A WEARABLE GAIT ANALYSIS SYSTEM USING INERTIAL SENSORS PART II
Evaluation in a Clinical Setting

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Abstract: The gold standard for gait analysis, in-lab 3D motion capture, is not routinely used for clinical assessment due to limitations in availability, cost and required training. Inexpensive alternatives to quantitative gait analysis are needed to increase the its adoption. Inertial sensors such as accelerometers and gyroscopes are promising tools for the development of wearable gait analysis (WGA) systems. The present study evaluates the use of a WGA system on hip-arthroplasty patients in a real clinical setting. The system provides information about gait symmetry and normality. Results show that the normality measurements are well correlated with various quantitative and qualitative measures of recovery and health status.

1 INTRODUCTION

Gait analysis (GA) is a tool that can aid the assessment of several physical and cognitive conditions. Perhaps the most widely adopted use of GA is in the treatment of cerebral palsy children (Chang et al., 2010), (DeLuca et al., 1997). A few other areas have also investigated GA as an aid to clinical assessment, e.g. Parkinson's disease (Salarian et al., 2004), (Frenkel-Toledo et al., 2005), and stroke (Cruz and Dhaher, 2008), (Silver et al., 2000). Despite many positive results, GA is still not routinely used in the clinical setting.

Several factors contribute to the low adoption of GA as a clinical tool. The gold standard for GA is 3D in-lab motion capture (MOCAP), which can considerably improve clinical assessment, e.g. (Lofterød and Terjesen, 2008), (Morais Filho et al., 2008). However, the interpretation of results requires specific training and experience, and its use as a routine procedure is not widely accepted from an economical perspective (Simon, 2004). In addition, a state-of-the-art MOCAP system is often not available in small practices and underpreviledged areas. The alternative to MOCAP is observational gait analysis (OGA), which is intrinsically subjective and sensitive to the observer's experience (Toro et al., 2003). Nonetheless, in 1999 Coutts (Coutts, 1999) argued that despite its limitations, OGA would never be totally replaced as the default GA method in the clinical environment because of ease of use.

Recently large efforts have been employed in developing low-cost, mobile GA systems that can complement OGA with objective, reliable, quantitative data. The success of such systems will hopefully incur in a wide-spread adoption of quantitative GA as a clinical tool. The design of these system may be guided by a few practical requirements:

- Easy to use: It is important that the system require no special training and very little extra effort from the staff in order to ensure cost effectiveness. It is also desirable that the system be used quickly and independent of infrastructure/location.
- Unobtrusive: To spare patients, who may be in pain or discomfort, the system must be small, light weight, and comfortable to wear. In addition, the system should not interfere with the patient's natural movements. Cumbersome equipment may make the patient feel self conscious, and act unnaturally.
- Valid and reliable: The information acquired by the system must be accurate, and representative of clinical assessment.
- Easy to interpret: Kinematic information and other specific gait parameters are mostly useful

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for clinicians who have experience with gait analysis. To ensure wide-spread adoption, the system must provide intuitive and easy to interpret information.

The present study aims at developing a small wearable system that fulfills the above requirements, and can be successfully deployed in the clinical setting. Part I of the study introduced a symbolic approach to the analysis of gait symmetry and normality using miniature accelerometers and gyroscopes. The proposed method was then compared to symmetry and normality measures extracted from 3D MOCAP kinematic data.

Part II now investigates the viability of using the system to evaluate patients in a real clinical setting. The data collection took place at the orthopedic ward at Sahlgrenska Univeristy Hospital, Mölndal, Sweden. Eleven unilateral hip-arthroplasty patients underwent GA with the proposed system at discharge, and once again approximately three months later. Measures of symmetry and normality were derived and evaluated against a timed 10-meter walk test and a EQ-5D health questionnaire.

2 RELATED WORK

Due to limitations in availability, cost and training required for 3D GA, this section only discusses GA methods that can be performed inexpensively and independently of a MOCAP gait lab, namely observational gait analysis (OGA) and wearable sensor systems.

