2011-01-01

Assessment And Evaluation Of Peripheral Neuropathy From Diabetic Mellitus Using Systems Analysis Approach

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ASSESSMENT AND EVALUATION OF PERIPHERAL NEUROPATHY FROM DIABETIC MELLITUS USING SYSTEMS ANALYSIS APPROACH

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by

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THESIS

Presented to the Faculty of the Graduate School of

The University of Texas at El Paso

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF SCIENCE

Department of Electrical and Computer Engineering

THE UNIVERSITY OF TEXAS AT EL PASO

December 2011

Acknowledgements

Without the guidance of my committee members, the unconditional help of my friends and family, I would have never been able to accomplish this master thesis.

First of all I need to thank the chair of my committee Dr. Thompson Sarkodie-Gyan, for inspiring me and guiding me through the process of elaboration of this thesis work. Thank you for challenging me and awakening the giant from inside me. Thank you also for your friendship.

Dr. Huiying Yu, thank you for your patience, time, and most of all friendship. You taught me and guided me through every single phase of this thesis, from the planning to execution and the results.

Dr. Starks, I met you as a freshman, you have seen my progress as a student and a person. Thank you so much for your support.

Dr. Vargas, thank you for your advice and support.

Dr. Amr Abdelgawad, thank you for your support and time. Thank you for making it possible to have access to diabetic patients. We do know you have a busy schedule, but you were always there to help.

Thanks ever so much to all my friends, who have become more a family: Pablo Rangel, Julio Torres, Ryan Price, Murad Alaqtash, Melaku Bogale, Luis Sagarnaga, and Deliala Buenrostro.

To my family, especially my sister Laura Espino.

And Special thanks to my beautiful and beloved wife Vanesa Garcia, who encourages me and supports me unconditionally.

Abstract

Currently in America 1 out of every 10 residents suffers from diabetes, and this tendency is likely to grow up to "1 of every 3" by the year [6]. Diabetes exhibits several complications. In 2005, the lead cause of stroke and heart disease was diabetes, 68% of the cases [1]. In 2008, 44% of kidney failure was associated with diabetes [1]. 60 to 70 % of cases of diabetes have a mild to severe nervous system damage [1]. Diabetic patients who have developed peripheral neuropathy tend to also develop foot ulceration. In an advanced stage a foot ulcer can lead to limb amputation. More than 60% of non-traumatic lower-limb amputations occur in people with diabetes [1].

There is a great need to develop efficient and reliable measurements for foot ulceration. By the use of novel sensory techniques [19], this study has provided an efficient and reliable measurement for foot ulceration that will lead to sensory feedback for brain plasticity. This study used an instrumental treadmill from Bertech ®, a Delsys® surface Electromyograph, an insole system from Teck-scan®, to monitor the conditions of the diabetic foot by measuring the Foot Pressure, electrical activities of the muscles (EMG), and the ground reaction forces (GRF). The ultimate goal of the study was to provide accurate and reliable information to medical doctors for an early diagnosis to improve the quality of life of the diabetic patients.

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Chapter1: Introduction

Currently 1 out of 10 Americans has type 2 diabetes [1]. It has been predicted that by 2050 one out of every three Americans will suffer diabetes if there is not a dramatic life style change. In 2010, U.S. residents within ages of 65 and older (26.9% of the entire population in the U.S.) had diabetes [1]. In the same year 215 people aged 20 years old or younger, were diagnosed with type 1 or type 2 diabetes. Diabetes is the number one cause of kidney failure, blindness, heart disease, stroke, and non-traumatic lower limb amputation [1]. Table 1.1 is an extraction from the Centers for Disease Control and Prevention, website from the 2010 statistics.

Table 1.1: Centers for Disease Control and Prevention 2010 Statistics

Group	Number or percentage who have diabetes
Age ≥20 years	25.6 million or 11.3% of all people in this age group
Age ≥65 years	10.9 million or 26.9% of all people in this age group
Men	13.0 million or 11.8% of all men aged 20 years or older
Women	12.6 million or 10.8% of all women aged 20 years or older
Non-Hispanic whites	15.7 million or 10.2% of all non-Hispanic whites aged 20 years or older
Non-Hispanic blacks	4.9 million or 18.7% of all non-Hispanic blacks aged 20 years or older

http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

These figures speak for themselves and each year there is 1.9 million new cases of diabetes. 60-70% of the people with diabetes have a mild to severe form of nerve damaging peripheral neuropathy (PN). This type of nerve damage is commonly known as “Diabetic Foot” [15].

