill in this information to collect demographic data and track changes regarding medication and prosthesis use.

The background information is required to be completed by the investigator in the pre-enrolment, and baseline assessment for each PLP patient of the clinical trial. There are inclusion criteria that need to be fulfilled in order for the patients to be accepted in the clinical trial and therefore the background information has been made in regards to those criteria. Previous treatments are required to be filled in since one of the criterions is that Neuromotus will be tested with patients where other PLP treatments have not worked for them. Moreover, it is significant that medication intake is monitored to verify that the new PLP treatment was the only factor relieving the PLP. Additionally, there are different medications used for SP than for PLP which explains why medications for PLP and SP are separated in the form. Keeping track of medication intake can give clinicians a good overview of the circumstances and changes occurring during the time of the treatment. This will be explained further in chapter 4.2.

Many believe that prosthesis use has an effect on PLS and PLP. Koojiman *et al.* [32] claim in their study that subjects with phantom pain used their prosthesis less than subjects without phantom pain and this seems to be in line with Lotze *et al.* [19] discovering that use of myoelectric prosthesis is correlated with reduced intensity of PLP and reduced cortical reorganization. Prosthesis use for each patient can thus be an important factor to follow from the beginning of the treatment. The complete background information form can be seen in appendix A.

4.2 Pain Tracking

There are many variables that need to be evaluated in time to capture the overall effect of the PLP treatment. The proposed questions used for the pain tracking portion of the Q-PLPT are justified below.

4.2.1 Pain Frequency

Questions 1 and 7 (See appendix B) regard how often the respondent experiences PLP or SP. The frequency is an important factor for analysing pain. These questions were based on the study specific questionnaire developed in Swedish by the BräckeDiakoni Rehab centre. The pain frequency can vary in time and is experienced differently between individuals, thus it is essential to track the frequency as well since it is equally important factor to measure as the intensity of pain which will be described in chapter 4.2.3.

1. *How often do you have phantom limb pain? (x)*

Constantly
Few times/day
1 time/day
Few times/week
1 time/week
1 time/month
None

7. *Do you have stump pain? (x)*

Constantly
Few times/day
1 time/day
Few times/week
1 time/week
1 time/month
None

4.2.2 Pain Characteristics

Questions 2.1 and 8.1 have 15 pain characteristics where each symptom and pain levels are reported. These questions are based on the validated SF-MPQ with modified intensity scale. The purpose of these questions was to discriminate among different symptoms and evaluate their changes in pain intensity over time with the use of numerical scale from 0 to 5. The pain might still be the same in one symptom descriptor but varies for another. Question 8.1 has the same structure as question 2.1 with the only difference of being about stump pain instead about PLP. Possible analysis of these questions can be done by summing up the total pain intensity as well as tracking each symptom in time by creating a simple graph where the x-axis indicates the treatment sessions and the y-axis indicates the intensity.

<i>No pain</i>	<i>Mild</i>	<i>Discomforting</i>	<i>Distressing</i>	<i>Horrible</i>	<i>Excruciating</i>
0	1	2	3	4	5

2.1 How do you currently perceive your phantom limb pain (PLP)?

- Throbbing*
- Shooting*
- Stabbing*
- Sharp*
- Cramping*
- Gnawing*
- Hot-Burning*
- Aching*
- Heavy*
- Tender*
- Splitting*
- Tiring-Exhausting*
- Sickening*
- Fearful*
- Punishing-Cruel*

4.2.3 Pain Intensity

Question 2.2 was added with the purpose to track the current intensity of PLP. The structure of the question was a NRS from 0 to 10 (See question below) based on VAS for pain [29]. Additionally, in order to make the questionnaire more attractive and visible for the subject, a face scale was added with permission from the Wong-Baker Faces pain rating scale.

2.2 What is your current phantom limb pain intensity?

0 = No pain 5 = Moderate pain 10 = Most possible pain



0 1 2 3 4 5 6 7 8 9 10

The questions regarding pain characteristics together with the NRS were used for stump pain as well (See question 8.2 below). Some individuals who experience PLP might also experience stump pain which is important to track during the clinical trial in case of negative impacts. It may occur that electrodes can irritate the sensitive skin on the stump and therefore increase stump pain.

2.2 What is your current stump pain intensity?

0 = No pain 5 = Moderate pain 10 = Most possible pain



0 1 2 3 4 5 6 7 8 9 10

4.2.4 Activity Interference

Activity interference with a NRS scale was added late in the development of the questionnaire. At first, an open question was created where the respondent was supposed to write the activity that is interfered by PLP and at what level. However, after few weeks of testing, the author found the particular question to be too open and its construction made it difficult to add many activities at once. In addition, this type of question can be time-consuming to respond and analyse. Instead, a general question regarding activities was added with NRS scale describing the pain interference to the activity, where 0 equals no interference and 10 describes extreme interference. This question has been modified to this study and is based on section 1, question nr. 2 in the questionnaire named Multidimensional pain Inventory (MPI) [34].

