Upper limb activity over time of subjects with complex regional pain syndrome type I as objectively measured with an Upper Limb-Activity Monitor; a multiple case study

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8.1 Abstract

**Background:** Recently, an Upper Limb-Activity Monitor (ULAM) has been developed to determine activity limitations of subjects limb Complex Regional Pain Syndrome type I (CRPSI). The ULAM is based on long-term ambulatory monitoring of signals from body-fixed sensors and allows valid and objective quantification of mobility-related activities and upper limb activity during everyday life. **Aims:** To explore upper limb activity over time in subjects with acute upper limb CRPSI as measured with this novel ULAM, and to compare the upper limb activity time course to the time course of other measures at the level of activity and impairment. **Method:** Four subjects with acute upper limb CRPSI were measured at four relatively fixed moments in time during a treatment protocol. Several ULAM outcome measures related to upper limb usage and mobility were used. Furthermore, we used three questionnaires at the activity level (RASQ, DASH, RAND36) and six impairment outcome indicators (VAS-moment, VAS-effort, volume, temperature, AROM, strength). **Results:** Objectively measured upper limb activity often improved; improvements of >5% were found for the majority (63%) of ULAM upper limb outcome measures at final assessment. The ULAM outcome measures had a time course more similar to the body-part specific questionnaire RASQ than the other two questionnaires. The time course of impaired temperature was most often in accordance with changes over time as measured with the ULAM: volume, AROM and strength were less frequently in accordance with the ULAM outcome measures, and both VAS scores showed least accordance. **Conclusion:** Clear changes in upper limb activity over time as measured with the ULAM were found. The relationships between the time courses of the ULAM outcome measures and other outcome measures for activity limitations and impairments were explainable. The current ULAM therefore has the potential to validly assess upper limb activity over time in upper limb CRPSI.
8.2 Introduction

Complex Regional Pain Syndrome type I (CRPSI) comprises a combination of impairments\(^1\),\(^2\) and usually leads to activity limitations in everyday life\(^2\)-\(^9\). Until recently, most CRPSI research concentrated on impairments, and when activity limitations were quantified merely scales and questionnaires were used\(^10\). This lack of instruments that allow objective measurement of activity limitations, together with the recently stressed importance of objective outcome measures for CRPSI\(^11\), and recent developments in the field of ambulatory accelerometry\(^12\) formed the basis of a novel Upper Limb-Activity Monitor (ULAM). This ULAM is based on long-term ambulatory monitoring of signals from body-fixed sensors and allows detailed objective quantification of mobility-related activities and upper limb activity during everyday life\(^13\). It is an extension of a validated Activity Monitor (AM)\(^14\)-\(^18\) and consists of acceleration sensors on forearms, thighs and trunk, connected to a waist-worn recorder (figure 8.1). The ULAM has proven its ability to detect limitations in the mean intensity, percentage and proportion of upper limb activity in chronic upper limb CRPSI patients when compared to healthy subjects\(^19\). Impaired active range of motion of wrist and digits, and grip strength were the most important factors explaining variability in activity limitations in chronic upper limb CRPSI as measured with the ULAM\(^20\). A cross-sectional comparison study of the relationship between ULAM and questionnaires in chronic upper limb CRPSI demonstrated the ULAM’s distinct place in the field of outcome assessment\(^21\); it offers an alternative but important insight into limitations of everyday functioning.

Figure 8.1: A subject wearing the ULAM in her home environment.

The ULAM has proven to be feasible and valid in transversal studies in chronic upper limb CRPSI\(^13\),\(^15\), but upper limb activity over time as measured with the ULAM has not yet been explored in a longitudinal setting. There is also no knowledge of whether changes in objectively measured upper limb activity are related to changes over time as measured with other instruments. This is an important methodological issue that has to be studied if the ULAM is to be used to monitor functioning of individuals or
groups over time in future (intervention) studies. Therefore, the research questions were:

- What is the time course of upper limb activity as objectively measured with the ULAM in acute upper limb CRPSI?
- Is the time course of upper limb activity as measured with the ULAM related to the time course of other instruments and outcome measures at the activity and impairment levels?