Diabetic foot is made up of various types of pathologies ranging from diabetic neuropathy, peripheral vascular disease, foot ulceration, to potential limb amputation [1]. A

person that suffers diabetes has a 60-70% risk of developing a foot ulcer. More than 60% of non-traumatic lower-limb amputations occur in people with diabetes [1].

Amputation is the final stage of diabetic foot, which is associated with significant morbidity and mortality, besides having immense social, psychological and financial consequences. Valuing the diabetic foot represents a very important element of the annual diabetic review. It is indeed crucial to identify the foot at risk at the earliest stage possible, so as to target preventive and therapeutic measures. This approach not only helps in reducing the significant morbidity and mortality associated with diabetic foot disease, but also represents major health care-associated economic benefits [1].

The main goal of this study is to provide a reliable and efficient method for monitoring the condition of the diabetic foot. This investigation monitored dynamic data of the diabetic patients, such as: the muscular activity in the lower limbs, GRF in 3 axes during a dynamic test, and irregular high pressure in the foot sole.

This investigation focused on finding abnormal behavior including inadequate muscle activation during the gait cycle, irregularities in the GRF, and extreme high pressures in the foot-sole, since these are the exhibited characteristics of diabetic patients with peripheral nerve damage. This study also investigated into the differences between walking over ground and on an instrumented treadmill (from Bertec ® inc.). By using the integration of multiple sensors, the information acquired from the one system is able to validate that of the other and vice versa. This is by virtue of the synchronization of the system at the acquisition period. It is indeed crucial to identify the foot at risk earlier, so as to target preventive and therapeutic measures at the earliest opportunity.

Chapter 2: Motivation, Why do this?

According to the American Diabetic Association, 25.8 million adults and children (or 7.8% of the population) have a form of diabetes in 2010 [1,15]. In the same year 18.8 million people were diagnosed with diabetes, and 79 million people were diagnosed as a pre-diabetic. From the American Diabetic Association statistics 60 to 70% of diabetic patients tend to develop peripheral neuropathy (PN) which results in nerve damage. 50% of diabetic patients who have developed the PN are asymptomatic, putting them at risk of injury [15]. The combination of nerve damaging and injury may result in foot ulceration and in severe cases to lower limb amputation. 60 % or more of the non traumatic amputation in the lower extremities occurs in people with diabetes [1]. Amputation is the endpoint of diabetic foot disease, which is associated with significant morbidity and mortality, besides having immense social, psychological and financial consequences.

The tremendous shock of losing a limb or being at the constant tread of losing it, impacts strongly into the patients and their families. This fear causes emotional disorder as anxiety and paranoia. The impact of losing a limb can immerse the diabetic patient into a depression, lowering his/her immune system. As a result of this, their physical recovering will be longer. Economically, after an amputation there is the additional need for special adaptation to their homes and vehicles, aside from the enormous medical fees. These special needs can be extremely expensive and some diabetic patients will not be able to afford them. The lack of these new and special needs will limit their daily lives ultimately reducing their quality of life. Each year the number of diabetic cases increases. This creates a great need, to develop efficient and reliable methods to measure foot ulceration.

Chapter 3: Specific Aim and Hypothesis

Our current society faces an epidemic of diabetes and its many consequences. To improve the life quality of our citizens, it is necessary to provide reliable and accurate dates with medical doctor, to provide the best possible decision for their diagnosis. Techniques used on daily bases by physicians to detect the possible areas where the diabetic patient can develop an ulcer, are semi-quantitative. We refer to the SW-monofilament and sensation vibration test as semi-quantitative since they relay on the experience and skills of those who apply the test as well as in the feedback of the patient. This thesis proposes to produce efficient and reliable measurement of foot ulceration that may be used to provide the required sensory feedback for the brain plasticity. This technique integrates the different signals from the multiple sensors. By enabling the data collection of the different systems simultaneously, the acquired data of one system can validate the data of others and vice versa.

Therefore, the main goals of this research project are:

- To monitor the diabetic foot through the measurement of Foot Pressure, EMG, and GRF.
- To efficiently and reliably measure the pressure in foot sole to avoid foot amputation.
- To measure to enable a compensatory strategy based on sensor feedback.

