Carilion Clinic Institutional Review Board

CONCLUSION FORM

Use this form to conclude your study with the Carilion IRB. Study conclusion means that all data analysis has been completed and no research activities are taking place. Please complete and sign this form and attach a summary of your findings.

Study Information

Complete Title of Study: Using Wireless Accelerometers to Quantify General Movements

Date of Original IRB Approval: 12-04-12

Carilion Principal Investigator: Dr. Andre A. Muelenaer, Jr, MD

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Study Coordinator:

Conclusion Information

1. Conclusion Effective Date: 12-16-2015

2. How many subjects were enrolled in your study? (For retrospective reviews, please state how many subjects were included in your study.) 14

3. Have there been any protocol deviations/violations since your last review?

   ☐ Yes X No

   If yes:

   - How many?
   - Have they all been previously reported to the IRB? ☐ Yes ☐ No
   - Please summarize any that have not been previously reported.

4. Have there been any local unanticipated problems or serious adverse events since your last review?

   ☐ Yes X No

   If yes:

   - How many?
   - Have they all been previously reported to the IRB? ☐ Yes ☐ No
   - Please summarize any that have not been previously reported.

5. Please attach a summary of the results of your study. Even if the results are not statistically significant, information about results should be provided if available. Final report - Research project of Benjamin Crzgun - MD/VTCSOM; Summary for MS-Mechanical Engineering OKmin Pyong - VT

Certification of Principal Investigator

Signature certifies that data analysis and research activities for the above-titled study are no longer taking place.

Signature of Principal Investigator

12/16/2015
Date

Using Accelerometers to Quantify General Movements for Early Identification of Cerebral Palsy

Cragun, Benjamin; Taylor, Ashley; Muelenaer, Andre; Wicks, Alfred

INTRODUCTION

Cerebral palsy represents a diverse group of non-progressive, neuromotor disorders that affect the developing infant brain (Rosenbaum 2006). Although the exact cause for cerebral palsy is often unknown, certain risk factors including perinatal hypoxia, asphyxiation, or maternal hemorrhage have been linked to development of infantile cerebral palsy (CP) (Krigger 2006, McIntyre 2012). Other risk factors include prematurity, low birth weight, intrauterine growth restriction, and prenatal infection (Crowther, 2013). The diagnosis of CP is often made when the infant fails to walk as other dysfunctions may be missed or thought normal (Durufle, 2014). Diagnosis can be made at ages as early as 3 months using General Movements assessments, leading to earlier intervention and improved outcomes (McIntyre, 2011). Cerebral palsy affects between 1 and 11.6 in 1000 children nationwide depending on prematurity and birth weight (Hirtz 2007, Himpens 2008). The prevalence has grown by 25% over the past twenty years due to new life-saving techniques for preterm infants (McIntyre 2012). Earlier intervention into an Enriched Environment has shown promising results due to neuroplasticity (Morgan 2013).

For almost thirty years, neurologists have been interested in the general movements (GMs) of infants because certain characteristics can indicate neurological development and dysfunction and allow for an earlier diagnosis of CP (Ferrari, 1990). General movements are spontaneous, complex movements that involve the head, trunk,

arms and legs and it is believed that they are caused by co-activation of antagonistic muscle groups (Hadders-Algra, 1993; Ferrari, 2011). GMs change over time from 'pre-term' to 'writhing' to 'fidgety' until purposeful movements take over. Fidgety movements are characteristic at 2-3 months post-term and are totally extinguished by 6 months. Normal fidgety movements consist of tiny, flowing, elegant movements occurring irregularly all over the body. In the presence of neurological dysfunction they lack fluidity, complexity, and variation. Abnormal general movements are caused by lack of supraspinal control (Hadders-Algra, 2003). The absence of normal fidgety movements at 2-3 months has been shown to be a strong predictor of neurological dysfunction – CP in particular (Prechtl, 1997). Definitely abnormal GMs at 'fidgety age' are associated with a high risk (approximately 70%) for the development of cerebral palsy, with the remaining 30% of children developing minor neurological dysfunction including mental retardation (Hadders-Algra, 1999). A study of at-risk 3-month-old infants using Precthl's method of assessing GMs showed a specificity and sensitivity of 96% and 95% respectively for predicting neurological outcome (Prechtl, 1997).

