The myofeedback-based teletreatment system and its evaluation

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Summary

The myofeedback-based teletreatment system allows patients to receive tactile and/or visual feedback on muscle activity and muscle relaxation times. Health-care professionals can analyse muscle activity and muscle relaxation times and provide guidance to the patient on the course of treatment. The system was evaluated in a small clinical trial. Qualitative data were obtained by interviews and visual inspection of graphical patient data during the trial. Quantitative data were based on post-trial data analysis. We used a revised version of the information systems success model to evaluate the teletreatment system, and focused on the success categories of system use and user satisfaction. The evaluation found good input data quality, system quality and information quality. Both system use and user satisfaction were good. Thus the teletreatment system appears suitable for small scale clinical deployment. However, the sensory components suffered from heavy use and embedded software problems which made them unreliable. Large scale deployment requires improvement in terms of durability and reliability of the system's sensors.

Introduction

Experimental studies have shown that patients with chronic pain have different muscle activation patterns compared to asymptomatic controls.[1–4] This is reflected in a prolonged activation of their muscles after a task, i.e. a decreased ability to relax their muscles. Patients may not be aware of this, because prolonged activation often occurs at rather low levels. Nevertheless, low levels of prolonged activation contribute to chronic pain if they occur for a long period of time.[5] According to Hermens and Hutten,[6] patients with chronic neck and shoulder pain show a long lasting adaptation of their daily activity patterns if they receive continuous feedback on their muscle relaxation times.

We have developed a myofeedback-based teletreatment system for patients with chronic neck and shoulder pain which creates awareness by the patient about muscle relaxation during their daily activities. The system was built with components from MobiHealth B.V.[7] and the research project Exozorg.[8] It allowed patients to receive immediate tactile and visual feedback on muscle activity and muscle relaxation times. Health-care professionals used the system to analyze data about muscle activity and muscle relaxation times and provided feedback to the patient on the course of their treatment. The present paper describes the system and its technical evaluation in a small scale clinical trial.

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Teletreatment system

The system provides a myofeedback-based teletreatment service for patients with chronic neck and shoulder pain. Development was characterized by several constraints, such as the project sponsor's (European Committee) requirement to re-use and adapt an existing system. We re-used the commercially available MobiHealth Service Platform (MHSP). This platform for mobile telemedicine services is owned by MobiHealth B.V.[7] and was successfully used in several international telemedicine research projects, such as MobiHealth,[9] HealthService24[10] and Awareness.[11] We also employed a wearable myofeedback system from the research project Exozorg.[8] The patient and the health professional interact via a data communications network to deliver the teletreatment service. The Internet provides secure data connections between the sub-systems.

Components

The Body Area Network (BAN) is worn on the patient's body and consists of a harness, wearable myofeedback system and a handheld computer. The harness has three holders for dry surface electrodes to enable surface electromyography

 DOI: 10.1258/jtt.2010.006004

(sEMG) measurements. Electrodes are located on the left scapula (reference electrode) and left and right trapezius muscle, on the central point between C7 and acromion (see Figure 1).

A wearable myofeedback system is connected to the electrodes of the harness. The Relaxation and Training (ReTra) system has two purposes: (1) sensing trapezius muscle activity via sEMG and providing tactile feedback (i.e. vibration) if a pre-specified muscle activity level is exceeded; and (2) transmitting wirelessly processed sEMG data to the handheld computer. The handheld computer (Figure 2) is a generic personal digital assistant (PDA) running the MyoTel application on top of the MobiHealth Service Platform. Every patient has a unique personal identification number. The application allows the patient to start and stop a measurement session and to receive personalized feedback on processed sEMG signals, i.e. the root mean square (RMS) and relative rest times (RRT) of both the left and right trapezius muscle. Patients receive instructions from the health-care professional about how to use the BAN and interpret the RMS-RRT graphs. In particular, the patient uses the RMS graphs to check the left and right RMS signals for 'quality'. For example, if the reference dry surface electrode makes bad or no skin contact, both left and right RMS graphs will show maximum y-axis values.