3. *During the past week, how much did the phantom limb pain interfere with your day-to-day activities? (x)*

0 = No interference

10 = Extreme interference



4.2.5 Pain Location

One day when testing the prototype with the subject, he explained that the location of his pain had change, which made a realization that there was a need for pain location tracking. If the pain location is migrating or decreasing, then it is an indication that the treatment is having some effect and needs to be reported. Two images were created for this type of question, where figure 4 shows the left hand with numbers from 1-23 and figure 5 shows the whole arm and forearm with numbered parts from 1-6. Each number indicates the location of the PLP where the subject was asked to specify the numbers referring to his PLP. In addition he was asked to indicate whether the pain is in the front and/or back of the hand/arm. The author thought it was of great interest to track how different patients analyse their own pain location of their phantom hand/arm, since this is a phenomenon that scientists still think is difficult to explain. Pain location is a promising method to use for pain tracking as in the beginning of the development of the questionnaire the subject's pain location decreased, indicating positive effect in alleviating PLP. Pain location instrument is an attractive and relatively easy method to analyse. Weiner *et al.* [41] tested pain location questionnaire on elderly patients in a nursing home, where a number was given for each location of the body. Their results suggested that this is a promising method for assessing pain where test-retest and reliability results were acceptable. Possible analysis of this question can be to track if numbers increase/decrease or calculate the amount of numbers chosen where a higher set of numbers describe a greater area. See questions 4.1-4.3.

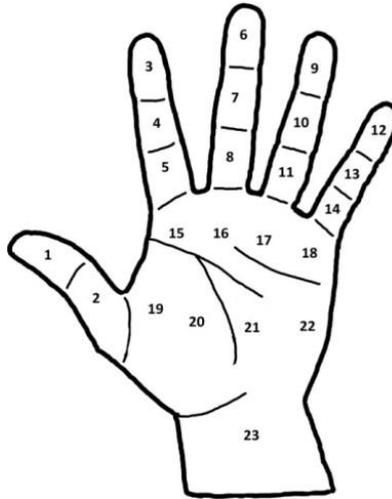


Figure 4: Showing the left hand with numbers describing each part of the hand. The aim of this method is to make the identification of PLP for the patients simpler to explain.

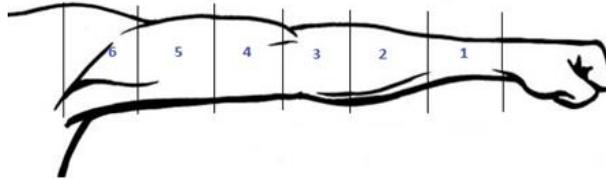


Figure 5: Shows the whole arm where numbers are given for each part of the arm in order to detect pain mapping.

4.1 Location of the phantom pain: (x)

- Arm
- Forearm
- Hand

4.2 If you have pain in your hand, write down the location(s) of the pain in the answer box (See figure 3 below):

4.3 If you have pain in your arm, write down the location(s) of the pain in the answer box (See figure 4 below):

4.2.6 Medication changes and Prosthesis Use

Medication monitoring and changes regarding prosthesis use are important factors to monitor for the clinical trial, as described in chapter 3. All changes need to be well documented in order for the clinical trial to be trustworthy and to minimize false results. For example, if a subject takes in a great amount of pain killers in one week and then in the clinical trial claims that the pain has decreased, this is an indication of false results

since it is problematic to determine whether the cause was the treatment itself or the pain killers. Proper monitoring can prevent this from occurring. Question 9 is regarding stump pain and has the same structure as question 5.1 regarding medication for the pain (See appendix B).

5.1 Have you changed your medication(s) or dose for your phantom pain since last treatment session? (x)

No
Yes

If new medication:

Name of the medication:

How long have you used the medication? (Days since last treatment)

What is the dose size?

How often do you take the medication? (#times/day)

Have you reduced/stopped using previous medication(s)?

If dose size changed:

Name of the medication:

What is the dose size?

How often do you take the medication? (#times/day)

The PLP can increase if new prosthesis is used since the stump can get sore and sensitive, which leads to increased SP and/or PLP. This was the case with the PLP subject in this study, where he reported that the PLP increased after having used new prosthesis for a week. However, he felt better approximately 2 weeks later when he had switch back to his old prosthesis. This is a good example of why a tracking of the prosthetic device change is necessary.

5.2 Have you changed your prosthesis since last treatment session? (x)

No
Yes

If new prosthesis

Name/type:

How long have you used it?

Why did you change prosthesis?

4.2.7 Sleeping Patterns

Questions 6 and 10 track the pain interferences on sleep. A good night sleep is important for everyone, therefore it is important to follow the sleep patterns associated with PLP and SP. Disturbed sleep can have dramatic negative effect to day-to-day activities and quality of life.

6.1 Have you had trouble sleeping for the past seven days because of the phantom pain?(x)

No
Yes

6.2 *If yes, how much did the pain disturb your sleep? (x)*

- Some difficulty*
- Moderate difficulty*
- Great difficulty*
- Extreme difficulty*

4.2.8 Phantom Limb Sensation

As has been described in chapter 2, PLS is described as a non-painful sensation of the missing limb. Phantom sensation like all other changes regarding the phantom limb should be monitored. PLS can vary in frequency and intensity, therefore question 11.1 has the same structure as questions 1 and 7. Question 11.2 is influenced by question 2.2.

11.1 *Do you have phantom sensation? (x)*

- Constantly*
- Few times/day*
- 1 time/day*
- Few times/week*
- 1 time/week*
- 1 time/month*
- None*

11.2 *Current phantom sensation intensity:*

0 = No sensation

10 = Very strong sensation



4.2.9 Telescoping

As it has been discussed in previous chapter, it is suggested that telescoping is positively related to PLP and cortical reorganization [5], [13]. It is therefore interesting to monitor telescoping over time and analyse if telescoping is in fact correlated with PLP. This question is modified from the study specific questionnaire made in Swedish from BräckeDiakoni Rehab centre.