The ultimate goal of this investigation is to provide valuable data to the physician. This will aid the physician to provide an early diagnosis of diabetic foot since this data contains quantitative information in comparison to the current devices and methods. This will help the diabetic community to improve their quality of life. This approach does not merely help in reducing the significant morbidity and mortality associated with diabetic foot disease, but also could have major health care-associated economic benefits.

Chapter 4: Background and Relevance

As diabetes progresses (Figure 2.1), the patients become exposed to higher glucose levels and this condition is then called Hyperglycemia. Hyperglycemia is one of the major complications of diabetes mellitus and can lead to an abnormal metabolic process which affects the Schwann cell (nerve cells which conduce electrical activity in neurons), nodes of Ranvier (joins of the Peripheral nerve system) [11], and microvessels damage (Peripheral vascular disease)[11]. The deterioration of the aforementioned cells can result in PN, Autonomic or Somatic. From the information provided by the Centers for Disease Control and Prevention in Chapter one, the autonomic neuropathy can attack all body systems such as cardiovascular system, visual system, renal system etc. One of the many systems affected in this case is the skin [15]. After the diabetic patient develops the PN autonomimic, the skin becomes dry and losses elasticity, that is, it becomes fragile, and as result the skin gets susceptible to injures. With this delicate skin condition the diabetic patient becomes susceptible to injuries [14,15]. The skin is fragile enough that even irregularities in their shoes can cause laceration. Any laceration can easily become infected and become a foot ulceration [14].

Somatic PN leads to a progressive loss of somatosensory sensitivity due to the nerve damage, proprioception and distal muscle function specially in lower limbs [11]. This loss of sensation can progress to a stage where the diabetic foot loses the protective sensation in the foot sole. Once the protective sensation is lost, the diabetic patient can get injured even without any knowledge of the laceration. Also, due to muscle dysfunction, their walking pattern is affected that leads to the development of the problem of the drop foot. These irregular locomotion increases their risk of getting injures. Any lacerations in the combination of somatic PN can quickly be infected if it not constantly monitored [3,4].

The degradation of the microvessels produces a reduced blood flow to the lower limbs producing ischemia or hypoxia [15]. Once the Ischemia is present, the feet of the patient get susceptible to injure easily. The combination of ischemia and any injury can lead rapidly to a foot ulcer. Due to the absence of sufficient blood in the wound, the healing process becomes slower, opening a window for infections. In the worse case, foot ulcers in the patients can lose the limb. Current statistics show than 80% of ulceration cases in lower-limbs end in the amputation of it [1].