The assessment of the quality of GMs developed by Heinz Prechtl is based on a gestalt evaluation of the movement pattern focusing on three parameters: movement complexity, variation, and fluency. Infants at 2-3 months have complex movements involving the limbs, trunk and head that are multi-axial, small and varied in velocity and direction. These movements constitute a normal neurological progression and the characteristic of the GMs change on a predictable timetable. This assessment of GMs is typically accomplished by recording the infants' movements for analysis at a later time. Video recording permits off-line evaluation, allows the observer to focus and offers movement replay at normal and high speed. Video

recording also enables data collection in the absence of a trained observer. Unfortunately, these recordings can take 20-40 minutes and analysis may take up to 8 hours by a skilled observer, thus limiting utility to research studies (Prechtl, 1997). Despite promising results, primarily only three groups have conducted the research and in almost thirty has not been widely accepted into clinical practice (Adde, 2007). The qualitative nature of the assessment method is problematic for inexperienced observers, although a review of 15 studies showed an inter-observer reliability of up to 88% (Einspieler, 2004). Additionally, the training is expensive and is not widely available. Despite strong data to suggest that general movement assessment is superior to traditional neurological evaluation, the method continues to be used primarily in research and has not translated into clinical practice (Spittle, 2011).

Several groups have recognized the need for a clinical tool to identify infants at risk for developing CP and have begun developing methods for identifying General Movements. Several have attempted video-based analysis (Adde 2010, Berge 2008, Abmann 2007). Meinecke et al have identified 53 video-based motion parameters to describe fidgety movements, with five being most important: skewness of the velocity of the feet, cross-correlation of the acceleration between the left and right foot, periodicity in the velocity of the feet, the area in which the speed profiles of the feet are outside of the standard deviation of the moving average of the velocity profiles, and the area in which the speed profiles of the feet differ from the moving average of the velocity profiles (Meinecke 2006). Others have recognized the difficulty of widespread implementation of video-based assessments and have applied accelerometers to meet this task. Cramped synchronized movements have been identified in a NICU environment in preterm infants using wireless accelerometers (Patterson 2010, Graven 2012). Ohgi describes accelerometer data obtained from movements of infants with brain injuries as non-linear and

chaotic, but results were limited as only a single accelerometer was placed on one limb (Ohgi 2008). Finally Heinze et al have shown good results in a pilot study using various combinations of parameters based on Meinecke's study using a decision tree method (Heinze 2010). However, the research has not yet yielded a tool applicable to the clinical setting.

Despite the challenges of assessing GMs, it is believed that early identification and thus early rehabilitation and intervention is beneficial in assisting children with neuromotor problems to develop to their full potential and prevent secondary complications (Einspieler, 2005; Richards, 2013). The infant nervous system is described as plastic, with the ability to change and adapt (Prechtl, 1997; Morgan, 2013). A simple, cost effective method for screening large numbers of infants at risk for CP is desirable. In this pilot study we demonstrated that infant movements can be measured using accelerometers. Using the data obtained in this study, we have created a database from which further data analysis techniques can be extrapolated and tested. We plan to create a method for automatic analysis of General Movements for earlier identification of cerebral palsy. We hypothesized that accelerometers can be used to identify fidgety general movements with equal or improved sensitivity and specificity compared to Prechtl's general movement assessment.

METHODS

Agreement from Carilion Clinic Institutional Review Board regarding the entire measurement procedure was secured. The author was trained and certified to assess GMs by the General Movements Trust, which hosts classes on Prechtl's method. These classes taught the differentiation and classification of movements. The method is based on gestalt observation of

the infants' movements, which are recorded and analyzed looking for overall GMs. The program provided a certificate showing competency in the assessment of GMs.

For the purpose of creating an automatic assessment method, a data collection apparatus was created from a crib, which was reinforced with soft padded walls to ensure the subjects are not distracted by the movement in the room as well as protected from injury if they roll into the walls (Figure 1). Data from four accelerometers and an HD video camera were collected using LabView® software (National Instruments, Austin, TX). Data were archived for later analysis. The accelerometers were small (3mm x 5mm x 1mm), weighed 0.7g, and operated on 2.2-3.6V and were sampled at a rate of 200 Hz. The data acquisition system has had a DC isolator added to ensure utmost safety of the subjects. The infants had the accelerometer devices strapped to each ankle and wrist with soft fabric hook-and-loop fastener and they were allowed to move freely in an unencumbered, restful state for approximately 5 minutes. This amount of time was more than adequate to perceive GMs using Prechtl's method, and provided ample accelerometer data for analysis.