12.1 *Do you feel that the phantom arm is shortened or even disappears into the stump, so called telescoping? (x)*

- No*
- Yes*
- Where? (Use figure 5 to identify the position of shortening)*

4.2.10 Phantom Mapping

A mapping of the phantom hand can be perceived on the stump or on other parts of the body. This question serves to track whether any changes of phantom mapping can occur during time of treatment. This question is modified from the study specific questionnaire from BräckeDiakoni Rehab centre.

13. Do you feel that touch in one part of the body can be perceived in the phantom part (phantom mapping)? (x)

No

Yes

Where?

4.2.11 Phantom Movements

The perception of phantom movement varies between patients as it does for PLP. It has been observed that the proposed treatment has effected both the perception of phantom motion and PLP [14]. Therefore it is of interest to monitor phantom movement to investigate correlation with PLP.

14. Please indicate how well you can move your phantom part:

0 = Not at all

10 = Easy to Move



See Appendix B for snapshots of the whole questionnaire in its original Excel format.

4.3 Pain Distribution

A pain distribution questionnaire has been developed to assess the fluctuation of chronic PLP during the time of rehabilitation. The subject is asked to estimate the percentage of time spent in a given level of pain for all intensity levels from 0 to 5 (0 indicates no pain and 5 indicates an excruciating pain). The time of each given level of pain can be estimated in minutes or hours and extrapolated to its corresponding portion from the total time. The standard tool for pain evaluation (VAS/NRS) provides information in a single point in time. However, chronic PLP patients have a more complex pain profile than a single pain since it fluctuates in time. Therefore, the efficacy of the treatment will be evaluated by the use of this weighted pain distribution (WPD) indicator.

An example of pain distribution reporting is displayed in Appendix C. The WPD is the sum of the portion of time (0 to 100%) multiplied by the pain level (0 to 5). The formula used to calculate WPD can be described mathematically as:

$$WPD = \frac{\sum_{p=0}^5 p \cdot t_p}{\sum_{p=0}^5 t_p}$$

Where t_p indicates proportion of time (0 to 1) and p indicates the pain level. Figure 6 shows the final prototype template of the pain distribution form.

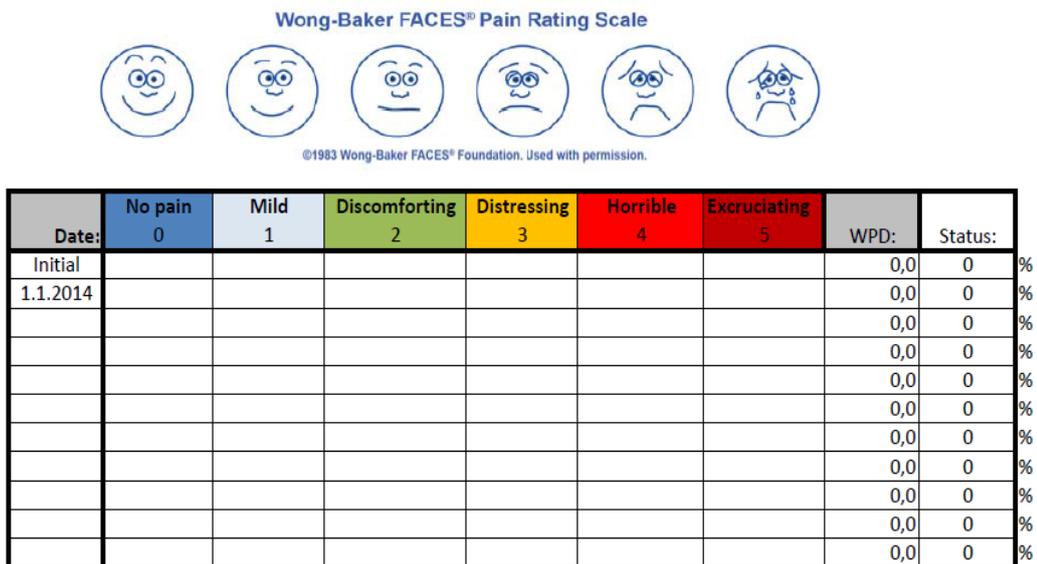


Figure 6: Pain Distribution in time form to evaluate the complexity of chronic PLP during

Protocol for filling the pain distribution:

For the clinical trial, the protocol of filling in the pain distribution form is facilitated by questions such as:

- Which level (0-5) are you in most of the time?
 - How much time in average are you in this level of pain?
- How much time in average are you in no pain?
- How much in average are you in *Excruciating pain* (level 5)?

If this is not the first time the patient answers the pain distribution questionnaire, then the investigator asking the questions should start by asking these questions:

- Are you still in level X the most of the time?
- Has your pain intensity changed since last treatment session?
 - If yes:
 - Has the pain decreased or increased?
 - Can you estimate how it has changed and in which levels?

4.4 Stand-alone Software Implementation

Stand-alone software was created with the aim to be used for the rehabilitation centres or for clinical trials with multiple patients. The main window shows a list of patients that have been added to the system (patients 1-6 are shown in figure 7). In order to be able to answer questions or visualize previous results, a patient needs to be selected to activate the related buttons. The user of the system knows that a certain patient has been selected when the *Selected User* field shows the name of the selected patient. If the user clicked a wrong name, then the button *Cancel selection* can be clicked and a new patient can be selected.