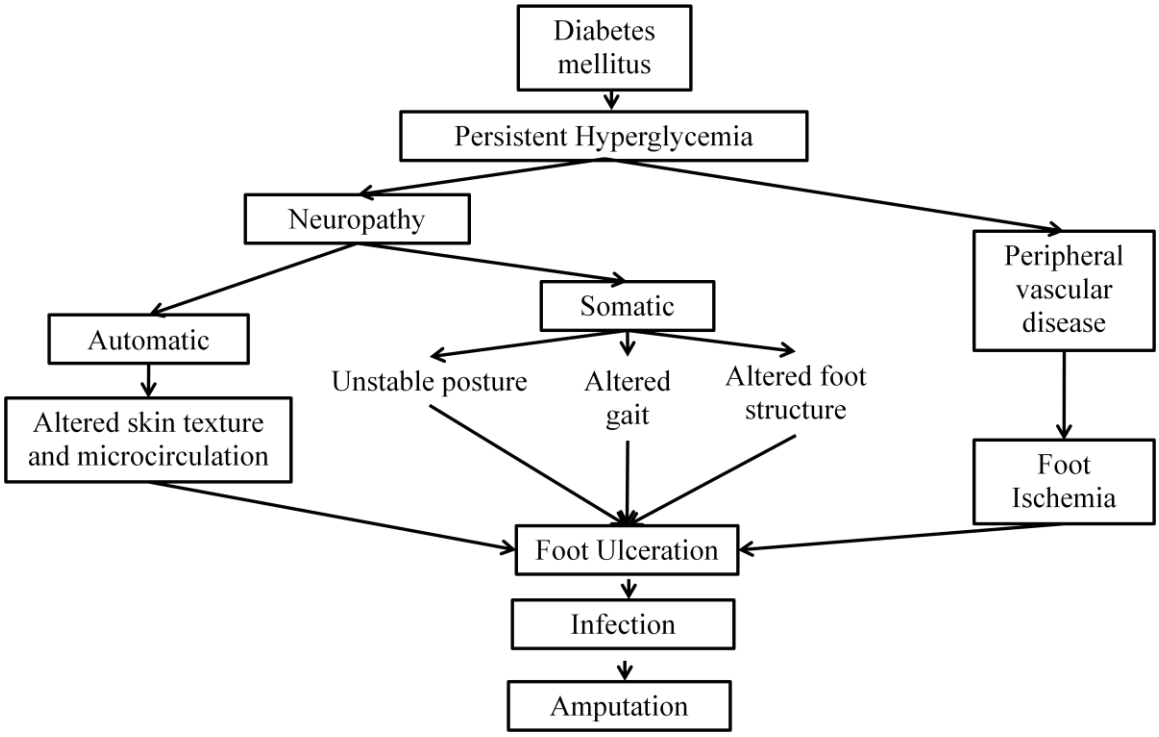


Figure 4.1: Diabetic Foot development

Chapter 5: State of the Art

5.1 Foot Pressure in the Foot Sole

In the last decade, several scientists and medical researchers have conducted investigations and developed techniques to quantify and diagnose the potential risk of diabetic foot. Among these techniques is also the measurement of the distribution of pressure in the foot plantar dynamically and statically. Once a patient develops PN there arises the gradual loss of plantar sensation causing motor alterations and leading to abnormal high pressures in the foot plantar [4]. From the research conducted by Antonella Caselli and colleagues, it was found that both the rear-foot and fore-foot pressures are increased in diabetic neuropathic foot [4]. Although these findings confirmed their hypothesis, some other relevant details were missing such as the EMG. Hence, this study monitored the GRF in three planes, but also we cross validate our GRF data with the F-scan data and EMG. This study provides the perspective of three reliable systems monitored the same problem.

5.2 Ground Reaction Force GRF

As consequence of the locomotion alteration due to the progress of the peripheral neuropathy, diabetic patients show mechanical difficulties during loading-off phase during the gait cycle [9]. A study conducted by Robert Van Deursen showed a significant small second peak characteristic of the off–loading phase in the vertical GRF [9]. This research took in consideration Deuresen's findings as well as the monitoring of the dynamic forces in the three planes.

5.3 EMG

A further complication related to the diabetic foot is an alteration of the motor controls in the lower extremities. Paula M.H. Akashi and colleagues found a delay on the activation of the lateral gastrocnemius (LG) and vastus lateralis (VL) during the gait cycle [4,10]. The EMG data and the vertical GRF were simultaneously collected. Due to the cases of progression and worsening of the PN, an alteration in the second peak of the vertical GRF was found that related to the delay in the EMG. The second peak of the vertical GRF becomes a function of the push-off phase [4,10]. This study bears some level of similarity to the one depicted in [4,10]. The distinguishing difference about the current study involves the implementation of other added strategies, the collection of the GRF in three planes (Mediolateral (FX), anterioposterior (FY), and vertical (FZ)), the 16 channel surface electromyography (sEMG) for monitoring the activities of eight muscles per limb. This strategy provides a robust and detailed data to the medical doctors to assist their diagnosis of diabetic foot.

5.4 SW monofilament, Biration Sensation (Tuning Forck and Biotesimeter)

To detect the possible areas of ulceration, clinicians use tools, the Semmes Weinstein (SW) monofilament Biothesiometer, and the Tuning Fork. There are many different types of SW monofilament measures. The most used are: 2.83, 3.61, 4.17, 4.6 5.07, and 6.1 (0.07, 0.4, 4.0,10, and 75 grams of force respectively) Clinical Usefulness [16,17]. Each one of them corresponds to a level of severity (normal, impediment to touch, impediment to protective sensation, lost of protective sensation, and untestable). SW monofilament tests (Figure 5.1) the patient's ability to sense a specific point of pressure in certain areas of the foot plantar such as the first, third, fifth metatarsal, toes, medial and lateral foot, and the heel. The patient is often asked of the sensation based on a pinch. This procedure is at least performed twice using the five monofilaments.