2.1 Observational Gait Analysis

Observational gait analysis (OGA) can be further divided into: naked eye observation (NE-OGA), and video-aided observation (VA-OGA). VA-OGA has a clear advantage over NE-OGA in that it allows more freedom to the observer, enabling pause, slow motion, and other functions. In some cases, quantitative measurements, such as joint angles (Embrey et al., 1990), can be directly calculated from the image.

VA-OGA is often accompanied by a form or questionnaire that facilitates the extraction of relevant information from the video. These forms typically employ binary or gross estimates of variables, such as Presence/Absence or Normal/Mild/Sever. Very frequently, new questionnaires are developed for specific studies or clinics, e.g. (Brunnekreef et al., 2005), (Kawamura et al., 2007). Although various questionnaires evaluate similar features, they often differ largely in rating scheme and variables of interest.

Two VA-OGA forms have been more thoroughly investigated and more widely adopted: the Visual Gait Assessment Scale (VGAS) (Dickens and Smith, 2006), (Brown et al., 2008) and the Edinburgh Visual Gait Score (EVGS) (Read et al., 2003), (Ong et al., 2008). Both questionnaires target the assessment of ambulatory children with cerebral palsy. Form and questionnaires have also been used to aid NE-OGA. The physician Rating Scale seems to be the most frequently used, (Koman et al., 1993), (Maathuis et al., 2005), (Wren et al., 2005), also targeted to children with cerebral palsy.

OGA can be complemented by other more quantitative measurements, such as average gait speed, average step length and other gait parameters. These are typically measured during walking tests, such as the 10-m walking test (Dean et al., 2001), (Kempen et al., 2011), or the timed up and go test (TUG) (Kristensen et al., 2007), (Nordin et al., 2008). The TUG is normally employed in studies where balance and risk of fall are of interest, as it requires that the subject stand up and sit down on a chair without help.

The 10-m walking test, on the other hand, is a simple way of determining, average gait speed, stride length and cadence. Average gait speed, for example, has been identified as an indicator of: activity of daily living function in geriatric patients (Potter et al., 1995); high risk of health-related outcomes in well-functioning older people (Cesari et al., 2005), and leg strength in older people (Buchner et al., 1996). Stride length is another interesting measure that has been associated with, for example, metabolic cost and impact during walking (Russell et al., 2010), (Mercer et al., 2003).

2.2 Mobile GA Systems

Current sensor and hardware technologies have made possible the creation of small wearable systems for GA. A large number of authors have dedicated their efforts to developing mobile, simpler alternatives to 3D in-lab GA. Such systems may be categorized according to the information they produce: spatio-temporal (ST) parameters, kinematics, or overall characteristics of gait. These categories are not necessarily mutually exclusive, but they represent different levels of information complexity.

ST parameters, such as stride time and velocity, can only convey information about when and/or where the foot hits the ground. One way to visualize this is to imagine that ST parameters could be calculated from a series of foot-prints over time. Systems that measure ST parameters are usually simpler and more commonly used. Some of the earliest systems employed foot-switches to determine initial and terminal contact, e.g. (Hausdorff and Ladin, 1995). More recently, studies have found accelerometer measurements valid and reliable means of determining walking speed, cadence, stride length and other ST parameters, e.g. (Saremi et al., 2006), (Senden et al., 2009), (Bautmans et al., 2011). Although ST information can be very useful, it does not represent the subject's gait pattern as a whole. It is important to know what happens between foot-prints.

The second category encompasses those systems that are able to extract kinematic data such as trajectories, and joint angles. Some of these systems provide only foot pitch and ground incline in addition to ST information, e.g. (Sabatini et al., 2005), (Bamberg et al., 2008). Others provide measures of joint angle progressions, segment rotations and accelerations, e.g. (Dejnabadi et al., 2005), (Mayagoitia et al., 2002b). These systems can provide an inexpensive alternative to in-lab 3D GA. However, proper training and experience are required for interpreting kinematic information. In addition, these systems are too cumbersome to be used for extended periods of times.