In addition, the patient uses a web-based diary to keep track of daily activities and pain scores using a Visual Analogue Scale. This enables the health-care professional to associate the patient's activities with the recorded trapezius muscle activity.

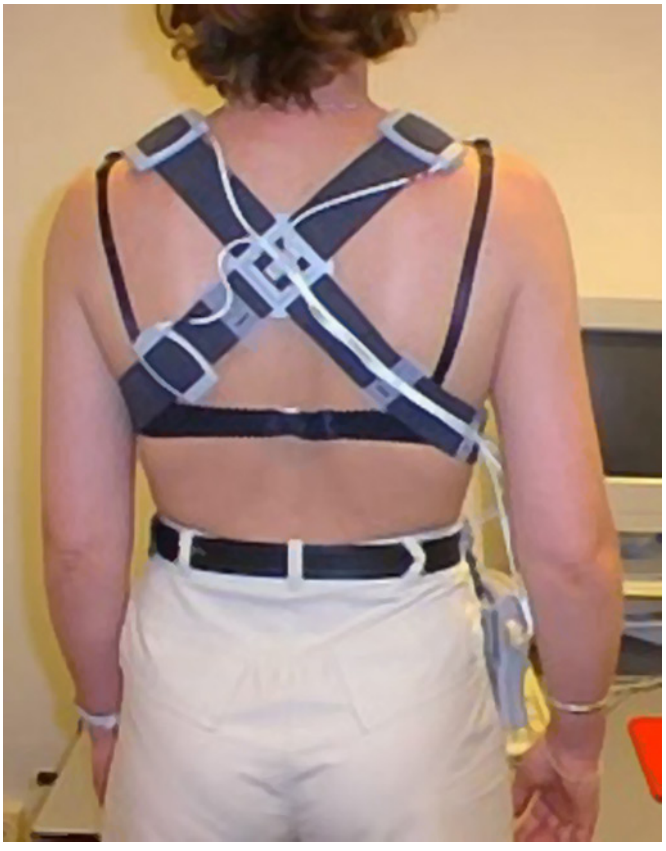

Figure 1 The Body Area Network harness

Figure 2 The relaxation and training system and the PDA. The image is copyright MobiHealth B.V.

The web portal allows the health-care professional to register a new patient, access and edit patient treatment information, access patient diaries and visualize the measurement data.

Registration is the first step in providing a new patient with the teletreatment service. The health-care professional chooses a patient identifier, enters the treatment period start and expected end dates, and the start and end dates of the first consultation period. The health-care professional can also visually inspect the measurement data of a particular patient, e.g. Figure 3 shows measurement data of a patient with a *view window* (i.e. time interval of interest) of 40 minutes.

The first and second graphs show all the recorded measurement data (RRT of the left and right trapezius muscle) over the whole treatment period (typically 4 weeks), providing the health-care professional with an overview of RRT data using a default view window of 4 hours. Both graphs are colour-coded to indicate the amount of the relaxation time (red = too little; green = satisfactory). Typically, the health-care professional selects a viewing window (e.g. 40 min) to inspect at a more detailed level the left and right RRT and RMS values (3^{rd}, 4^{th}, 5^{th} and 6^{th} graph respectively of Figure 3). The RMS graphs also show the observed maximum and minimum RMS values in relation to an arithmetic mean RMS if the number of measured RMS values is larger than the number of pixels on the horizontal axis of the graph, i.e. the ratio of RMS values to graph pixels is larger than 1.

The RMS mean is:

$$\mathrm{RMS}_{\mathrm{mean}} = 1/\mathrm{n} \sum \mathrm{RMS}_{\mathrm{i}}$$

where n is the number of RMS values in the selected viewing window divided by the width in pixels of the graph; hence, n is equal to the number of RMS values per graph pixel.