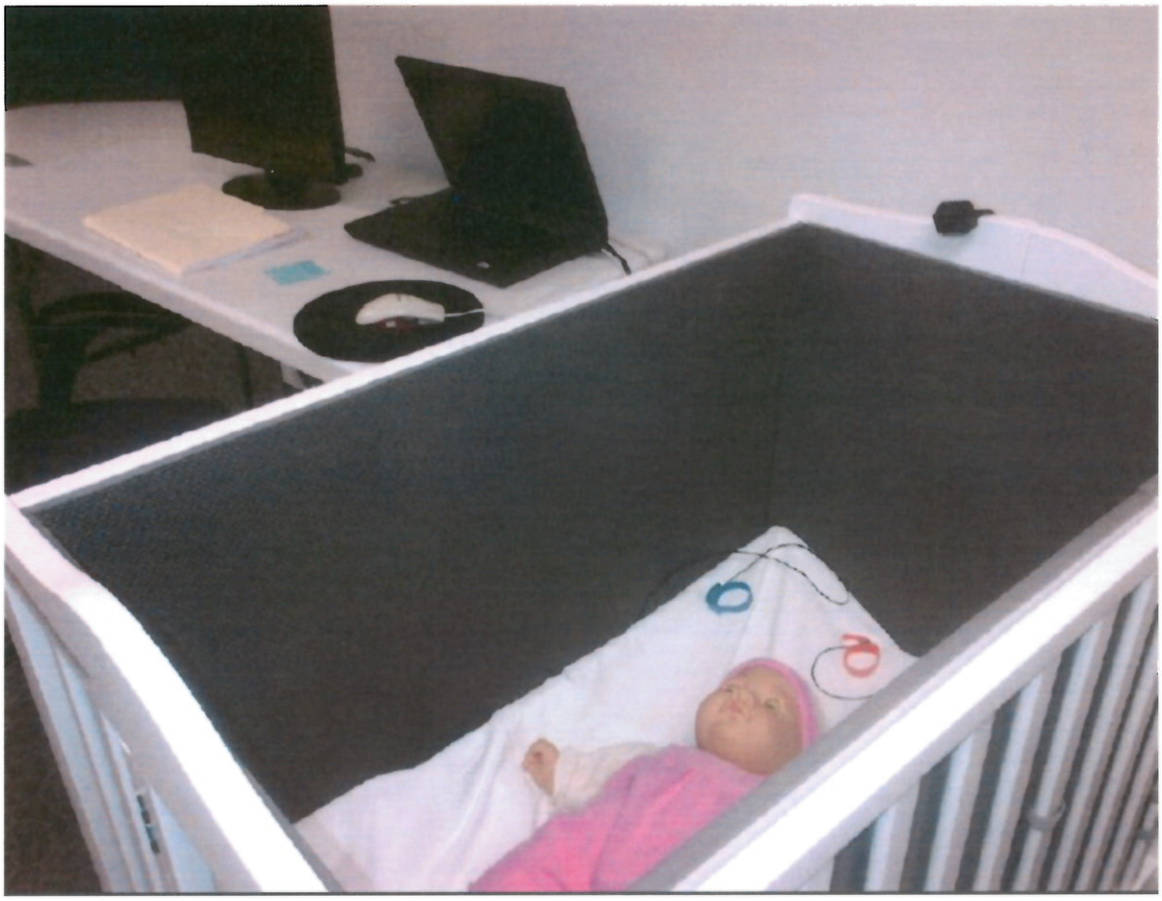

Figure 1: Modified crib with reinforced walls

For this pilot study we recruited 10 subjects between 2-4 months of age with normal neurologic exams from the general pediatrics clinic and informed consent was obtained from the parents. The parents were informed that participation was voluntary and they could stop measurement at any time. The fidgety movements have not been explored to provide any suitable simulation to adequately replicate the motion, thus actual infants were required. Three-month-old infants were necessary because the fidgety general movements peak at age 3 months and are extinguished completely by 6 months. We excluded any infants that were born earlier than 37 weeks or had a birth weight less than 2500 grams. We determined that 10 subjects would provide enough data to show the functionality of the design and allow for development of

data processing protocols. We performed the traditional general movements assessment by recording the infants in an environment protected from stimulation while simultaneously recording the infants' accelerometer data. We used four 3-axis low-g micromachined accelerometers to record the translation motion in all axes in the wrists and ankles of the patients (Figure 2). The general movements were recorded by both video camera and accelerometers for a total of five minutes in supine position and a calm state (Figure 3). The video analysis was completed by one certified to assess General Movements by the General Movement Foundation.