The third category aims at extracting more general characteristics of gait such as gait symmetry (Gouwanda and Senanayake, 2011), gait regularity (Moe-Nilssen and Helbostad, 2004), and balance (Allum and Carpenter, 2005), (Mayagoitia et al., 2002a). Although this information may be derived from ST and/or kinematic data, systems can be made much simpler if they directly measure general characteristics. For example, (Moe-Nilssen and Helbostad, 2004) measures gait symmetry using only one accelerometer placed on the lower back, whereas all methods mentioned in the previous categories make use of at least one sensor node on each lower limb. General characteristics of gait are usually not enough for determining the cause of the subject's gait abnormality. However, they are easy to interpret and can be used to monitor the subject's progress after treatment has been established.

Although measures of symmetry have been largely investigated, measures of gait normality are lacking. In Part I of the present study a measure of normality was introduced, derived from three sensor nodes containing accelerometers and gyroscopes. This measure was compared to measures of normality computed from 3D kinematic data. In Part II of the study, the viability and usefulness of the proposed normality index is investigated in a clinical setting.

3 METHOD

3.1 Data Collection

Eleven patients were included in the study. All patients had undergone unilateral hip-arthroplasty for the first time and presented no other physical or cognitive conditions. The group was composed of four women and seven men, the mean age was 69±15 years, mean weight was 81±20 Kg, and mean height was 172±9 cm.

The data collection was designed to be very quick in consideration of the patients, most of whom were in great discomfort. The patients were equipped with three Shimmer® sensor nodes. One node was placed on each outer shank, approximately three centimeters above the lateral malleolus, the remaining node was placed directly under the navel. Sensors were secured on the skin with surgical tape. The sensor nodes were synchronized with the help of beacon signals from a host computer and the data was stored on-board in a micro SD card.

The patients were then asked to walk by themselves along a 10-meter walkway at a comfortable speed, twice. The walkway was marked with black tape on the floor. The time and number of steps taken to complete the walkway were recorded at each time.

This procedure took place on the day the patient was discharged from the hospital, and a few months later, when the patient came back for a follow-up evaluation. The average number of days spent at the ward after surgery was 4±1 day. The time between baseline and follow-up measurements was 108±15 days. All patients employed a walking aid during baseline measurements, six used two crutches and five used a walker with wheels. During follow-up measurements six patients used one crutch and five patients walked without any aiding device.

Patients filled out an EQ-5D™ health questionnaire (Swedish version) approximately two weeks before surgery, and soon after their follow-up session. The EQ-5D™ is a standardized instrument for use as a measure of health outcome, developed by the EuroQol Group (www.euroqol.org). The English version of the questionnaire, validated for Ireland, is shown in Figures 1 and 2. Each answer is given a value from 1 to 3, good health state results in low values.

This study was approved by the Regional Ethics Board in Gothenburg, Sweden.

3.2 Observational Gait Analysis

The time, Tm, and number of steps, $NumSteps$, taken to complete the 10-meter walk test were used to com-

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility	
I have no problems in walking about	1
I have some problems in walking about	2
I am confined to bed	3
Self-Care	
I have no problems with self-care	1
I have some problems washing or dressing	2
I am unable to wash or dress myself	3
Usual Activities (e.g. work, study, housework, family or leisure activities)	
I have no problems with performing my usual activities	1
I have some problems with performing my usual activities	2
I am unable to perform my usual activities	3
Pain/Discomfort	
I have no pain or discomfort	1
I have moderate pain or discomfort	2
I have extreme pain or discomfort	3
Anxiety/Depression	
I am not anxious or depressed	1
I am moderately anxious or depressed	2
I am extremely anxious or depressed	3

Figure 1: EQ-5D™ Part A: English version validated for Ireland. ©*1990 EuroQol Group EQ-5D™ is a trademark of the EuroQol Group.*

pute average speed, $Speed = 10/Tm$ (m/s), and average step length, $StepLeng = 10/NumSteps$ (m). In addition, step length was normalized by the patient's height. These variables were used as reference for the improvement of the patient, under the assumption that average speed and step length should increase as the patient recovers.