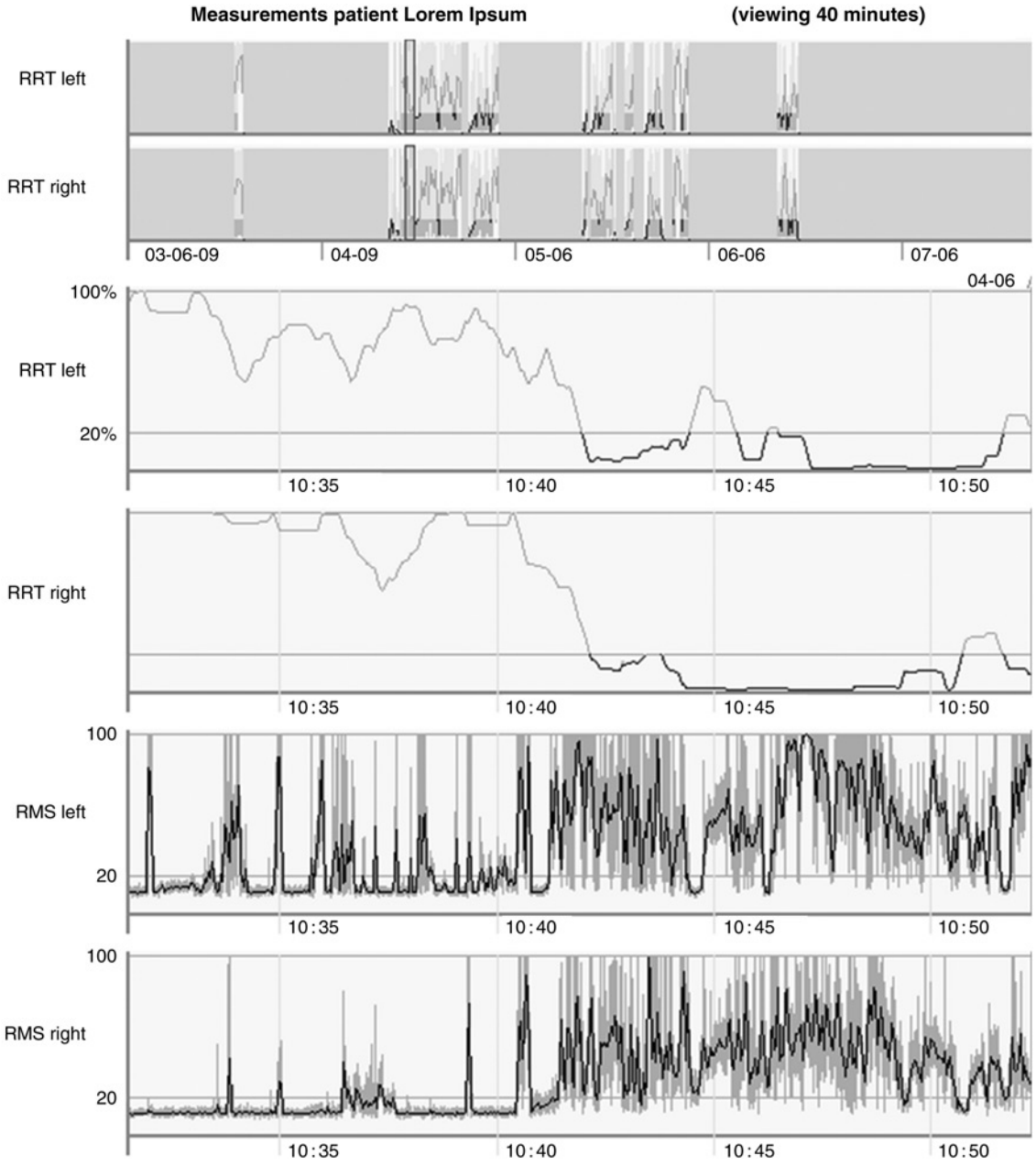

Figure 3 Example patient measurement data (zoom-level 40 min). The image is copyright MobiHealth B.V.