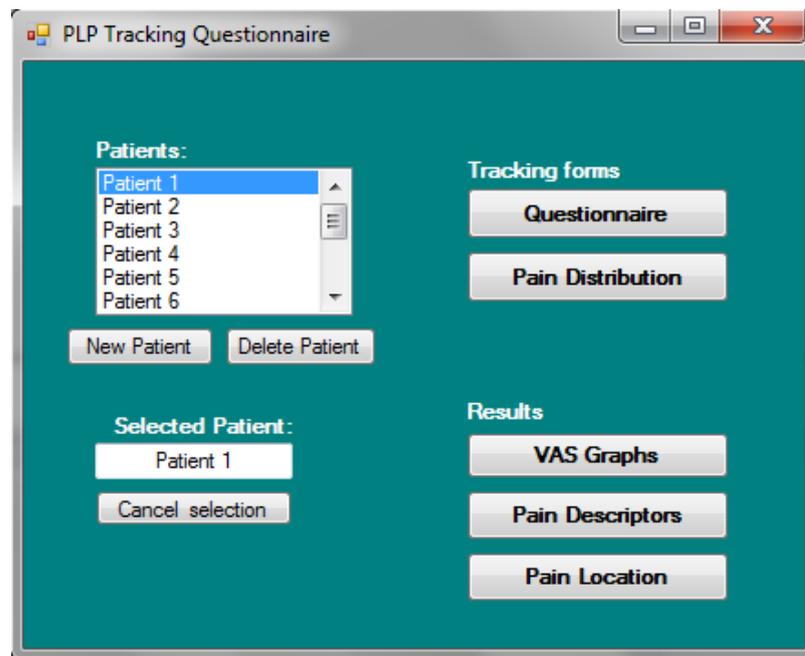


Figure 7: Main form of the stand-alone software.

The button *New Patient* is selected in order to add a patient to the system. A new window pops up as can be seen in figure 8. This data is based on the background information (appendix A).

Figure 8: New user – Background Information

When starting the pain tracking questionnaire, the user clicks the button *Questionnaire* from the main window, which opens a new window, as can be seen in figure 9. The user answers the questions by sliding a track bar to the desired value. When all questions have been answered, the user clicks the *Next* button and the second part of the questionnaire appears.

Figure 9: Pain Tracking Questionnaire Form 1

Figure 10 shows the second part of the questionnaire. When all questions have been completed, the user clicks the *Next* button and the last part of the questionnaire will appear.

Question Form

Instructions: You can choose one or many symptom descriptors if it applies.

How do you currently perceive your phantom pain?

Throbbing 0 1 2 3 4 5

Shooting 0 1 2 3 4 5

Stabbing 0 1 2 3 4 5

Cramping 0 1 2 3 4 5

Sharp 0 1 2 3 4 5

Gnawing 0 1 2 3 4 5

Hot-Burning 0 1 2 3 4 5

Aching 0 1 2 3 4 5

Heavy 0 1 2 3 4 5

Tender 0 1 2 3 4 5

Splitting 0 1 2 3 4 5

Tiring-Exhausting 0 1 2 3 4 5

Sickening 0 1 2 3 4 5

Fearful 0 1 2 3 4 5

Punishing-Cruel 0 1 2 3 4 5

Have you changed your prosthesis since last treatment session?
 Yes No
If yes, explain why:

Have you changed your medication since last treatment session?
 Yes No
If yes, explain why:
What are the changes?

Do you feel that touch in one part of the body can be perceived in the phantom part? (phantom mapping)
 Yes No
If yes, explain where:

Have you had trouble sleeping because of phantom pain/stump pain since last session?
Some difficulty
No trouble sleeping
Some difficulty
Great Difficulty
Extreme difficulty

0 - No pain, 1 - Mild, 2 - Discomforting, 3 - Distressing, 4 - Horrible, 5 - Excruciating

Next

Figure 10: Pain Tracking Questionnaire Form 2.

Figure 11 contains the third part of the questionnaire, which is about the location of PLP and the frequency of PLP, SP and PLS. When all questions have been completed, the user clicks *Submit Questionnaire*. Then the window closes and the answers are saved in a XML file. These questions are based on the developed pain tracking section of the Q-PLPT (See appendix B).

The screenshot shows a web browser window with a questionnaire form. The form is titled "Questionnaire form" and contains the following sections:

- Hand Pain Location:** A question asks "If you have PLP in your hand, look at figure 1 and then click on the number that indicates the pain location:". Below this is a list of numbers 1 through 9, each with a corresponding checkbox. To the right is Figure 1, a diagram of a hand with 23 numbered regions.
- Arm Pain Location:** A question asks "If you have PLP in your arm, look at figure 2 and then click on the number that indicates the pain location:". Below this is a list of numbers 1 through 6, each with a corresponding checkbox. To the right is Figure 2, a diagram of an arm with 5 numbered regions.
- Pain Frequency:** Three questions ask "How often do you have phantom pain?", "How often do you have stump pain?", and "How often do you have phantom sensation?". Each question has a dropdown menu with the text "-Please select-".
- Telescoping:** A question asks "Do you feel that the phantom arm is shortened or even disappears into the stump, so called telescoping?". Below this are radio buttons for "Yes" and "No".
- Explanation:** A text input field labeled "If yes, explain where:" is provided for users who select "Yes".
- Submit Button:** A button labeled "Submit Questionnaire" is located at the bottom right of the form.