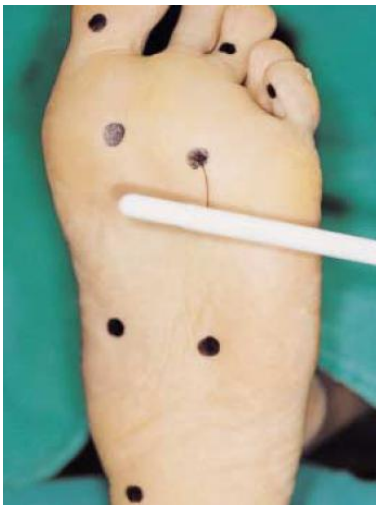
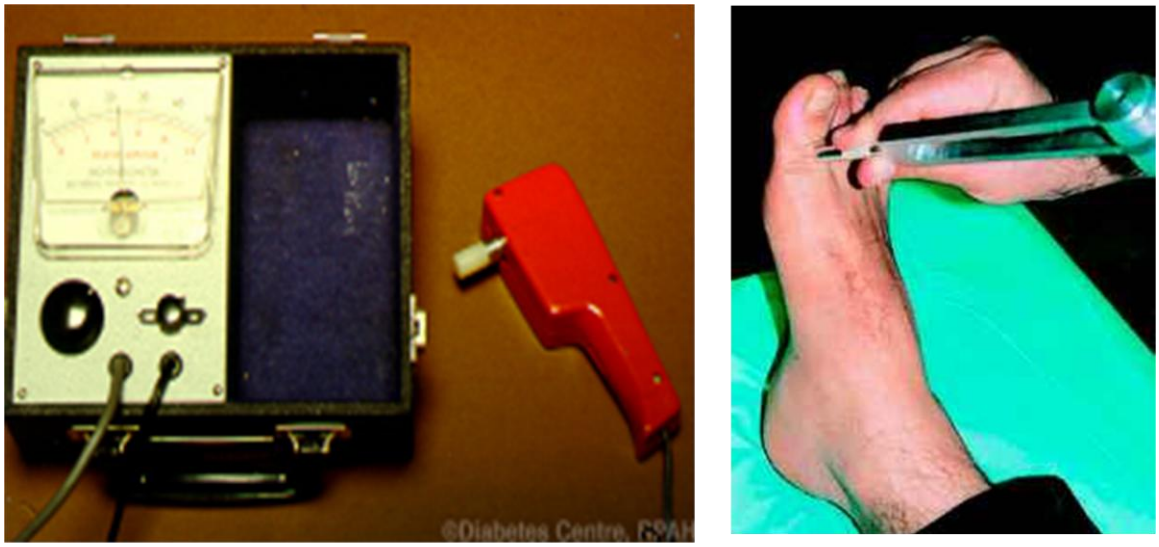


Figure 5.1: Monofilament and areas of testing.

The tuning fork (Figure 5.2b) provides a vibration sensation test. It vibrates at 128 Hz during the test and it is placed in a perpendicular position with respect to the test area [15]. The tested areas are: first, third, fifth metatarsal, toes, medial as well as lateral foot and the heel (same areas test with SW monofilament). The tested areas are randomly chosen and they are usually tested three times. There is a possible risk of ulceration if the patient fails two times.

The Biothesiometer (Figure 5.2a) provides an evaluation of the vibration perception threshold (VPT). This medical tool vibrates at 100 Hz and it measures in a linear scale of 0-50 Volts [24]. This device targets same areas as the SW monofilament and tuning fork. While the patient is being tested, it is held against each one on the areas of interest. If a patient could not detect a value above 25 V he/she is considered being at risk of foot ulcer [15].

However, these tests are still not a complete quantitative measure. They rely on constant calibration, verbal feedback from the subject and the experience of the clinician or therapists at performing and interpreting the results of the test.



(a) (b)

Figure 5.2: Biothesiometer (a) and Tuning Fork (b).

Chapter 6: Method

6.1 Experimental Design

To accomplish the aims of this research, three different systems were used along with the technique.