The RMS envelope is an indication of changing trapezius muscle activity levels. In addition, the health-care professional can use the patient diaries to associate the patient's daily activities to trapezius muscle activity levels. In particular, a patient diary contains the Visual Analogue Scale pain scores at the start and end of a day for the neck, left-right shoulder and upper back. Activity descriptions are entered by the patient for the period 06:00-22:30 at 30 min intervals.

Functional architecture

The MyoTel application provides the patient with a login screen to access the teletreatment service. Subsequently, the patient uses a PIN-code for authentication. Following successful patient authentication, the MHSP establishes a secure communications link between the PDA and the Back-Office system and exchanges control data between the PDA and the Back-Office system. Using an encrypted communications link in combination with an authentication strategy based on a patient PIN-code and PDA token, complies with the FDA's Internet Use Guidelines.[12]

After establishing a secure communications link, the MHSP sends device control data to the ReTra via a Bluetooth link. Subsequently, the ReTra starts to measure sEMG data at 500 Hz, calculates and sends RMS values to the PDA at a frequency of 8 Hz. In addition, the ReTra starts to calculate muscle activity levels and vibrates upon exceeding a pre-defined relative rest time.

The ReTra uses a RMS threshold level to start the calculation of relative rest time for the left and right

trapezius muscle. Voerman *et al.*[13] set a threshold level of 10 μV. We used 20 μV due to the relatively high noise level of the ReTra system. The relative rest time is calculated over a 60 s time interval. The ReTra vibrates if in 80% of this time interval, RMS values exceed the 20 μV threshold.

The PDA receives RMS values and calculates the RRT. Recalculation of RRT is equal to the ReTra, but necessary because the ReTra only forwards RMS data to the PDA. Next, RMS and RRT data are displayed and in parallel transmitted near real-time (approximately 2 s delay) by the PDA over the communications link to the Back-Office system.

For every measurement session on a PDA, the server system creates a measurement data file that identifies the session, and stores RMS, RRT and PDA resource data in this file. In addition, the server provides a function for live viewing of received measurements session data. Health-care professionals may use live viewing of RMS data to check the quality of the received data and if necessary, remotely support a patient in adjusting the harness and properly positioning the dry surface electrodes.

A health-care professional uses the web portal to obtain secure access to the teletreatment service. After login, the following web pages are available: Patients, New patient, Care professionals and Helpdesk. These operations allow the health-care professional for example to add a new patient, select and read patient information including RMS and RRT data visualization, and change treatment and observation periods stop dates.

System evaluation

The literature shows that proper evaluation of a telemedicine system is challenging. We decided to use the approach of DeChant *et al.*[14] This has four stages of assessment which depend on the maturity of the system's technology. Stage one and two are aimed at proving the technical and clinical feasibility of the telemedicine interventions, whereas in stage three and four more global impacts on health care of the telemedicine interventions are evaluated. However, this framework does not provide practical guidance. DeLone and McLean[15] introduced their Information Systems Success Model, a framework that distinguishes six success categories. This model has emerged as the dominant framework for system evaluation research, although others have revised it somewhat.[16,17] In the revised model there are three phases (system creation, system use and system impacts) and several distinct success categories (e.g. input data quality and system use) that have both a temporal and causal relation. For example, system quality and information quality affects the use of a system, which, in turn, would affect user satisfaction, service impact, individual task performance and organizational effectiveness. We evaluated the teletreatment system from a technical perspective, based on the revised model.

We obtained system evaluation data from five validation trials. Qualitative data were obtained by interviews and visual inspection of patient data during trials. Quantitative data were based on post trial data analysis. Four centres used the system in five validation trials in four different European countries. The duration of the trial was eight months and in total 126 female patients with chronic pain were recruited: 67 in the intervention group and 59 in the control group. In total, 20 (13 intervention group and 7 control group) patients dropped out of the trial because of technical difficulties in using the equipment, personal or family circumstances or changes in health status. The MyoTel project used 17 patient Body Area Networks, one Back-Office System and five web portals (one for every care professional). In addition, our experts addressed two technical performance criteria from a clinical perspective: availability of data and EMG data quality. We added statistical information obtained from the Back-Office System to provide data on system use.