Figure 11: Pain Tracking Questionnaire Form 3

In the main window, there is a button named *Pain Distribution* where the patient fills in the proportion of time spent in a given level of pain. This was discussed in details in chapter 4.3. The number showing the sum will be red until the sum reaches 100%. When 100% is reached, the patient can click *Preview* button to visualize his result. If the user figures out that he/she wrote the wrong numbers, he/she can cancel and start over. When satisfied, the user can click *Submit*. Extra features of the software are to print or save the figure showing the overall view of pain distribution in time. The Pain Distribution example form can be seen in figure 12.

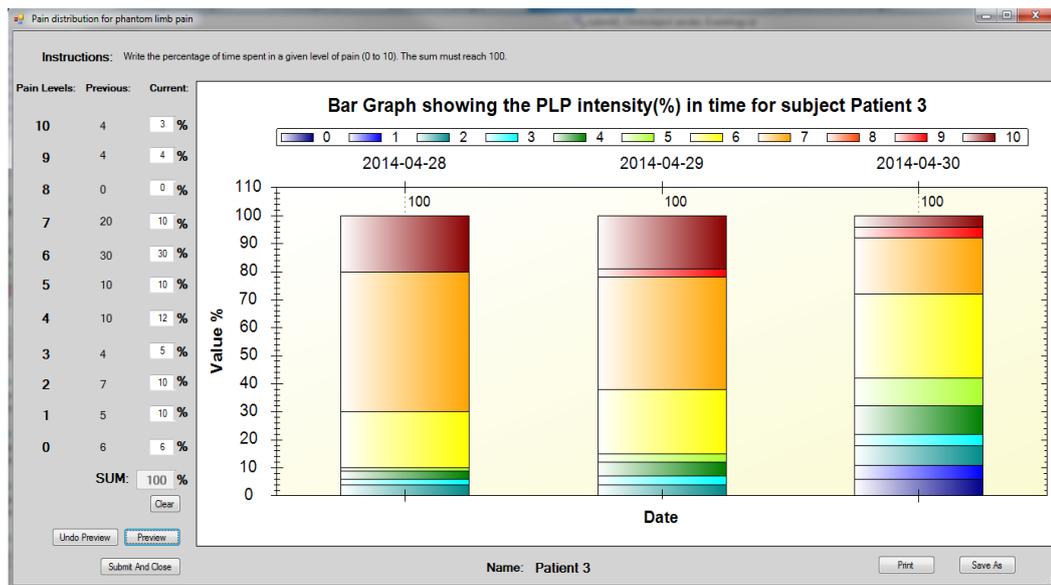


Figure 12: Pain Distribution example

If the user wants to visualize the progress, then he/she can click the button *VAS Graphs* from the main window, which open a window showing various results of the responded questionnaire. The first graph shows the WPD over time. The graph below (dark red) shows the intensity of PLP in a single point scale. The same occurs for SP, PM and PLS. The last graph in figure 13, named lowest PLP, describes the lowest level of pain the patient experiences over time.

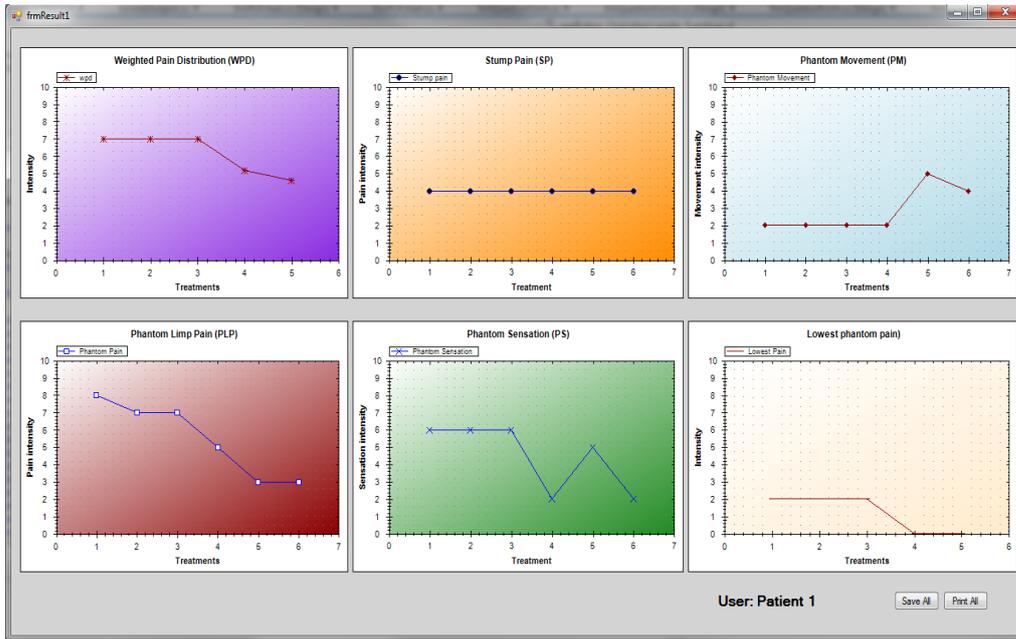


Figure 13: Showing the results of the pain tracking questionnaires. This is done to help users visualize the results.