8.3 Method

Design, subjects and treatment regimen
Because changes in upper limb activity are more likely in acute than in chronic upper limb CRPSI, subjects having CRPSI-related complaints for less than 10 weeks were recruited from the outpatient pain department (H.J.K.) for this multiple case study. Four subjects with fractures as causative event volunteered and were assessed four times during a treatment regimen. CRPSI was diagnosed according to Veldman’s criteria \(^{22}\) that are similar to those of the International Association for the Study of Pain \(^{23}, 24\). Subject A was a 48-year old man with non-dominant side CRPSI who worked with the police detective force, was divorced and lived with his two children. Subject B was a 58-year old man with non-dominant side CRPSI, worked as a mechanic, was married and lived with his wife and child. Subject C was a 71-year old woman with non-dominant side CRPSI, was married and lived with husband. Subject D was a 52-year old man with dominant side CRPSI, worked as a night-watchman, was married and lived with his wife and two children. Unfortunately, there still is no well accepted evidence based treatment algorithm for CRPSI \(^{11}, 25, 26\). Moreover, treatment efficacy to reduce impairments (i.e. mainly pain) has scarcely been demonstrated with methodologically sound studies \(^{27}\), let alone treatment efficacy to reduce activity limitations \(^{10}, 25, 28\). Therefore, a reasonably standardized treatment regimen \(^{b}\) was used that aimed at improving activity and everyday functioning, in addition to reducing impairments. For a chronological overview of the subjects’ CRPSI history see figure 8.2.
Figure 8.2: Chronological overview of the patients’ CRPSI history from the causative event in week 0 up to final assessment at T3, including treatment parameters.

Abbreviations and content / function of treatment parameters:
CRPSI = Complex Regional Pain Syndrome type I, GP = general practitioner, PT = physical therapy / physical exercises and connective tissue massage with some pain allowed aimed at functioning, MT = manual therapy /segmental approach and physical exercises with some pain allowed aimed at functioning, Vn= n
th visit department, Tn = Outcome measurement 0-3, vitC = vitamin C / radical scavenger, ket = ketanserin / vasodilator capillaries, verap = verapamil / vasodilator large vessels, carn = carnitine / stimulator aerobe metabolism when perfusion is normalized and reduction of free radicals, ion nx = iontoforesis n times that week with ketanserin, inf = infusion n times that week with carnitine, DMSO = di-methyl sulfoxide / radical scavenger, flui = fluimecil, radical scavenger, opd = hospital outpatient department
Instruments and outcome measures

The ULAM enables objective determination of whether or not the upper limbs are active when a subject is performing one of these mobility-related activities: lying, sitting, standing, walking, climbing stairs, cycling and general movement. Based on this information and ‘feature’ signals derived from the raw acceleration signals, several ULAM outcome measures can be calculated. Because extensive descriptions of measurement technique and automated signal analysis have been provided previously we would like to refer to these studies. The following ULAM outcome measures, with lower scores indicating more limited activity, were used:

- \( \% \text{dyn} \): the percentage of the measurement period that dynamic mobility-related activities (i.e. the body motions walking, climbing stairs, cycling and general non-cyclic activity) were performed,
- \( \text{int}\text{sit} \& \text{int}\text{stand} \): the mean intensity of upper limb activity of the involved side while the subjects were sitting and standing, expressed in g (9.81 ms\(^{-2}\)),
- \( \%\text{sit} \& \%\text{stand} \): the percentage of the time that the involved upper limb was active while the subjects were sitting and standing,
- \( \text{prop}\text{sit} \& \text{prop}\text{stand} \): the proportion of the intensity of activity of the upper limb of one upper limb relative to the intensity of activity of the other upper limb, expressed as a ratio.