Data quality

We assessed the quality of data provided by the ReTra and the Back-Office System. It is important that the data presented to the patient and health-care professional preserved the essential signs and patterns captured by the ReTra. In addition,it is important that there is accurate processing of the RMS data by the PDA to obtain RRT data.

Experts at each centre performed visual inspections of the RMS and RRT data for abnormal values during the trial. Figures 4 and 5 depict good and bad data, respectively. Good data are characterized by RMS values that do not exceed the maximum value (100 μV) and remain below the lower threshold (20 μV) in case of trapezius muscle rest (see the two lower graphs in Figure 4). Bad data show 'clipping' (i.e. exceed the maximum value) of RMS values, typically shown as a continuous horizontal flat line at the top of the RMS graph.

Data quality problems were detected during the trials. The majority of the problems were due to bad contact between the dry surface electrodes and the patient's skin. In general, data quality problems occurred at the start of a measurement session and were quickly detected by the patient via visual inspection of the RMS signals on the PDA display. The solutions for the data quality problems were relatively straightforward and implemented in the early phase of the trial: (1) apply a little gel to the dry surface electrodes to increase skin contact; and (2) train patients and professionals how to place the dry surface electrodes and how to interpret the visual feedback of the RMS data on the PDA and on the web portal.

Reliability

A total of 67 patients used the system. Consequently, the harness including the dry surface electrodes and their cups