The user can press the button called *Pain Location* from the main window and see the location of the PLP since the start of the treatment as can be seen in figure 14. This follow-up makes it possible to analyse whether the pain has changed location over time.

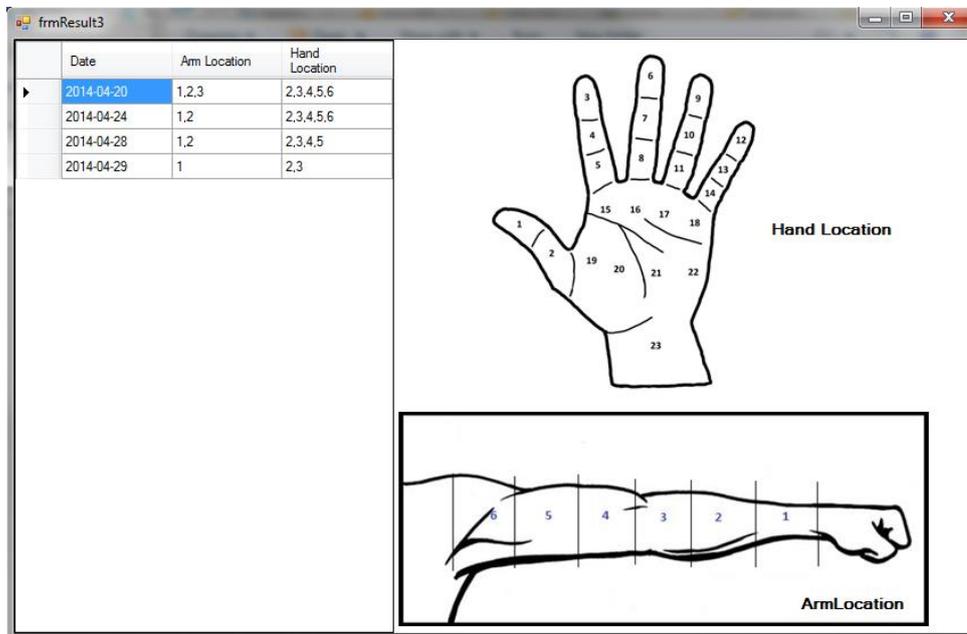


Figure 14: Example showing a follow-up of PLP location over time.

5. Discussion

To be efficient in design and data collection, careful thoughts need to be taken into consideration for each question used in the questionnaire. Creating questionnaires is a challenging task and requires iterative evaluations of each question. In this study, the author needed to have a thorough understanding of the epidemiology of PLP, and associated factors. in order to be competent in developing the Q-PLPT. However, PLP is an interesting phenomenon that is difficult for scientists to fully understand, thus making the development of the questionnaire even more challenging.

Pilot testing of the Q-PLPT with a chronic PLP patient allowed the author to react and modify according to the patient's suggestions and feedback. Moreover, feedback was provided from one of the clinicians who will be conducting the clinical trial in the future. The piloting of the Q-PLPT was conducted in a realistic scenario of a clinical data collection.

5.1 The Development

The types of questions used in the Q-PLPT were mostly closed questions in order to decrease variability and additional work load. Scaled responses (NRS) were also used since it is a common, simple and validated tool to describe pain intensity in a simple way. Moreover, additional questions were created since the author thought there was a lack of certain information in order to evaluate all variables of PLP over time.

5.1.1 Pain Distribution over Time

The first prototype of the pain distribution questionnaire had a pain scale from 0 to 10 (where 0 indicates no pain and 10 indicates the worst possible pain). It was decided after several weeks of testing the first prototype that this was too complicated to fill out by patients and/or clinicians. Feedback from the subject regarding the pain distribution was not as positive as the rest of the Q-PLPT and it was more time consuming than estimated since there were so many levels of pain the subject needed to fill in or modify. Additionally, the Q-PLPT was introduced to an occupational therapist who also thought the 11 point scale for pain distribution was complicated. Therefore, a decision was made to modify and simplify the pain distribution questionnaire from 11 point scale into a 6 point scale where each number indicated a verbal pain intensity descriptor. Appendix C shows the final prototype.

5.1.2 Limitations

As was mentioned in chapter 3, a limitation of this study was that the questioners were only tested on one patient. However, it is currently being tested with a new patient, and will soon be used in the clinical trial. Testing the Q-PLPT with a chronic PLP patient was valuable and important for this thesis. The subject discussed his daily pain frequently while answering the Q-PLPT and consequently new ideas of questions were recognized.

5.2 Challenges in Current PLP Questionnaires

There are many drawbacks with the current report forms used to analyse PLP. First of all, the VAS and NRS are only measured in a single point in time which does not capture the complexity of pain due to fluctuations over time. The VAS or NRS alone are not sufficient measures, which is why the idea of creating a pain distribution over time was developed. Other pain report forms were analysed by the author who believes that they are not adequate to track PLP over time. To clarify, the drawback of the CPGS questionnaire mentioned in chapter 2.3 is that it is not accurate enough to be used to track small pain changes in intensity during time of rehabilitation, although it classifies individuals in 5 pain grades. The CPGS is more suitable to be used as before/after questionnaire. Furthermore, the GQPAA questionnaire discussed in chapter 2.3 is more convenient to be filled out only once as a background form. Thus, the author believes it is not adequate for tracking the pain intensity during rehabilitation treatments. The Q-TFA has the same drawbacks as the previous named questionnaires, since it does not assess PLP over time and its main objective is to analyse the before and after prosthetic use and patients quality of life. Furthermore, the MPQ is too complex and does not capture the overall variables required for the assessment. The SF-MPQ is a good assessment tool for PLP tracking, but it is not sufficient alone. However, the author based few questions of the Q-PLPT on the SF-MPQ since that questionnaire is the most popular validated questionnaire used to assess PLP.