3.3 Inertial Sensor Gait Analysis

The method used to compute symmetry and normality from the sensor data is described in more detail in Part I of this study. The sensor data is first symbolized into equiprobable symbols. The periods between consecutive similar symbols are calculated and represented as period histograms. Symmetry is calculated from the gyroscope data of the shanks as the relative error between the histograms derived from the right and left sides. Similarly, Normality is derived from the accelerometer data of the waist as the difference between the subject's histograms and histograms derived from a reference set of healthy individuals. The reference data set was obtained from healthy, con-

To help people say how good or bad a health state is, we have drown a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

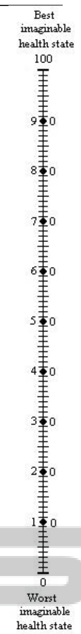

Figure 2: EQ-5D™ Part B: English version validated for Ireland. ©*1990 EuroQol Group EQ-5D™ is a trademark of the EuroQol Group.*

siderably younger individuals, average age 34 ± 13 years, walking normally.

The histograms are normalized to stride time so as to be independent of stride frequency. This normalization by stride variables is common in kinematic gait analysis and it ensures that results are not biased by gait cadence, stride length or speed.

During the follow-up session, the gait of the patients may be considerably different from those of the reference group. Nonetheless, it is expected that patients' gait patterns approach the reference group more at follow-up than at baseline.

3.4 Data Analysis

The Spearman's rank correlation coefficient was used to evaluate the correlation between two variables. The non-parametric Wilcoxon rank sum test was used to compare two distributions, and a Kruskal-Wallis test was used to compare more than two distributions. All linear model approximations were calculated based on least mean square errors.

The area under the receiver operating characteristic curve (AUC) was used to evaluate the discriminatory power of the normality index. The ROC curve was constructed based on tests performed on the same individuals. Therefore, any statistically significant comparison between different AUC must take into account the correlated nature of the data. A nonparametric approach based on generalized U-statistics was used to estimate the covariance matrix of the different curves (DeLong et al., 1988).

All measurements included two trials, which were used to assess the test-retest reliability of each index using intra-class correlation coefficient (ICC) type A-1 as a measure of absolute agreement (McGraw and Wong, 1996). All tests were bi-directional with confidence level, $\alpha = 0.05$. All data analysis was undertaken in MATLAB (MathWorks, Natick, MA).

4 RESULTS

All but one participant answered the EQ-5D™ questionnaire on both occasions. The values of the answers given to each category were added to a single score for that category. Results from before the operation and after the follow-up session are shown in Figure 3. Lower scores correspond to more patients in better health. The biggest changes were regarding mobility, usual activities and pain/discomfort.

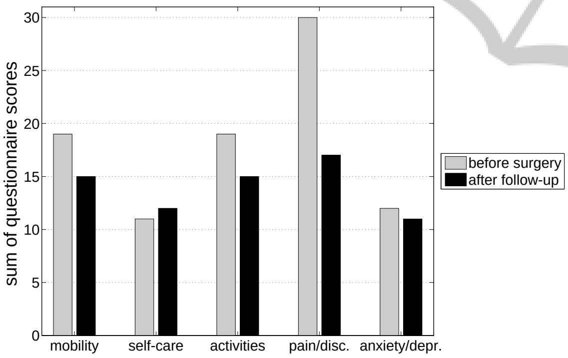

Figure 3: Questionnaire results from before the surgery and after the follow-up sessions. Lower scores correspond to more patients in better health.