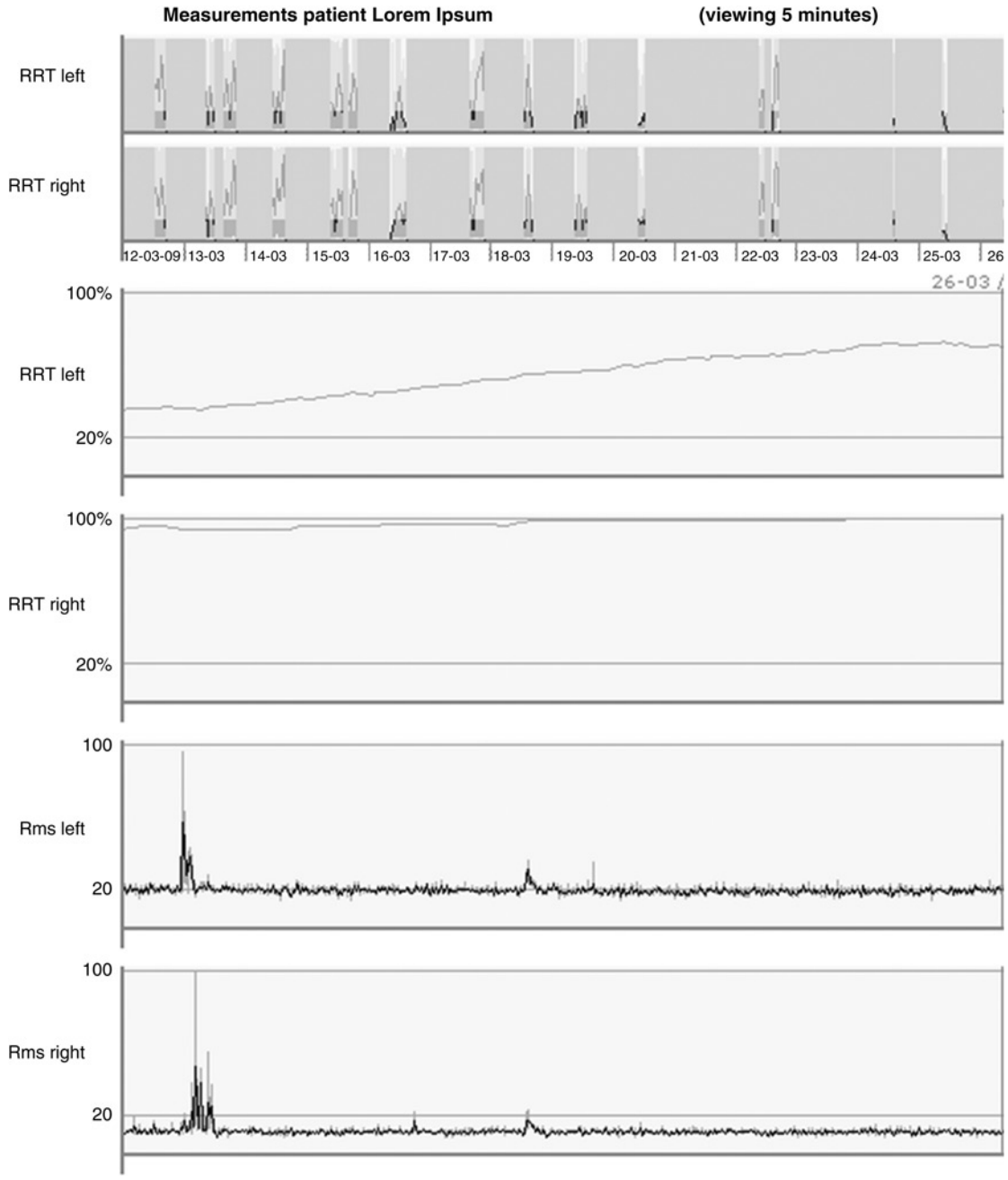

Figure 4 Good RMS and RRT data. The image is copyright MobiHealth B.V.

suffered from heavy use. The main complaints were bad electrode contact due to dried-up electrode cups and harness-cable breakage. We replaced parts of the harnesses after a problem occurred, but could not redesign or improve the quality of the harness. The reliability of the ReTra myofeedback system was also a problem. Four out of 17 (24%) ReTra systems suffered from software problems and were repaired by the manufacturer. We also had a minor problem with the PDAs: one out of 17 (6%) needed a battery replacement.

The remaining parts of the teletreatment system (e.g. the MobiHealth Service Platform, Back-Office and web portal) worked flawlessly during the trial. In particular, the uptime of the Back-Office System was 100% during the trial and stored a total of 30 MByte of measurement data (see Figure 6).

The whole data communication network infrastructure, including four different public mobile phone networks in four countries, performed without any problems.

Response time

We took five samples at random during the trial, and measured the delay between introducing a high RMS data value (a change in trapezius muscle state