The author believes that the reason for why McGill and VAS are the most used questionnaires for PLP is that since these assessments have been used for a long time, people tend to follow the trend and use the same forms even though the questions do not capture the complexity of PLP. To conclude, the final version of the proposed Q-PLPT tested in this thesis, gave satisfactory results and each question has been tested repeatedly. Thus, it has the potential to provide a more comprehensive monitoring of PLP.

5.3 Future Work

As the improvement of the new treatment software Neuromotus proceeds, it is of great importance to continue the development of the Q-PLPT and the PLP tracking software. The future goal is that Neuromotus, together with the PLP tracking software, will be made widely available in order to help individuals with PLP all over the world.

The following activities remain:

- Analyse the reliability, validity and consistency of the Q-PLPT for individuals that have suffered an amputation.
- Further software development and validation.

6. Conclusion

PLP is a condition extremely difficult to treat and it affects the majority of individuals that have suffered an amputation. The proposed PLP tracking questionnaire (Q-PLPT) was developed and tested for adults with upper limb amputation. The Q-PLPT will be used in an upcoming clinical trial for a new treatment for PLP based on MPR, AR-VR, and gaming. Once the efficacy of this new treatment is confirmed by the clinical trial, the developers expect to extend its use to lower limbs and other neuropathic pain conditions, where the Q-PLPT would be equally applicable.

It is believed by the author that the proposed Q-PLPT covers all relevant questions required in order to collect important changes in PLP perception over the course of a treatment. Additionally, the author believes that the WPD together with the basic pain tracking questions are compelling tools to capture the complexity of the PLP. However, further work is required in order to test the reliability and validity of the Q-PLPT.

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Appendix A

Note: Answer the background questionnaire in the beginning of the treatment (only once)

Background Questionnaire					
Patient ID :	XXX-XX				
Gender (F/M):					
Date of birth (yyyy-mm-dd):					
Date of amputation (yyyy-mm-dd):					
Reason for amputation:					
Amputation location:					
Do you or have you used medication for your phantom pain?					
if yes:	Name of the medication:	Medication name A	Medication name B	Medication name C	Medication name D
	When did you start using this medication? (yyyy/mm)				
	How long have you used the medication? (months)				
	What is/was the dose size?				
	How often do you take the medication? (#times/day)				
Do you still use this medication? (yes/no)					
Have you tried other PLP treatments?					
if yes:	What is the name/description of the treatment?	Treatment 1	Treatment 2	Treatment 3	Treatment 4
	When did you start this treatment? (yyyy/mm)				
	Did your phantom limb pain decrease?				
	Why did the treatment stop?				
Do you use prosthesis?					
if yes:	How much do you use the prosthesis (#hours/day):				
	Prosthesis type:				
	How long have you been using the prosthesis?				
Do you or have you used medication for your stump pain?					
if yes:	Name of the medication:	Medication name A	Medication name B	Medication name C	Medication name D
	When did you start using this medication? (yyyy/mm)				
	How long have you used the medication? (months)				
	What is dose size?				
	How often do you take the medication? (times/day)				
Do you still use this medication? (yes/no)					

Appendix B

Instructions:

The patient should answer the questions before each treatment session in order to track the PLP progress

Questions that end with (x) mean that the answer box should be marked with an x.

Questions with numbers are supposed to be answered with a certain level that best describes the answer.

Note that you can mark more than one pain characteristic in questions 2.1 and 8.1 (if it applies).

Patient ID:	XXX-XX
Gender:	
Date of Birth:(yy/mm/dd)	

Modified questionnaire based on study specific questions from the BräckeDiakoni RehabCenter and the SF-MPQ

Date:

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Phantom limb pain

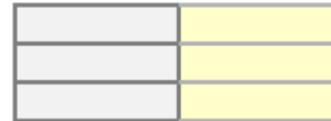
1. How often do you have phantom pain? (x)
 - Constantly
 - few times /day
 - 1 time/day
 - few times/week
 - 1 time/week
 - 1 time/month
 - None

0 = No interference 10 = Extreme interference



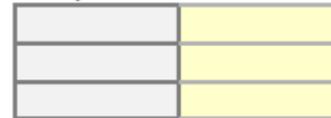
4.1 Location of the phantom pain (x)

- Arm
- Forearm
- Hand



4.2 If you have pain in your hand, write down the location(s) of the pain in the answer box (See figure 1 below)

- Pain location number(s):
- Palmar(front) (x)
- Dorsal(back) (x)



4.3 If you have pain in your arm/forearm, write down the location(s) of the pain in the answer box (See figure 2 below)

- Pain location number(s):
- Anterior side (front) (x)
- Posterior side (back) (x)