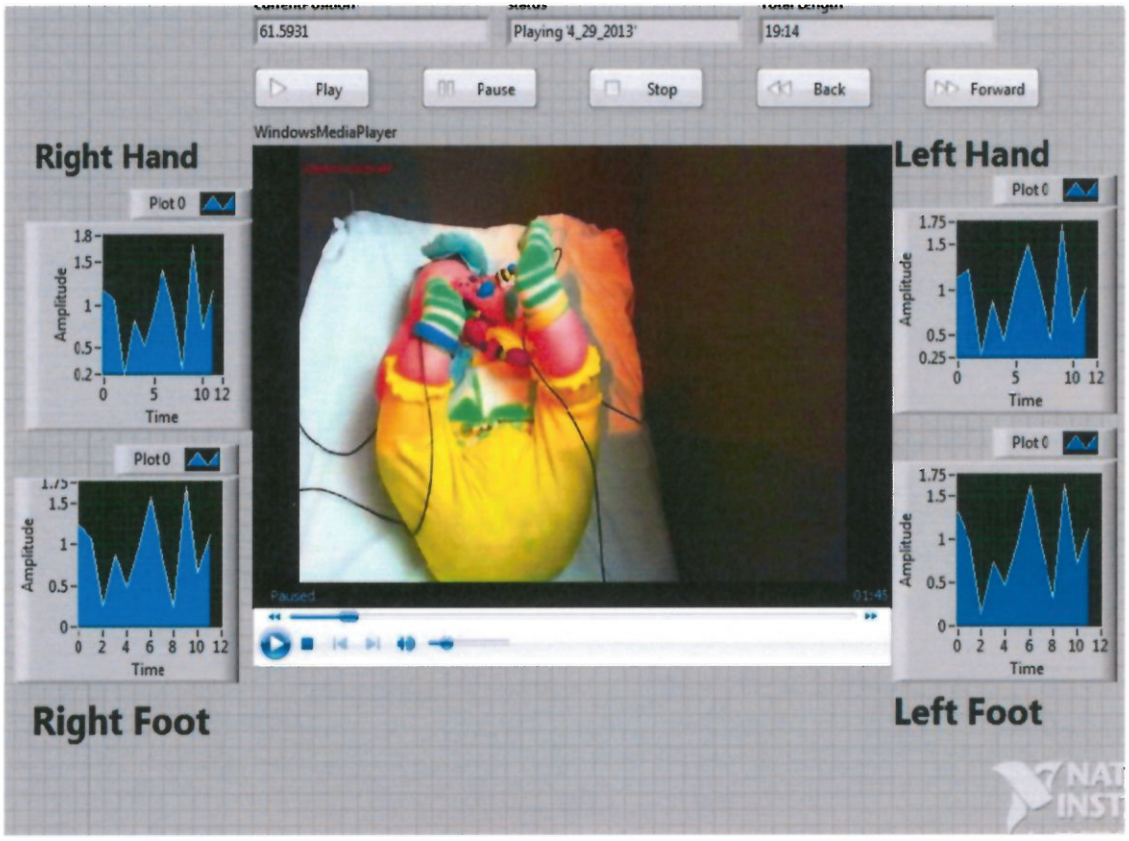

Figure 2: Data collection software showing data points for all limbs

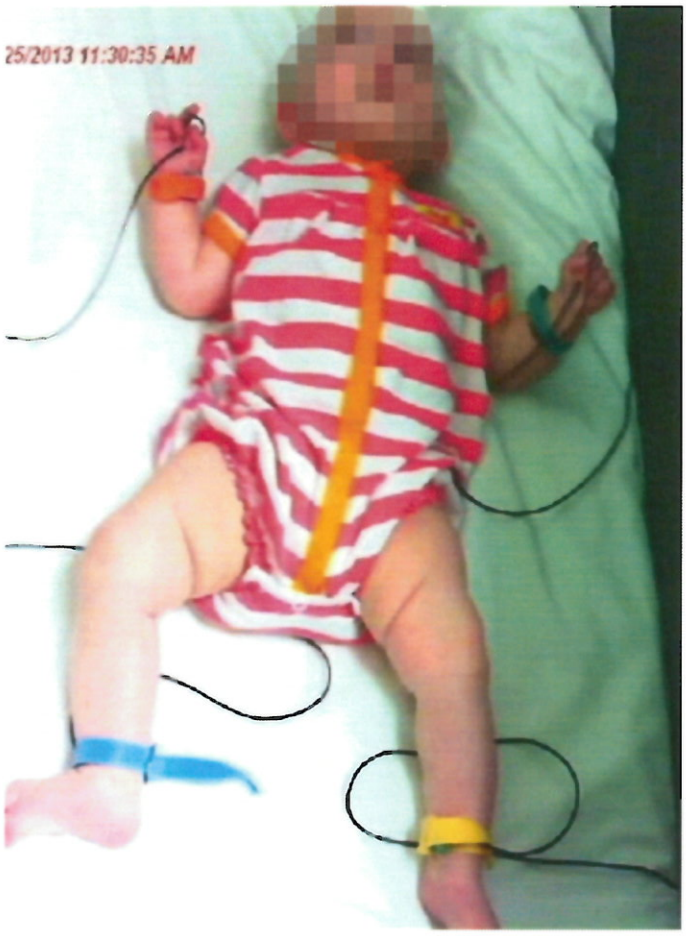

Figure 3: View from HD camera at foot of bed, the accelerometers are attached to limbs and are clearly visible

The accelerometers provide a complete description of the movement of each of these limbs. The video and the accelerometer data were identically time stamped to facilitate correlation and analysis. A GMA-trained individual identified windows of time in the video in which the infants displayed fidgety movements in individual limbs. This provided a binary label for each movement, either fidgety present or fidgety absent. The labels were then compared to the accelerometer data.