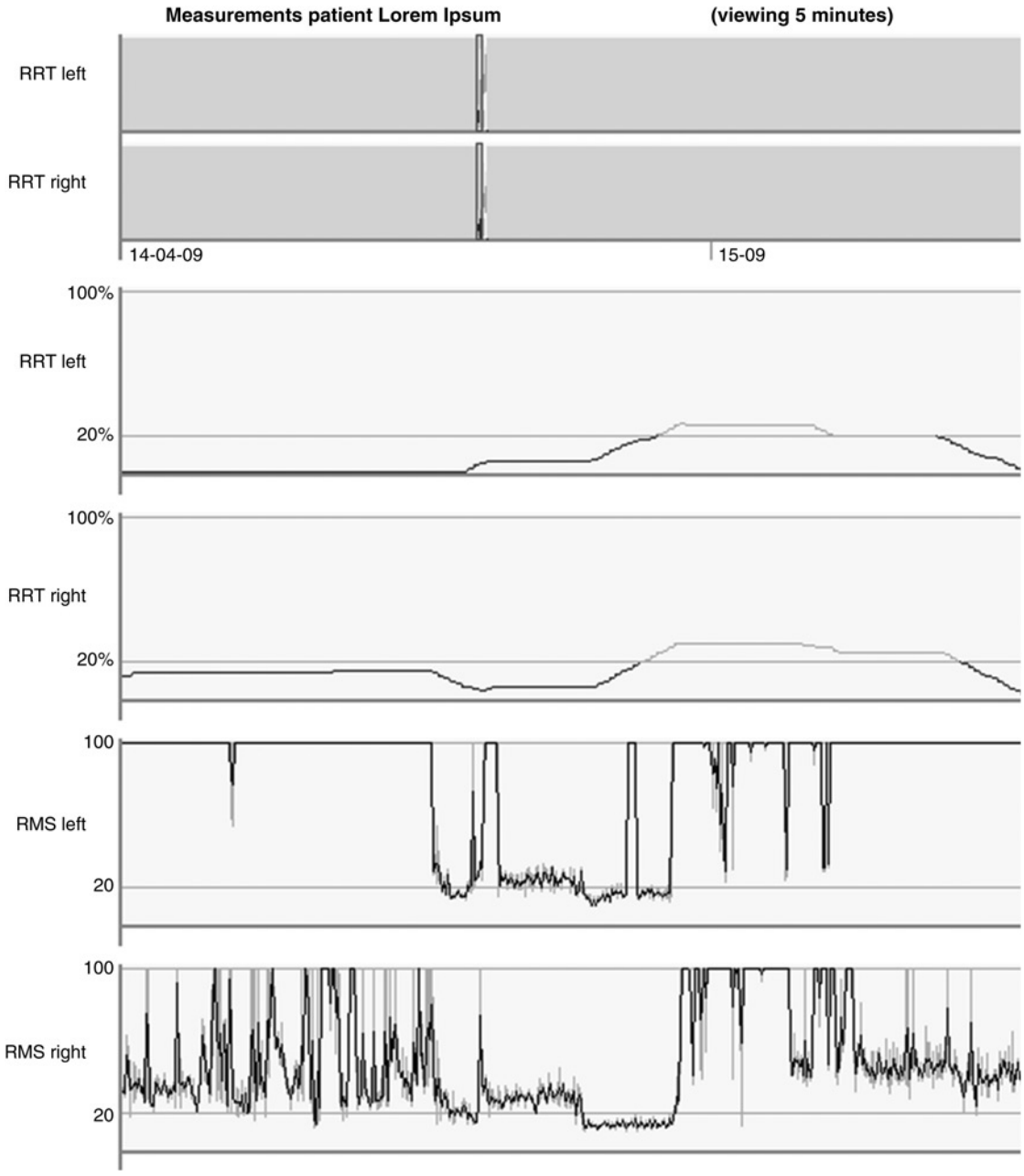

Figure 5 Bad RMS and RRT data. The image is copyright MobiHealth B.V.

from relaxed to tensed) at the patient side and the graphical presentation on the web portal. The average delay was five seconds. In addition, we used the same method to measure the 'local feedback' delay between introducing a high RMS data value and graphical presentation on the (patient) PDA. The average local feedback delay was one second.

We used a maximum response time of one second for every action performed on the graphical data by a health professional. In total, 30 samples were taken at random during the trial to measure the delay between pressing a left or right mouse button (switching between two zoom-levels) and the appearance of a new graph. The delay was too small to be measured because a new graph appeared immediately after pressing a mouse button.

Functionality

A typical teletreatment period of one month resulted in 64 separate measurement files per patient. Health professionals use the web portal to select either separate measurement files or a single aggregated measurement file. Following selection, measurement data are processed on-demand by the Back-Office System and presented graphically. Health professionals could quickly assess the treatment efficacy over different time intervals.