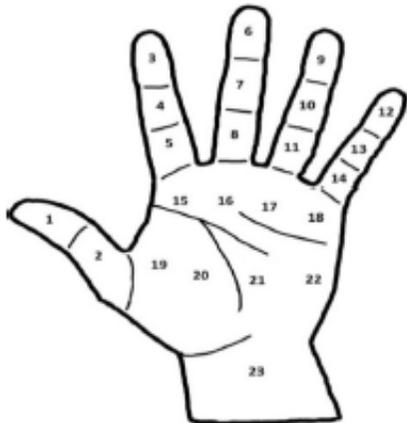
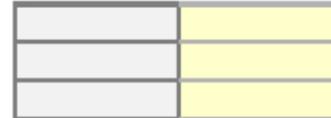


Figure 1 - (For question 4.2)

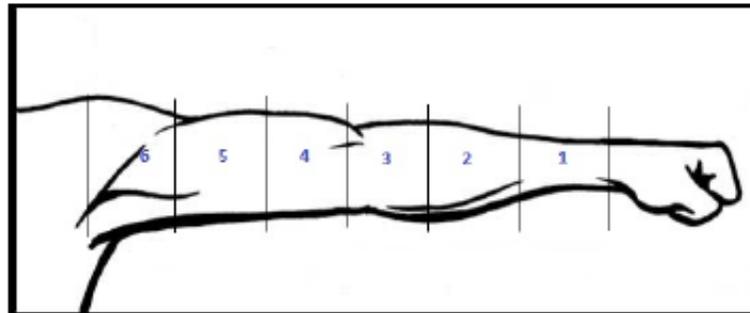


Figure 2 (For question 4.3 and 12.1)

5.1	Have you changed your medication(s) or dose for your phantom pain since last treatment session? (x)			
	No			
	Yes			
	If new medication:	Name of the medication?		
		How long have you used the medication? (days)		
		What is the dose size?		
		How often do you take the medication?(#times/day)		
		Have you reduced/stopped using previous medication?		
	If dose size changed:	Name of the medication?		
		What is the dose size?		
		How often do you take the medication?(#times/day)		
5.2	Have you changed your prosthesis since last treatment session? (x)			
	No:			
	Yes:			
	If new prosthesis:	Name/Type:		
		How long have you used it?		
		Why did you change prosthesis?		
6.1	Have you had trouble sleeping for the past seven days because of the phantom pain? (x)			
	No			
	Yes			
6.2	If yes, how much did the pain disturb your sleep? (x)			
	Some difficulty			
	Moderate difficulty			
	Great difficulty			
	Extreme difficulty			

8.2 What is your current stump pain intensity?

0 = no pain, 5 = moderate pain, 10 = most possible pain

0	1	2	3	4	5	6	7	8	9	10		

Wong-Baker FACES® Pain Rating Scale

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9. Have you changed your medication(s) or dose size for your stump pain since last treatment session? (x)

No

Yes

If new medication:

How long have you used the medication? (days/weeks)

What is the dose size?

How often do you take the medication? (#times/day)

Have you reduced/stopped using previous medication?

If dose size changed:

Name of the medication?

What is the dose size?

How often do you take the medication? (#times/day)

10.1 Have you had trouble sleeping for the past seven days due to stump pain? (x)

No

Yes

10.2 If yes, how much did the pain disturb your sleep? (x)

Some Difficulty

Moderate Difficulty

Great difficulty

Extreme difficulty

Phantom sensation

11.1 Do you have phantom sensation? (x)

- Constantly
- few times /day
- 1 time/day
- few times/ week
- 1 time/week
- 1 time/month
- None

11.2 Current phantom sensation intensity

0 = no sensation, 5 = moderate sensation, 10 = very strong sensation



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12. Do you feel that the phantom arm is shortened or even disappears into the stump, so called telescoping? (x)

- No
- Yes
- Where?

(Use figure 2 to identify the position of shortening)

13. Do you feel that touch in one part of the body can be perceived in the phantom part? (phantom mapping) (x)

- No
- Yes
- Where?

14. Please indicate how well can you move your phantom part

0 = Not at all

10 = Easy to move



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Appendix C

Appendix C shows the final prototype of the developed Pain Distribution in time.

New Pain Distribution Template

Instructions:

Write the percent of time spent in a given level of pain (0 to 5) since last treatment. The sum must reach 100, at which point the "Status" will display "OK".

Wong-Baker FACES® Pain Rating Scale



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Date:	No pain 0	Mild 1	Discomforting 2	Distressing 3	Horrible 4	Excruating 5	WPD:	Status:
Initial	5	20	12	13	20	30	3,13	OK %
2014-01-01	6	21	12	13	19	29	3,05	OK %
2014-01-02	7	22	12	13	18	28	2,97	OK %
2014-01-03	8	23	12	13	17	27	2,89	OK %
2014-01-04	9	24	12	13	16	26	2,81	OK %
2014-01-05	10	25	13	12	15	25	2,72	OK %
2014-01-06	11	26	13	12	14	24	2,64	OK %
2014-01-07	12	27	13	12	13	23	2,56	OK %
2014-01-08	13	28	13	12	12	22	2,48	OK %
2014-01-09	14	29	13	12	11	21	2,40	OK %
2014-01-10	15	30	14	11	10	20	2,31	OK %
2014-01-11	16	31	16	9	9	19	2,21	OK %

Total Pain decrease: 29,393 %