Symmetry results for baseline and follow-up measurements are shown in Figure 4 for each subject. Measurements were averaged over both trials of each session. The symmetry index ranges from 0 to 100, a low symmetry index indicates good symmetry whereas a high value indicates asymmetry. According to the proposed index, gait symmetry improved at follow-up for approximately half the subjects. The asymmetry at follow-up may be caused by the use of one crutch. The symmetry index according walking aid is shown in Figure 5. There is a clear difference between the symmetry of patients using two crutches at baseline and patients walking with no aid at follow-up. However, none of the distributions were significantly different.

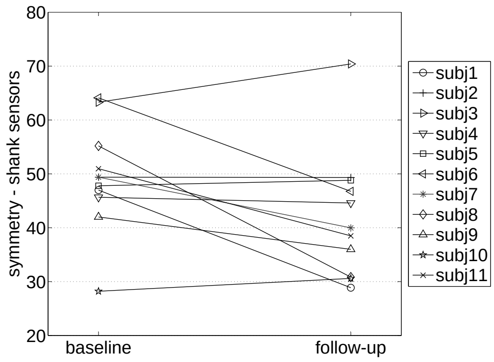

Figure 4: Symmetry results at baseline and follow-up. The two distributions are not statistically significantly different.

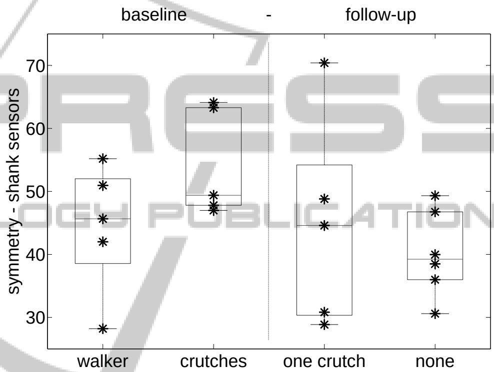

Figure 5: Symmetry results according to walking aid. Besides the data points, the plot presents box-plot representations of the distributions. The whiskers represent the smallest and largest observations, the edges of the box correspond to the lower and upper quartiles, the horizontal line indicates the median. The distributions are not statistically significantly different.

Normality results are shown in Figure 6, measurements for each patient were averaged over both trials of each session. Similarly, the normality index ranges between 0 and 100, and a low value indicates good normality. In this case, the follow-up measurements were better than baseline measurements for all patients. A Wilcoxon test indicated that baseline and follow-up groups were statistically significantly different, $p<0.0001$. Figure 7 illustrates the distribution of the normality index according to walking aid. As expected, the normality index for those patients walking without aid was, on average, better than the others. A Kruskal-Wallis test indicated that the free walking group was statistically different from the walker and crutches groups, and that the one crutch group was statistically different from the walker group.

In order to calculate the correlation between normality and walking aid, each category was represented by a number. In the order shown in Figure 7, walker was represented by 1 and no-aid was repre-

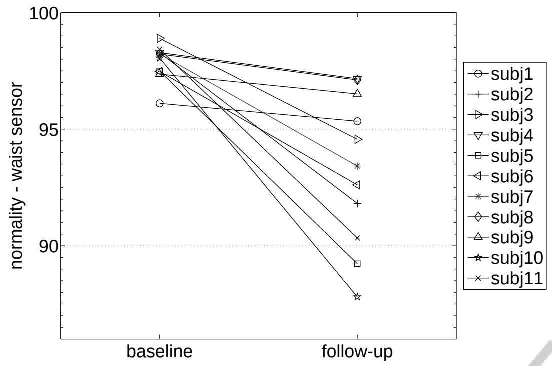

Figure 6: Normality results at baseline and at follow-up. The two distributions are statistically different according to a Wilcoxon rank sum test, p<0.0001.