Patients were not uniformly enthusiastic about the design of the harness. It was quite cumbersome to put on and take off. Obtaining good quality (RMS) data from the dry surface electrodes was difficult due to poor skin contact. The

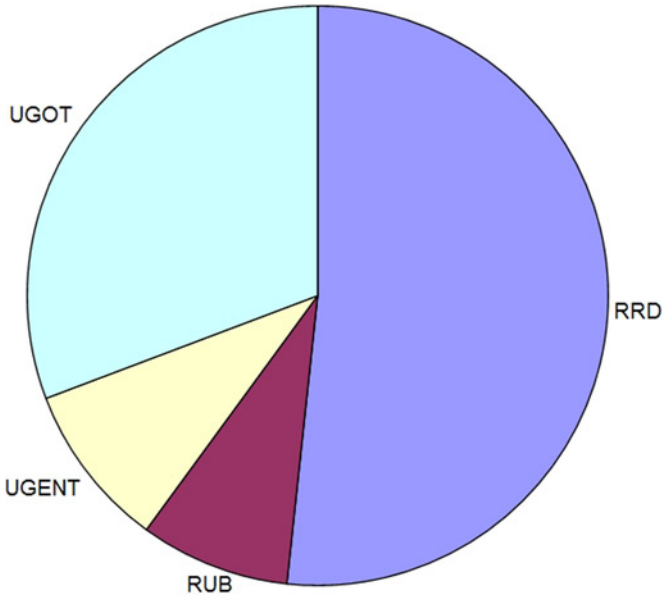

Figure 6 Back-office data storage from the four centres (RRD: Roessingh Research and Development; RUB: University of Bochum; UGENT: Ghent University; UGOT: University of Gothenburg)

majority of these problems occurred at the start of a measurement session and were quickly detected by the patient. However, the feedback algorithm in the ReTra deduced wrongly high muscle activity levels and consequently the ReTra vibrated frequently; the erroneous vibration-feedback was frustrating for the patients. Eventually four patients (6%) dropped out of the trial because of 'technical difficulties'. This was thought to be related to the design of the harness, erroneous vibration feedback and the reliability problems of the ReTra. In addition, the application of gel to increase skin contact was not always appreciated by the female patients, who were worried about stains on their clothes. Patients were however satisfied with the PDA's Graphical User Interface and the direct visual feedback they received.

We expected the battery capacity of the ReTra (four hours lifetime) and the PDA (eight hours lifetime) to be important. Patients and health professionals were trained to replace the ReTra battery and recharge the PDA battery. No difficulties were reported and we therefore conclude that battery maintenance was not a problem.

Information quality

The information quality of the system was perceived to be high. Both patients and health professionals appreciated the PDA's Graphical User Interface. It was easy to understand, interpretation of both RMS-RRT graphs was good and the direct visual feedback on muscle activity was relevant. Health professionals were pleased with the web portal. It provided a complete overview of all their patients participating in the trial. The patient information page provided relevant information for the treatment, such as treatment start/stop times, consultation times, patient diaries and different options to select measurement data. The health professionals appreciated the graphical representation of large quantities of the RMS-RRT data on the web portal. In particular, they liked being able to see unprocessed RMS data at a 2-minute zoom-level and by a click of the mouse zoom quickly through 11 different levels (from 2 minutes up to 8 days) while keeping good quality graphical representation.

User satisfaction

The overall user satisfaction was good by both patient and health professionals. The quality of the wearable myofeedback system (i.e. ReTra) and harness needs improvement. Health-care professionals reported ReTra stability problems that caused unforeseen additional interaction with the patients. Patients were satisfied with the PDA's Graphical User Interface and the direct visual feedback. Health-care professionals were satisfied with the web portal's functionality. There was a sufficient amount of good quality RMS-RRT data per patient for chronic pain treatment.

The information quality of the system was perceived high by both patients and health-care professionals. In particular, the Graphical User Interface of both the PDA and portal was highly appreciated. It was easy to understand, interpretation of both RMS-RRT graphs was good and the direct visual feedback on muscle activity on the PDA display was relevant.

Conclusion

Patients with chronic neck and shoulder pain can change their daily activity patterns if they receive continuous feedback on their muscle relaxation times. The myofeedback teletreatment system for this category of patients was investigated in validation trials with 126 female patients with chronic neck and shoulder pain. The overall conclusion about system use and user satisfaction was good. This suggests that the system is suitable for small scale clinical deployment. Large scale clinical deployment will require certain system improvements.

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