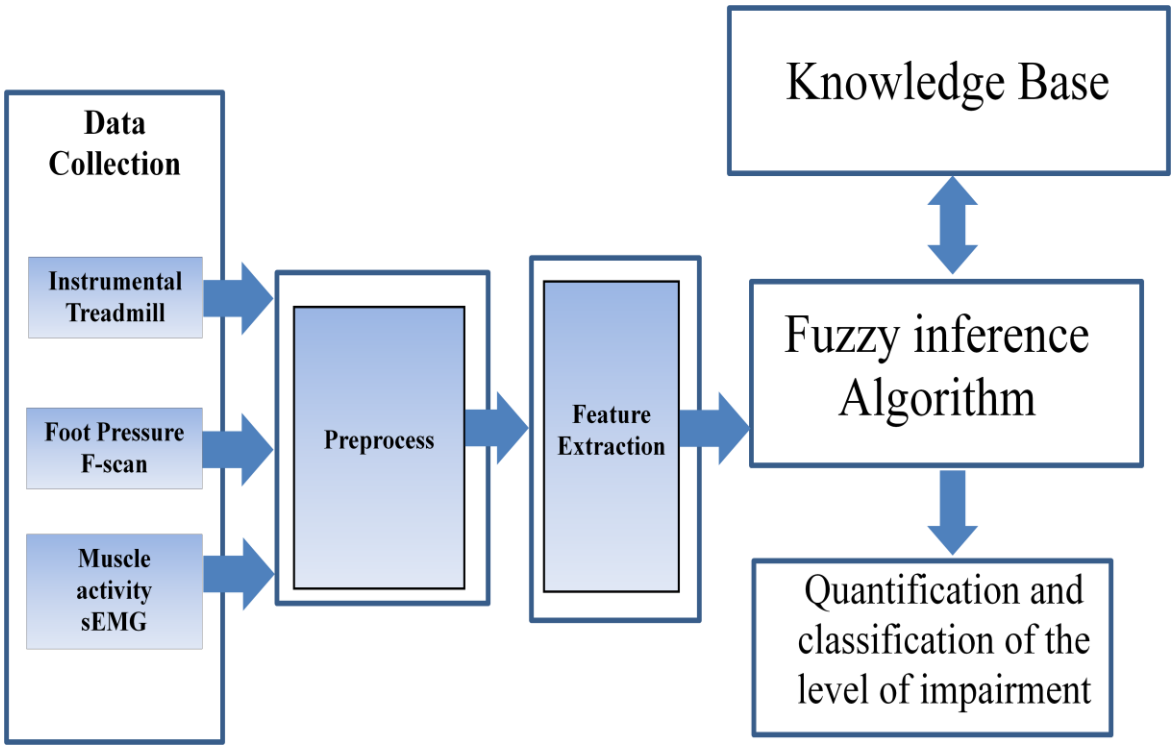


Figure 6.1: Sensor fusion driven computational intelligence scheme.

Figure 6.1 illustrates the three systems and their respective sensors which monitored different physiological aspects of all the participants. The muscular activity was monitored by using a Bagnoli™ Desktop EMG Systems from Delsys ® inc. This was a 16 channels surface Electromyogram. The EMG measured the electrical activities of the eight muscles in both the left and right limbs. These muscles are: soleus (Sol), tibialis anterior (TA), gastrocnemius lateralis (LG), vastus lateralis (VL), rectus femoris (RF), biceps femoris (BF), gluteus medius (Gmed), and erector spinae (ES). Muscular activity can provide useful information in the prevention of

diabetic foot. According to Paula M.H Akashi and her colleagues [2], diabetic neuropathy affects specifically the motor controls of the lower extremities during gait and static posture due to a gradual loss of somatosensory sensitivity, proprioception and distal muscle function. These irregularities were found as a delay in time of the lateral gastrocnemius and vastus lateralis [2]. For this research study eight muscles were monitored, since we consider this set of muscles can provide a more accurate and robust data.

The F-scan insole from Tekscan® was used to acquire the foot pressure distribution in the foot sole. Previous research work conducted by Antonella Caselli and colleagues have shown that high plantar pressure is a strong indicator of diabetic foot [2]. It can also be conceived that irregular high pressure peaks and the frequencies of their reoccurence in the static and dynamic measure can be used as another good indicator of diabetic foot [4,10]. The areas target by the F-scan will be the Big toe, Metatarsal 1, Metatarsal 2, and Heel. The selected areas were 4 by 4 cm. These areas are the same areas tested in SW-monofilament. The results of the SW-monofilament will be used to cross validate the out the F-scan.

When a Diabetes Mellitus (DM) patient develops PN a gradual loss of sensitivity occurs in the foot plant. Through the foot plant sensitivity the brain modulates the strike force of the feet on the ground. An alteration to the GRF could be used as an indicator that a DM patient is at risk of developing diabetic foot [9]. GRF can show if the subject is applying excessive amount of force which results in loss of plant sensation [9]. For this study a double belt instrumental treadmill from Bertec was used to capture the GRF data of each participant (healthy and diabetic patient) in three different planes: Fx (mediolateral), Fy (anterior posterior), and Fz (vertical).