RESULTS

We recruited 12 healthy infants with an average corrected gestational age of 13.9 weeks (standard deviation +/- 3.5 weeks) (5 male, 7 female) from the general pediatrics clinic. One subject was not included due to equipment failure, and two others had one channel from one limb not register. While these patients cannot be included in the cross correlation between limbs, the fidgety movement data is still present in the other 3 limbs and thus were included. However, there are a total of 9 subjects with complete movement data (Table 1).

Table 1: Subject age and description of data use

Subject #	Sampling Frequency (hz)	Age (weeks)	Special Notes
1	200	15	
2	200	16	
3		Computer Error	
4	200	8	
5	200	11	JST connection failed, channel 12
6	200	17	JST connection failed, channel 12
7	200	14	
8		11	
9		9.7	
10		19.6	
11		15.6	
12		16.4	

While blinded to the accelerometer data, the gestalt video analysis of these infants was performed per Prechtl's method and identified all infants in the normal range of fidgety movements. The video was further analyzed identifying individual limb movements that are characteristically fidgety while excluding movements that are large amplitude sweeping motions and the motionless times as well. These individual movements were classified with a binary scale as fidgety present or fidgety absent.

Each accelerometer provides three dimensional voltage data, which is converted to acceleration (m/s^2) data with data points in the X, Y, and Z axes (Figure 4). A magnitude of acceleration (m/s^2) is extracted from these data points using the formula $M = \sqrt{x^2 + y^2 + z^2}$ and plotted against time (Figure 5).

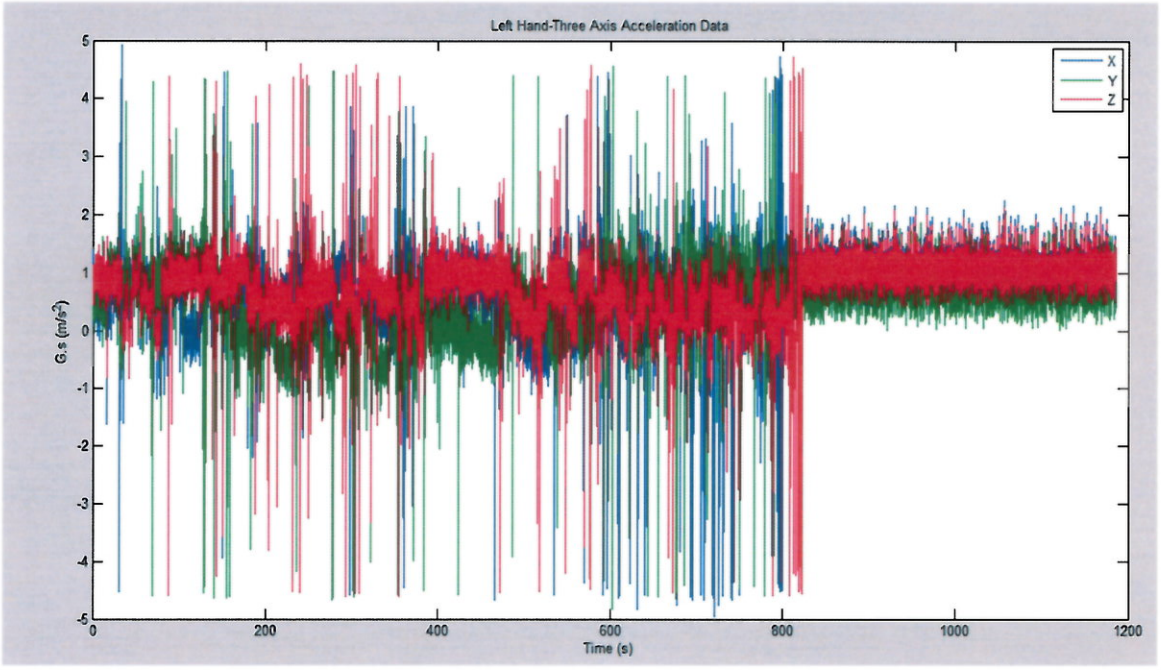

Figure 4: accelerometer data from one limb. X= time (s), Y= acceleration given in gravity