Because there was no guaranteed treatment effect and no ‘gold standard’ for objective measurement of changes in activity limitations over time, the time course of the ULAM outcome measures was compared to the course of questionnaires. Three questionnaires were used that also aimed at measuring limitations of everyday functioning, but with other measuring techniques and different operationalisations of the concept functioning than the ULAM. We assumed that if functioning changed over time, this had to be reflected to a lesser or greater extent in both ULAM and questionnaires, depending on the strength of the conceptual relationships between the instruments and similarities regarding instrument characteristics. The following questionnaires were used:

- **RAND36 Health Survey**: the RAND36 is a generic questionnaire that has been used in CRPSI research. Although it was most responsive of five generic questionnaires, it was less responsive for upper limb disorders because of ceiling- and floor-effects,
- **Radboud Skills Questionnaire (RASQ)**: the RASQ is a reliable body-part specific questionnaire especially developed for subjects with upper limb CRPSI that compares the current effort certain activities cost to pre-CRPSI. Its responsiveness has not been studied specifically,
- **Disabilities of Arm Shoulder and Hand Questionnaire (DASH)**: the DASH function and symptom score is a 30-item body-part specific questionnaire that mainly measures limitations of everyday activity of subjects with upper limb disorders but also contains some impairment items. Except for our study, it has not been used in CRPSI but responsiveness was sufficient after carpal tunnel release.
The time course of several impairment outcome indicators was also explored. Most of these impairments have been described as a responsive multi-component score for (acute) upper limb CRPSI \(^ {28, 41}\):

- **VAS-effort**: pain intensity resulting from effort as measured with a visual analogue scale,
- **VAS-moment**: momentary pain intensity as measured with a visual analogue scale
- **Volume**: the difference in volumetric measurements (oedema, atrophy) between both hands in relation to the volume of the non-involved side as measured with a fluid overflow volumeter,
- **Temperature**: temperature of the dorsal side of the involved hand relative to the non-involved side as measured with an infrared thermometer,
- **AROM**: maximum active range of motion (AROM) within pain threshold of the wrist and two most impaired fingers of the involved hand relative to the non-involved side as measured with a goniometer,
- **Strength**: four point grip strength of the involved hand relative to the non-involved side as measured with a portable hand-held dynamometer.

Impairments were converted to a range of 1-10 with a score of 1 to be interpreted as absence of that impairment and 10 as severely impaired. For a more information we would like to refer to other studies \(^ {20, 41}\).

**Protocol**

All assessments were in the subjects’ home environment. Informed consent was signed, the ULAM was fitted and information regarding treatment was obtained. The subjects were instructed to continue everyday activities while wearing the ULAM, except for swimming, bathing or showering. To avoid fatiguing the subjects and to assess wearing comfort, the ULAM was worn for 24 hours although 48-h measurements are technically possible. After removing the ULAM, it was asked whether the wearing period was representative for the rest of the days of that week, a gross overview of activities performed was noted to support data interpretation, and questionnaire and impairment scores were obtained. The exact ULAM measurement technique and output parameters were not explained until final assessment. All subjects agreed with this protocol, which was approved by the local medical ethical committees.

**Data-analysis**

To determine the time course of objectively measured upper limb activity, the absolute values of the ULAM outcome measure scores were analysed at assessments t0 to t3. Changes in the absolute values of all outcome measures at t1, t2 and t3 compared to baseline (t0) were subsequently normalized to visualise their course in time. The maximum change compared to baseline (either positive or negative, either for time interval t1-t0, t2-t0 or t3-t0) was set at 100% (or -100% in case of a negative change). These normalized change scores were shown in bar graphs for both the individual subjects and the group (n=4). A from a clinical
viewpoint ‘ideal pattern’ for the outcome measures would be that the normalized time 
interval for t3-t0 was at +100%, whereas the t2-t0 and t1-t0 intervals were both at 
respectively lower percentages. Such a pattern meant that the more time had passed, 
the more a subject's functioning had improved (irrespective of whether positive 
changes in functioning were due to treatment or natural recovery). It has to be 
noticed such figures do not display the magnitude of changes between different 
outcome measures but only the direction of changes over time. To compare the time 
courses, we calculated how often changes over time between consecutive follow-up 
assessments (t1-t0, t2-t1 and t3-t2) as measured with the ULAM outcome measures 
were in the same direction as changes over time as measured with other outcome 
measures. For each combination of two outcome measures twelve delta pairs (4 
assessments, so 3 deltas for each of the 4 subjects) were analysed. The higher the 
number of changes in the same direction for two outcome measures (either in a 
positive or in a negative direction), the more similar the time course between these 
outcome measures.