6.2 Subjects

Seventeen healthy volunteers without diabetes and any motor impairment in the lower limbs participated in this study. Twelve of them were male within the ages of 24-36 years, while 6 of them were female between 25 and 38 years. This study also included a total of 11 volunteers with diabetes mellitus. Six of them were female within the age range of 41 and 67 years old, and five males between 43 and 67 years, respectively. These patients were recruited based on the approval of the UTEP Institutional Review Board (IRB). The diabetic patient (DP) group was gathered under the following criteria: at least three years of being diagnosed of Type 2 diabetes; No motor impairment in the lower extremities; No history of foot ulceration.

Before any data was collected, all the volunteers (Healthy and Diabetic), read carefully our inform consent form which also contains the IRB to conduct this type of investigation. The volunteers gladly signed it after they accepting all the terms and conditions.

Table 6.1: Anthropometric data of the Control group.

Female	Age (Yrs)	Height (cm)	Weight (Kg)	BMI(kg/m2)	**Male**	Age (Yrs)	Height (cm)	Weight (Kg)	BMI(kg/m2)
FH01	38	165	58.5	21.5	MH01	26	74	167	26.5
FH02	25	155	54.4	22.6	MH02	30	90.1	171	30.8
FH03	27	153	49.5	21.1	MH03	24	67	176	21.6
FH04	27	165	92.3	33.9	MH04	31	193	92.2	24.8
FH05	26	154	57	24	MH05	24	185	8.3	22.9
FH06	26	168	67.5	23.9	MH06	25	164	81.5	30.3
					MH07	24	178	77.5	24.5
					MH08	28	182	88.2	22.2
					MH09	25	184	77.6	22.9
					MH10	36	174	84.6	27.9

Table 6.2 : Anthropometric data of the type 2 diabetes group without motor impairment.

Female	Age (Yrs)	Height (cm)	Weight (Kg)	BMI (kg/m2)	Years of Bing Diagnosed	**Male**	Age (Yrs)	Height (cm)	Weight (Kg)	BMI (kg/m2)	Years of Bing Diagnosed
PF01	56	153	67.5	28.8	5	PM01	43	179	96.6	30.2	6
PF02	60	155	94.2	39.2	21	PM02	65	176	78.5	25.3	30
PF03	67	146	71.9	33.7	15	PM03	61	187	137	39	20
PF04	41	153	75.2	32.2	9	PM04	67	160	86	33.6	12
PF05	63	150	74.4	33.1	6	PM05	47	161	75.9	29	10
PF06	63	164	79.2	29.4	20						
PF07	40	153	79.4	33.9	6						
PF08	54	157	79.9	32.4	4						

6.3 Experimental Procedure

A detailed procedure was explained to every participant (DP and Healthy) prior to the performance of the procedure. Every participant wore running shorts. Preliminary anthropometric data was taken from each subject. After this, all three systems were attached onto the subject as described next.

6.4 Software Set Up

LabVIEW software of Texas Instruments was used to synchronize the simultaneous data collection and set the frequencies of acquisition. The Delsys Inc. ® surface EMG was set at 1000Hz [2, 8]; the Tri-axial Accelerometer-Gyroscope and the instrumental treadmill were set at 100Hz. The F-scan was also set at 100Hz according to the treadmill speed. The F-scan has its own software "Fscan Research 7.52".

6.5 Sensor Placement

EMG

The surface electromyographic (sEMG) electrodes were allocated over the following muscles (Figure 6.2): soleus (Sol) over posterior side of the leg, parallel to the muscle fiber. Tibialis anterior (TA), placed between the knee and ankle, lateral to the tibia bone.

Gastrocnemius lateralis (LG), placed on upper half of the posterior aspect of the calf. Vastus lateralis (VL), placed in the lower end of the thigh, approximated 6 cm above the kneecap. Rectus femoris (RF), the electrode is placed on the thigh between the hip bone and knee. Biceps femoris (BF), the electrode is placed half way between the ischial tuberosity and the lateral epicondyle of the tibia. Gluteus medius (Gmed), the electrode is placed three centimeters towards the spin, going from the hip bone. Erector spinae (ES), the electro is placed to two cm from L1 [19].