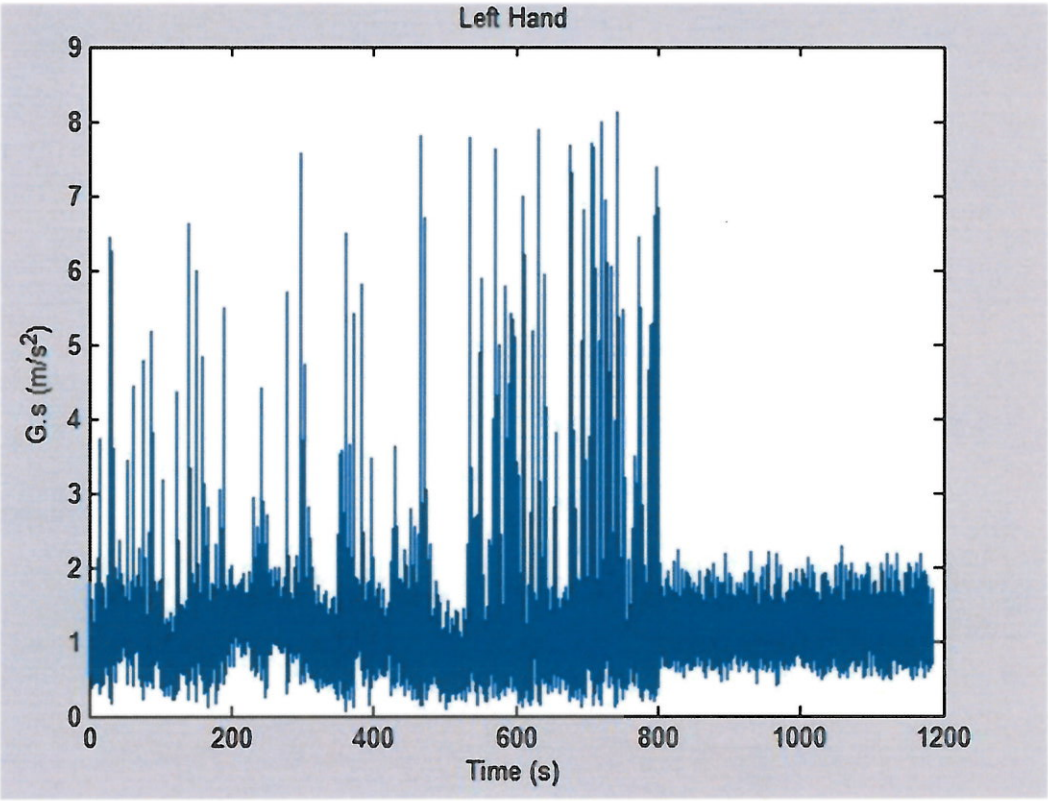

Figure 5: Magnitude of acceleration (m/s^2) from one limb, shown against time (s)

Comparison of the video to the acceleration data clearly shows spikes with large movements, a baseline close to 1 G, and other movements of low amplitude acceleration just above the baseline (figure 6). We identified the fidgety movements, which correlate most strongly with the movements just above the baseline (Figure 7). The data will likely need to be integrated to obtain velocity as other studies have identified acceleration and velocity as important parameters in the recognition of GMs (Meinecke 2006, Graven 2012, Patterson 2010).

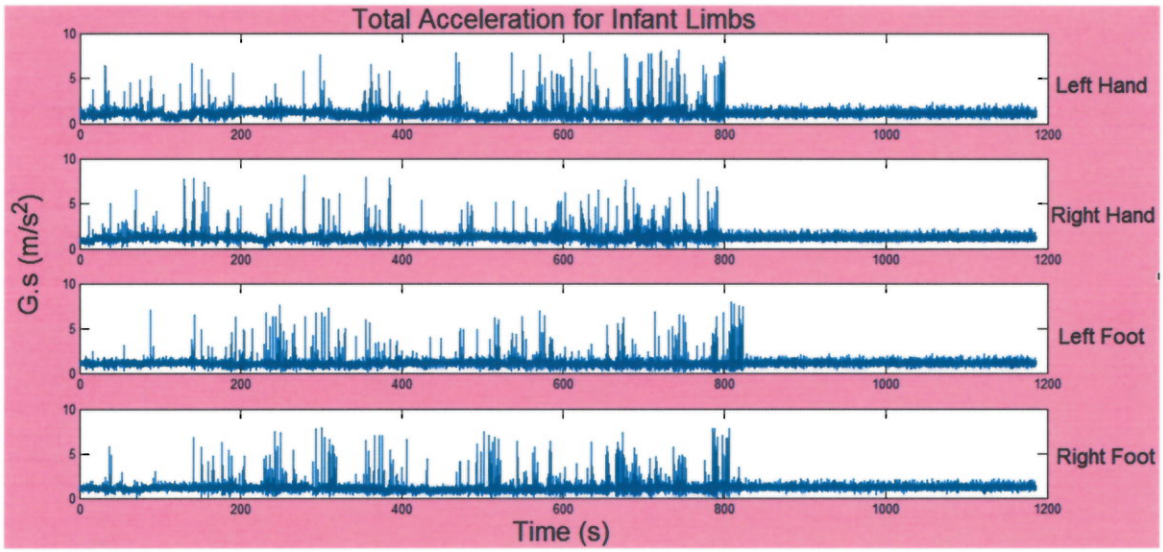

Figure 6: Magnitude of acceleration (m/s^2) for all 4 limbs plotted against time (s).