8.4 Results

The subjects did not report any problems wearing the ULAM although they had to get 
used to it for a few minutes each time it was fitted. The ULAM outcome measures 
propsit and propstand were missing at three assessments due to technical problem 
with the sensor on the non-involved forearm. These outcome measures were only 
presented in table 8.1 and not further analysed.

Time course of upper limb activity

The ULAM outcome measure %dyn fluctuated over time in subject A, whereas the 
absolute values of its outcome measures related to upper limb usage indicated 
clearly improved functioning between t0 and t1 (table 8.1). The apparent stabilisation 
of upper limb outcome measures at t2 and t3 was probably due to 24-h ULAM 
wearing periods that were not representative (i.e. inactive) for other days of that 
week. Nevertheless, all ULAM outcome measures demonstrated improvements at 
the end of the 3-months period compared to baseline; intsit +24%, %sit +28%, 
intstand +25% and %stand +7%. The three questionnaires also indicated improved 
functioning at t3 compared to baseline. The impairment outcome indicators AROM 
and strength had clearly improved (≥ 2 points) and temperature had clearly worsened 
after 3 months. At final assessment, subject A was working full-time and started 
jogging again.

Subject B's upper limb activity as measured with the ULAM had not changed much at 
the end of the 3-month measurement period compared to baseline (intsit +7%, %sit - 
2%, intstand +4%, %stand +1%, propsit +18% and propstand +1%); improved propsit 
was mainly due to decreased activity of the non-involved side (table 8.1). Although 
the 24-h ULAM wearing period was representative for that week at t3, it was 
unrepresentative for previous assessments because the family-dog had died; the
Upper limb activity over time as measured with the ULAM. The percentage and intensity of upper limb activity were worse which may have been due to less petting. The questionnaire scores had not changed much at the end of the 3-month period. At final assessment, only both VAS scores had worsened and the other impairments had hardly changed compared to baseline. So subject B’s overall functioning did not appear to change much during the measurement period. It has to be noted, however, that his treatment did not pass problemless with a delayed start and premature ending of physical therapy in addition to an unintentional too small dose of medication.

Table 8.1: Overview of absolute values for the ULAM outcome measures, the questionnaire outcome measures and the impairment outcome indicators of the four subjects and the group. - unrepresentative day for the rest of the days of that week. + unrepresentative 24 hours. * could not be computed due to a technical problem.
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The %dyn performed by subject C was lower than the other subjects (table 8.1). Despite an unrepresentative inactive 24-h ULAM period at t1, the majority of ULAM upper limb outcome measures clearly indicated improved functioning between t0 and t1 (except for propsit), and was relatively stable at t2 and t3 (except for propstand at t2). The worsened propsit and propstand scores were due to less increased activity of the involved side compared to increase activity of the non-involved side. At the end of the 4-month period, all ULAM outcome measures indicated improved functioning; intsit +158%, %sit 123%, intstand +25%, %stand +2%, propsit +3% and propstand +14%. All questionnaires also indicated improved functioning after 4 months, also with major improvements between t0 and t1. After 4 months, volume, AROM and strength were clearly improved (≥ 2 points) and no impairment had worsened.

The ULAM outcome measure %dyn varied over time in subject D and was generally high (table 8.1). The unrepresentativeness of two 24-hour ULAM periods (i.e. overactive t0 and inactive t3) was reflected in %dyn and in upper limb activity during sitting. After 4-months, the upper limb activity outcome measures during sitting had hardly changed compared to baseline (intsit +1%, %sit -4%, and propsit -1%), whereas the two outcome measures during standing indicated improved functioning despite unfavourable unrepresentativeness (intstand +32%, %stand +9%, and propstand +13%). The questionnaires RASQ and DASH showed (continuous) improvements over time compared to baseline, whereas the RAND36 scores slightly varied but had not changed after 4 months. All impairments had improved after 4 months, except for VAS-moment that was already least impaired in subject D.