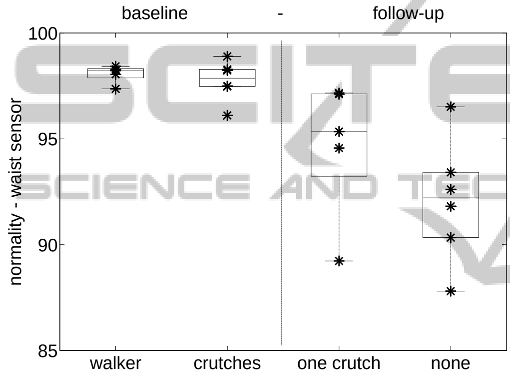

Figure 7: Normality results according to walking aid. A Kruskal-Wallis test indicates that the distribution of no walking aid is significantly different from distributions of two crutches and walker. The one crutch distribution is significantly different from the walker distribution. Normality is well correlated with walking aid, according to a Spearman's rank correlation coefficient of r=-0.78, p<0.0001.

sented by 4. The resulting Spearman's rank correlation coefficient was r=-0.78, p<0.0001.

The normality index also correlates well with both average speed, r=-0.79 p<0.0001, and normalized average step length, r=-0.76 p<0.0001. Normality values for each individual trial are shown against average speed values in Figure 8, and against normalized step length in Figure 9. On both plots the linear model approximation is shown as a solid line, and the 95% confidence interval (CI) for predicted observations is shown as dotted lines. The mean average speed at baseline, 0.46±0.16 m/s, was significantly different from the speed at follow-up, 1.06±0.22 m/s, p<0.0001.

Normality results were also compared to the EQ-5D™ answers that varied the most between before the surgery and after follow-up, namely mobility (Figure 10), usual activities (Figure 11), and pain/discomfort (Figure 10). In all cases, there is a

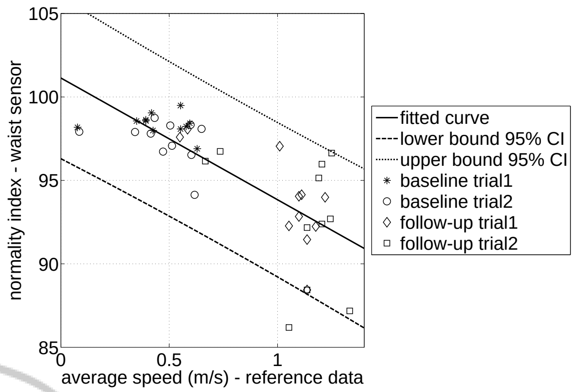

Figure 8: Normality compared to average speed. Variables are well correlated, Spearman's rank correlation coefficient r=-0.79, p<0.0001. The solid line indicates the linear model approximation a+bx, where a=95.5 with confidence interval (CI) [94.9, 96.3]; and b=-2.6 with CI [-3.3, -1.9]. The dashed and dotted lines indicate the 95% CI of predicted observations.

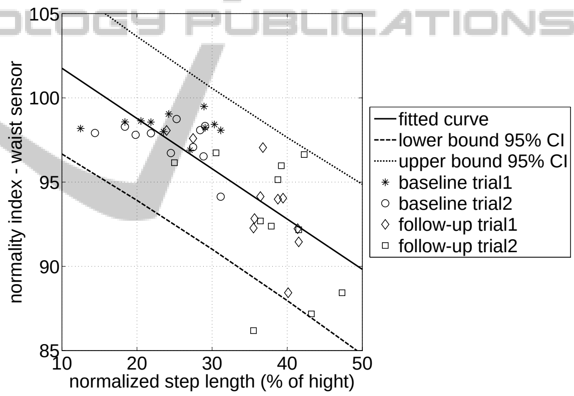

Figure 9: Normality compared to average step length. Variables are well correlated, Spearman's rank correlation coefficient r=-0.76, p<0.0001. The solid line indicates the linear model approximation a+bx, where a=95.5 with confidence interval (CI) [94.9, 96.3]; and b=-2.5 with CI [-3.2, -1.8]. The dashed and dotted lines indicate the 95% CI of predicted observations.

tendency for better health to be accompanied by better normality index. This correlation is particularly strong between normality and usual activities scores, Spearman's r=0.75, p=0.0127. There was no correlation between the health scale in Part B of the questionnaire and normality.