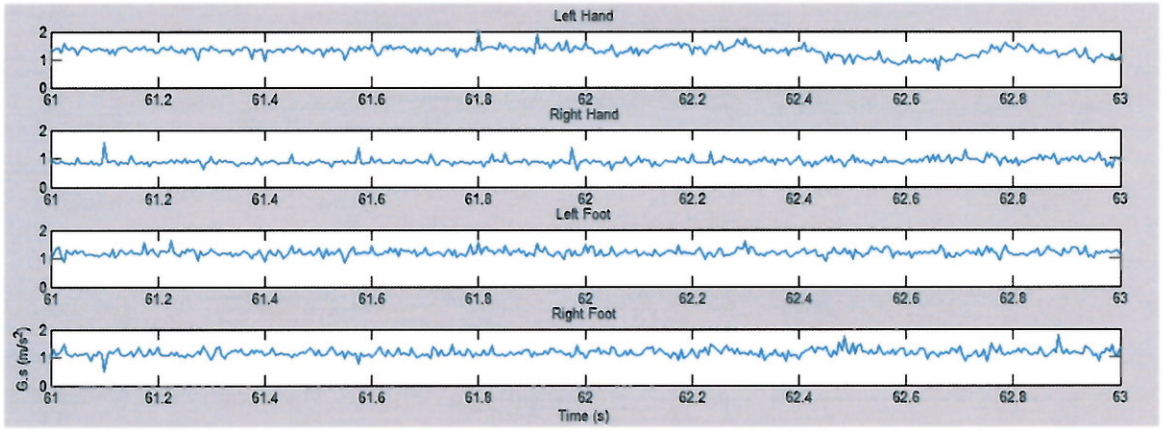

Figure 7: Magnitude of acceleration for a 2 second segment. The left hand (topmost graph) was identified as fidgety during this segment while the rest of the limbs remained motionless.

DISCUSSION

The healthy subjects provided a basis on which to test the normal parameters of this device and software. The accelerometer data obtained and compared to the video analysis

showed very small amplitude motion, which describes the fidgety movements. We factor out the large amplitude movements and focus on the small, fidgety movements that appear just above the baseline. This shows that fidgety movements are measured using our device. We have successfully created a database that will be useful in developing methods for identifying fidgety movements.

This study has shown that fidgety movements can be recorded using simple accelerometers, however the hypothesis of the study remains unanswered for the time being. The protocol and data processing algorithm generated from the data recorded by the accelerometers remain to be tested in the future. This project simply demonstrates that accelerometers can be safely placed on children and used to collect movement data. It remains to be seen whether an effective clinical tool that reliably identifies general movements will be developed.

Although the data from this study are stated as above, there are a number of limitations to the results. This was meant to be a pilot study and as such the sample size was small. This will limit the generalizability of the results and limit the accuracy of the parameters used to recognize normal movements. As the database continues to grow, the results will become more generalizable. Another limitation is that we tested the device only on healthy subjects. Having identified certain motions as fidgety, the non-fidgety motions can be compared to the motionless and large amplitude motions. In this manner, the data provides an internal control. Future research must be conducted with at-risk infants who are more likely to have absent fidgety movements. We hope to identify characteristic differences between healthy and affected infants. The general movement assessment based on the gestalt observation of the infant's movements, but our devices will only receive input from the wrists and ankles. Movements of the trunk, neck,

head, and fingers will not be visible to our sensors and limit the effectiveness of our device. Additionally, we are simplifying three-dimensional movement data into a single point described as magnitude of acceleration. The data lost in this process may perhaps have an application in the development of data processing techniques, but this remains to be shown. More research must be done to delineate the uses of the device and the accuracy in recognizing the presence or absence of the fidgety general movements before generalizations can be made about the prediction of cerebral palsy. Lastly, in the event that we are successful in showing that our device can in fact identify fidgety movements, it remains to be seen if it will actually overcome the issues that have prevented the generalized clinical use of Prechtl's GM assessment.

In the future, these data will be analyzed with machine learning techniques and a hidden Markov model, which will provide a set of coefficients that express consistent properties of the data between subjects. A hidden Markov model is a complex statistical method, which allows us to identify parameters upon which to analyze the patterns of movement. Further extrapolation of the data may include Fourier transforms to look for patterns in the frequencies of the fidgety motions. Graven et al did a similar study with cramped synchronized general movements on premature infants in a NICU setting. They were able to identify GMs using several machine learning techniques with varying sensitivities and specificities. They used support vector machines, decision trees, and dynamic Bayesian networks observing the output from random forests (Graven 2012). We plan to compare the results from these as and others to identify the method that most accurately recognizes fidgety movements. The further analysis using a Fourier transform for power analysis, integration of the accelerometer data to determine movement velocity and position, plotting into a hidden Markov model, and application of machine learning techniques will be completed over the next two years as part of a graduate project.