At the group level, %dyn was relatively constant ranging between 11.4-12.0% (table 8.1). At the end of the on average 3½ months period, the four ULAM upper limb outcome measures all indicated improved functioning: intsit +38%, %sit +29%, intstand +21% and %stand +4. The questionnaire scores also indicated improved functioning for the group over 3½ months time. Because the magnitude and moments of changes in impairments varied between individual subjects, only volume, AROM and strength had clearly improved compared to baseline at the end of the measurement period.

**Time course of normalized change scores**

The patterns of normalized change scores were 'clinically ideal' only for a few outcome measures (figure 8.3, see also method section); actually primarily for the ULAM outcome measure intstand, the RASQ questionnaire, and the impairment outcome indicator AROM. Questionnaires more often displayed such a pattern than the ULAM outcome measures that, in turn, more often displayed such a pattern than the impairment outcome indicators. Not one 'clinically ideal' pattern was found for subject B. For subjects A, C and D, the majority of questionnaire and impairment outcome measures displayed their maximum normalized positive change (+100%) for the t3-t0 time interval, which was not true for the ULAM outcome measures. Outcome measures that displayed a maximum normalized negative change (-100%) or did not
change during two or more of the time intervals were mainly at the impairment level, and mainly for subject B. Overall, the ULAM outcome measure %dyn appeared dissimilar to the other ULAM outcome measures. The normalized change scores of subject B were clearly divergent from the other subjects.

Figure 8.3: Overview of normalized change scores of all outcome measures for three delta scores (t1-t0, t2-t1, t3-t2), for both the individual subjects and the average score of these subjects as a small group. The maximum change compared to baseline (either positive or negative, either for time interval t1-t0, t2-t0 or t3-t0) was set at 100% (or -100% in case of a negative change).
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**Time course ULAM outcome measures in relation to other outcome measures**
Calculations of how often changes over time between consecutive assessments (t1-t0, t2-t1 and t3-t2) were in the same direction (table 8.2) showed that the time course of ULAM outcome measures was most often in the same direction with the RASQ. The changes in functioning as measured with the RAND36 and DASH were less often in the same direction as the ULAM outcome measures. The DASH showed a number of changes in the same direction as the ULAM outcome measures about equal to the impairment outcome indicators volume, temperature, AROM and strength; both VAS scores clearly had lower numbers. Of the ULAM outcome measures, the time course of intstand was best related to the time course of both the questionnaire and impairment outcome measures.

**Table 8.2:** The time course of the five ULAM outcome measures in relation to the time course of the questionnaire and impairment outcome measures. It was calculated how often changes over time between follow-up assessments and baseline assessment (t1-t0, t2-t1 and t3-t2) as measured with the ULAM outcome measure were in the same direction as changes over time as measured with the other outcome measures.

<table>
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<tr>
<th>RAND36</th>
<th>RASQ</th>
<th>DASH</th>
<th>VAS effort</th>
<th>VAS moment</th>
<th>volume</th>
<th>temperature</th>
<th>AROM</th>
<th>strength</th>
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</table>

**8.5 Discussion**

When the absolute values of the ULAM outcome measures at final assessment were compared to baseline, objectively measured upper limb activity of these four subjects with acute upper limb CRPSI often improved. Improvements of >5% were found for the majority of ULAM upper limb outcome measures (10/16, 63%), despite actually unchanged functioning in subject B and the sometimes very short time intervals
Upper limb activity over time as measured with the ULAM

between assessments. Because we had no idea as to how limited the subjects would be or how fast changes over time would occur, small time frames were considered appropriate for the present study, however. Although these four subjects showed more limited upper limb activity than thirty subjects with chronic CRPSI as previously measured with the ULAM \textsuperscript{19, 20}, this should not be interpreted as a confirmation of the supposition that functioning is generally more limited in acute than in chronic CRPSI. CRPSI clearly is a syndrome and usually varies enormously between subjects with respect to type and magnitude of impairments and activity limitations, as well as the duration of these consequences of the syndrome.