Improvement in normality was calculated as the difference between baseline and follow-up values. Figure 12 shows how improvement in normality correlates with number of days spent at the ward after surgery. Although a Wilcoxon test indicated that there was no statistically significant difference be-

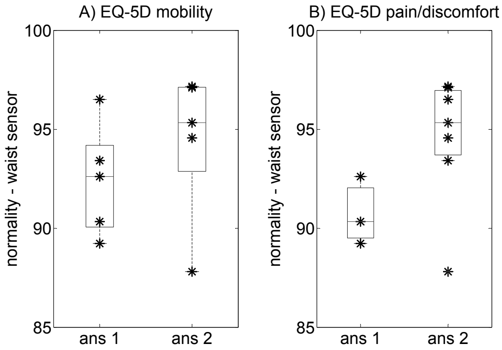

Figure 10: Normality compared to EQ-5D™ answers regarding (A) mobility and (B) pain/discomfort. Mobility answers - ans 1: I have no problems in walking about; ans 2: I have some problems in walking about. Pain/discomfort answers - ans 1: I have no pain or discomfort; ans 2: I have moderate pain or discomfort.

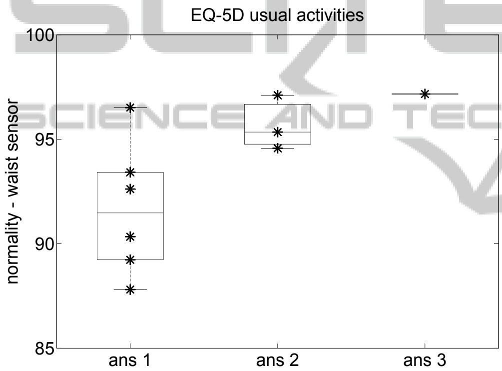

Figure 11: Normality compared to EQ-5D™ answers regarding usual activities. Ans 1: I have no problems with performing my usual activities; ans 2: I have some problems with performing my usual activities; ans 3: I am unable to perform my usual activities. Variables are well correlated, Spearman's rank correlation coefficient r=0.75, p=0.0127.

tween groups, the Spearman's rank correlation coefficient was r=-0.75, p=0.0081. There was no correlation between improvement in normality and days between baseline and follow-up sessions.

The normality index can also be evaluated based on its discriminatory values. That is, the ability to differentiate baseline measurements from follow-up measurements. The AUC was 0.94, confidence interval (CI) (0.87, 1.00), $p<0.0001$. The test-retest reliability was also high, r=0.81, CI (0.60, 0.92), $p<0.0001$.

5 DISCUSSION

The average speeds at baseline and follow-up are in agreement with measurements reported in (Kennedy

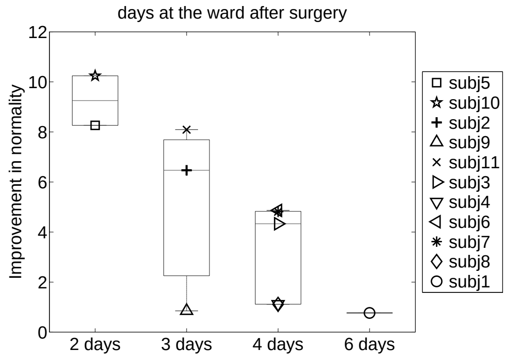

Figure 12: Improvement in normality compared to days spent at ward after surgery. Improvement in normality is the difference between normality values at baseline and at follow-up. Although the distributions are not statistically different, variables are well correlated, Spearman's rank correlation coefficient r=-0.75, p=0.0081.

et al., 2005), 0.46 m/s less than 16 days after hip replacement surgery and 1.17 m/s more than 20 days after surgery. Average gait speed of approximately 1 m/s three months after surgery were also reported in (Aminian et al., 1999). According to (Macnicol et al., 1980) the greatest improvements in gait speed are observed within the first three months postop. The follow-up measurement can, therefore, be considered representative of patient's improvement in gait speed. In addition, (Palombaro et al., 2006) determined that changes in speed superior to 0.10 m/s are clinically meaningful after hip fracture treatment. The changes in speed observed from baseline to follow-up, 0.60 ± 0.29, are therefore also clinically meaningful.