We hope that the database created with these subjects will help identify unique data analysis protocols for better recognizing fidgety movements and therefore identification of cerebral palsy. The method described has the potential to be more sensitive than Prechtl's method because small movements may be recognized by the accelerometers while missed by the naked eye.

The implications of these findings are far reaching. We will be able to overcome the limitations of Prechtl's assessment method to provide clinicians with a clinical tool for assessing risk of developing CP with very little training. In addition, an automated device would remove the subjectivity of inexperienced observers and allow for widespread adoption of a screening test for at risk infants. Earlier identification of those at risk for developing CP would allow for earlier enrollment in interventional therapy. Therapy may be able to preserve some amounts of function due to the plasticity of the infant nervous system.

The device clearly shows that infantile movements can be measured using accelerometers. This opens the door for many exciting applications of this device. Neonatal abstinence scores have always been subjective and may change depending on the nursing staff, the state of the infant, or the ambient noise of the NICU. The accelerometers could be applied to normal motor development to help identify children who are falling behind on coordination and other milestones.

CONCLUSIONS

Prechtl's method for identifying general movements in infants is subjective and it is costly to train and certify caretakers to complete accurate assessments. We have shown that movements can be accurately measured with accelerometers at 3-months of age. We have

created a database of infant movements and have taken the first step for creating an analysis method that will identify fidgety movements on a background of larger movements and motionlessness. Further research and development of this device will be conducted, and eventually we will be able to test our hypothesis that this device may be used identify infants at-risk for identifying cerebral palsy at an earlier age.

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Summary- Part II: MS- Mechanical Engineering. Thesis- Okmin Pyong, 7 Dec 2015

Cerebral Palsy(CP) is a syndrome due to damage to the brain before, during and after the birth. CP can be caused by: prenatal disinfection, radiation treatment, drug addiction, placenta disorder, umbilical cord disorder, respiratory obstruction and brain tumor etc. The most common symptoms of CP is difficulty in body movement control and muscle coordination. Although the brain damage itself does not spread or worsen after the brain damage occurs, the related symptoms affect the development of the infant continuously. Therefore, it is important to detect CP in the early stages. Also, early intervention can help the infant with CP to reduce the impact of permanent impairments [1]. According to Celebralpalsy.org, the current average diagnostic period for CP is 18 months [2]. However, CP directly impacts the development of correlated movement as the infant development. By detecting the lack of the correlated movement in the infant, the diagnostic period may be reduced to 6 to 8 months from 18 months. Therefore, a signal processing technique to detect this correlated motion can be useful to assist this diagnoses.

One of significant correlated motions in infant development is bilateral coordinated movement (BCM). BCM is defined as "Bilateral coordination refers to the ability to coordinate both sides of the body at the same time in a controlled and organized manner" [3] According to Dr. Esther Thelen, the coordinated movement shown in the infant shifts from the birth till 20 weeks by observing the alternating kicking movement patterns. [4] In addition, BCM shows the multiple interactions between the hemispheres of the brain, low quality of the BCM after 20 weeks was suggested as early symptoms of CP. To verify the assumption, the analytical method to measure the BCM between limbs was required.

Because the signal from the infant movement is non-stationary, which means that characteristic of the signal changes with respect to time, a time-frequency method is suggested. The signals are acquired through MEMS accelerometer and NI DAQ system with LabView software. Also, to evaluate the correlated relationship of the two limbs' movement, coherence which describes relevance between signals in the frequency domain was developed in Matlab. To obtain the adequate coherence in time-frequency domain, multiple averaging methods were applied. Artificially generated BCM by researcher was evaluated to verify this analysis. The result is shown as high coherence (> 0.7) as expected. Finally, data from a two month old infant was analyzed to verify the assumption in which, an infant hardly shows the high BCM before 20 wks. The result shows a low quality of correlated movement (< 0.2).

The analytical tool to quantify BCM was designed to diagnose CP earlier than the standard 18 months' time frame. In the future, research on multiple subjects will be needed to standardize the coherence numerically between the normal and abnormal patterns in BCM development. Also there is an expectation to apply this method as a self-observation tool. For example, other motor disturbance diseases like Parkinson's diseases and multiple sclerosis have a patterns of changing BCM patterns according to the severity stages of the diseases. Finally, the signal processing technique can be implemented to the wearable devices already embedded with accelerometers and gyroscope.