The finding that the body-part specific RASQ had a time course more similar to the ULAM than the RAND36 and DASH was probably due to more similarities with respect to operationalisation of functioning and other instrument characteristics, as was also found in chronic CRPSI \textsuperscript{21}. Changes over time as measured with the impairment outcome indicators were less well related to changes as measured with the ULAM than the questionnaires were, which was already expected because impairments are operationalisations of functioning at a different level than ULAM and questionnaires (i.e. body impairments versus a person's activity). Among the impairments, the time course of volume, temperature, AROM and strength were more frequently in accordance with the ULAM outcome measures than the VAS pain scores, which was not really surprising because, especially in acute CRPSI, pain can vary widely during the day \textsuperscript{41}. It has to be noticed that the present VAS scores were not very high; the four subjects may therefore not have been representative for acute CRPSI with respect to pain intensity. The divergent time course of %dyn was also not unexpected considering the population studied; the present subjects had an upper limb disorder and were not limited with respect to mobility at the group level, which was also found in chronic upper limb CRPSI \textsuperscript{19}. The present 11-12 %dyn did not differ from chronic upper limb CRPSI or healthy subjects \textsuperscript{19, 12, 13, 15-18, 29, 30}.

The present results, in our opinion, demonstrate that the current ULAM outcome measures have the potential to validly assess changes in upper limb activity over time of subjects with upper limb CRPSI in future longitudinal studies. Although the ULAM is considered potentially sensitive for changes in upper limb activity, some aspects will have to be studied before definite conclusions can be drawn, however. An important methodological issue of a ULAM measurement is between-measurement variability. Variability between measurements can be the result of several factors. First, everyone’s level of everyday physical activity will vary, even within ‘representative days’, and thus the level of upper limb activity in CRPS patients will also vary. The intra-individual biological variability of upper limb activity as measured with the ULAM could not be investigated as yet because we have only performed 24-h measurements. Between-day-variability for %dyn has been studied in 48-h measurements with the ULAM’s older sibling AM \textsuperscript{29, 30}, however, and appeared to be 1.1% and 1.3% in two different patient groups and 0.8% in healthy subjects. Some between-day variability for upper limb activity will not be problematic as long as
it is relatively small compared to actual changes in upper limb activity. However, intra- and inter-individual between-day variability have to be studied for both patients and healthy subjects to determine to which degree changed upper limb activity as measured with the ULAM falls under biological variability and above which threshold changed upper limb activity can be considered as clinically relevant. Such a study may lead to an advice about the number of monitoring days that is needed. Moreover, related to the number of monitoring days, knowledge of biological variability is also important to determine the required sample size for future intervention studies.

Second, besides the random fluctuation within a probably limited range, some days may clearly be different from “regular” days. For example, in the current study 6 of the 12 measurement days were not representative according to the patient’s own opinion. This was due to unusual overactivity such as organising a barbeque party, or unusual inactivity such as going to a lecture, take an unexpected day off from work or hot humid weather. Such unrepresentativeness of the 24 hours was logically not (or less) reflected in the questionnaire scores because questionnaires measure a perceived average score over the last few days whereas the ULAM measured what subjects actually did during that specific 24-hour period. Concerning the possible negative effects of unrepresentativeness of the measurement day on validity, it will stay important to ask a patient about this matter. Possibly, measurement days that are not representative should not be included in the analysis in future studies. Moreover, increasing the number of measurement days will also address this problem.

Finally, the instrument itself can be a source of within-measurement variability. It has to be noticed that the ULAM upper limb outcome measures are rather rough; the ULAM detects upper limb activity but does not yet allow valid measurement of every aspect of upper limb usage as a consequence of the measurement technique. However, due to our experiences and data from previous studies we think that this latter point is less important than the issue of between-day variability in everyday physical activity. Nevertheless, improving the reliability and validity of the ULAM itself will remain an ongoing issue.

8.6 Conclusion

In general, clear changes were found in upper limb activity over time as objectively measured with the ULAM. The relationships between the time course of the ULAM outcome measures and the time course of other outcome measures for activity limitations and impairments appeared to be logical and explainable. It was therefore concluded that the current ULAM outcome measures have the potential to validly assess changes in upper limb activity over time of subjects with upper limb CRPSI. However, the issue of between-day variability needs further study in a larger population during a longer time period.
Upper limb activity over time as measured with the ULAM

8.7 References