Measures of gait normality correlate well with both gait speed, Figure 8 and step length, Figure 9. Given that speed and step length are measures related to patient recovery, there is a good chance the normality index is also a good indicator of recovery. Unfortunately, no other quantitative gait parameters were available in the data set to demonstrate that the normality index correlates to recovery when the data is corrected for speed. However, in Part I of this study symmetry and normality measures are shown to correlate to joint-angle curves normalized to stride time, not containing any velocity information. The normality index is also normalized to stride time and as such is independent of walking cadence. It is expected that the normality index would differentiate between normal and abnormal patterns at the same speed. Further investigations are needed to support this assumption.

Another factor supporting the usefulness of the normality index is its correlation with the type of walking aid used during the test, Figure 7. The test-retest reliability and discriminatory power of the index were also satisfactory. Overall, the proposed index can possibly be developed into a reliable and clinically relevant measure of gait normality.

Another interesting result was the correlation between improvement of normality and number of days spent at the ward, Figure 12. Whereas there was no correlation between improvement in normality and number of days between baseline and follow-up. This possibly suggests that the rate of recovery at the ward is indicative of the total rate of recovery, which is little affected by the recovery time at home. This assumption should be further investigated.

Normality results and the answers to the EQ-5D™ questionnaire showed some positive trends. Greater discomfort and difficulties in performing usual activities seem to be accompanied with worse normality, Figure 10. Besides the self-assessment questionnaire, the use of walking aids was also considered an indication of how well the patient's health status was, i.e. patients who did not need any walking aid were, on average, in better condition than those who used one crutch. Another indicator of recovery was the number of days the patient spent at ward, assuming that patients who recovered better or more quickly were discharged sooner. The normality index seems to be in agreement with all the above mentioned qualitative health status assessments.

Symmetry results are difficult to judge due to the variety of walking aids used. The large variety of symmetry at follow-up, Figure 4, was mostly influenced by the patients using one crutch only. This could be explained by the fact that some patients were more dependent on the crutch and consequently leaned more to one side. Whereas some patients barely used the crutch for support.

Due to their recent surgery, patients were very uncomfortable during the baseline measurements. It was important to keep the data collection as simple and quick as possible. No more than five minutes had to be spared by the patient to complete the entire procedure, and they were all willing to participate in the study. Briefness is also important for the staff responsible for the procedure so that the addition of GA is not an extra burden. The placement of the sensors was also quick and easy. However, in the future, the waist sensor should be placed on the lower back so as not to be affected by subjects' different shapes and sizes.

Another issue with the present study is that the number of participants was very small. Any statistical inference on the results is greatly affected by the sample size. However, results are promising and suggest that a larger study will likely produce positive results.

At the ward where the data was collected, gait analysis is not normally used, and most records are based on rough qualitative descriptions. This lack of quantitative measures makes the assessment of patient improvement a difficult and very subjective task. The introduction of a simple 10-meter walk test can already provide quantitative measures of speed and stride length. The addition of a wearable GA system, however, can quickly increase the amount of quantitative data to include more complex measures of symmetry and normality.

6 CONCLUSIONS

The present study investigated the viability of using a wearable gait analysis (GA) system to assess patients in a real clinical environment. The proposed system served as a tool to facilitate the extraction of certain gait characteristics, namely symmetry and normality. The system was easy to use and did not require more than five minutes to complete the entire test procedure. It was small, light weight, and did not interfere with the patient's movements. In addition, the information provided by the system correlated well with the level of recovery and health status of the patients in a very intuitive way. The proposed system, therefore, fulfills the practical requirements that are essential to the successful implementation of wearable GA systems as clinical tools.

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