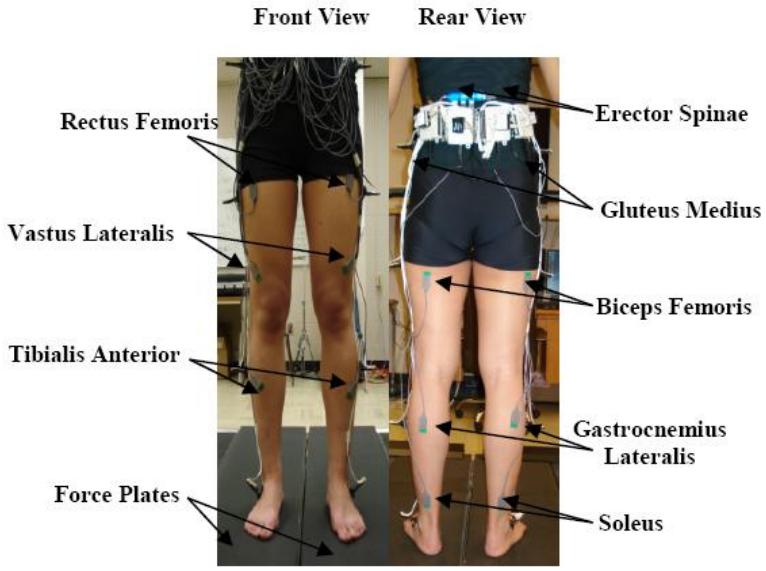


Figure 6.2: EMG Electrode placement on the lower extremity.

F-scan

All subjects brought their own comfortable shoes and the insoles were inserted in them accordingly. The insole sensor covered all the area of the foot sole for an effecting collection of the pressure data, especially in our areas of interest.

Figure 6.3: Fscan system (a) and insoles (b).

6.6 Instrumental Treadmill

The instrumental treadmill was initialized. Subsequent to the calibration and sensor placement, the volunteers were asked to walk on the instrumental treadmill to familiarize with it. This also enabled the determination of the subject's natural walking speed.

6.7 Triggering

The different systems were triggered synchronously to enable simultaneous capture of the sensor data. To perform this triggering and acquisition of data, a Labview program was built for the treadmill and EMG. This program enabled the simultaneous data collection and the triggering of the F-scan.

The output of this program was a simultaneous triggering of the three systems. Before each trial started, it was necessary to run a pretest to ensure the systems enabled and operated properly. During the data collection the research team acknowledged that any type of delays needed to be avoid since them can result in fatigue and in bad measure.

6.8 Trials

The trials started by asking the participants to step in to the treadmill. At this point all the sensors were placed and most of the device and software calibration were done. To complete the calibration of the Fscan insoles, the software of Tekscan® was opened and the weight (in kilograms) of the volunteer was added to the software (this was used to normalize the pressure according to each subject). While these parameters were introduced to the software the participant needed to stay steady for six seconds.

The treadmill was set at the natural pace of each subject (previously obtained) and then collected 100 seconds of data using the four systems. If during the trial the participant was insecure of their ability to keep balance while the treadmill was running, a security harness was providing to them. At all times on of the research, the team was behind the volunteers in case of any emergency.

The software was set to proceed with the rest of the trials before the over ground trials started. Five overground trials were recorded using the sEMG and Fscan. Each one of the overground trial was approximately five meters in length. Between trials the data was saved and revised in order to proceed with the next trial. The complete procedure took about one hour. Subjects were able to dictate when they were ready to proceed with each test and were given a resting period of at least five minutes between each trial.

Chapter 7: Data processing

7.1 Analysis

The processing of the acquired data was performed after its acquisition. The data were categorized according to the type of trial performed.

EMG

The process of filtering the EMG raw data (Figure 7.1) consisted of three stages. In the first stage a forth order Butterworth band pass filter with a cut off frequency from 20 to 300 Hz was applied to the raw data as shown in Figure 7.2. According to De Luca in 1997 [8] between these frequencies the most significant power is set [19]. The next two stages consisted of a technique called “envelop technique” which applies a full wave rectifier and low pass filter. Full wave rectifier is an elegant form to refer to an absolute value (figure 7.3). A fourth order Butterworth low pass filter, with a cut off frequency of 4 Hz (Figured 7.4) was the last stage in this processes.

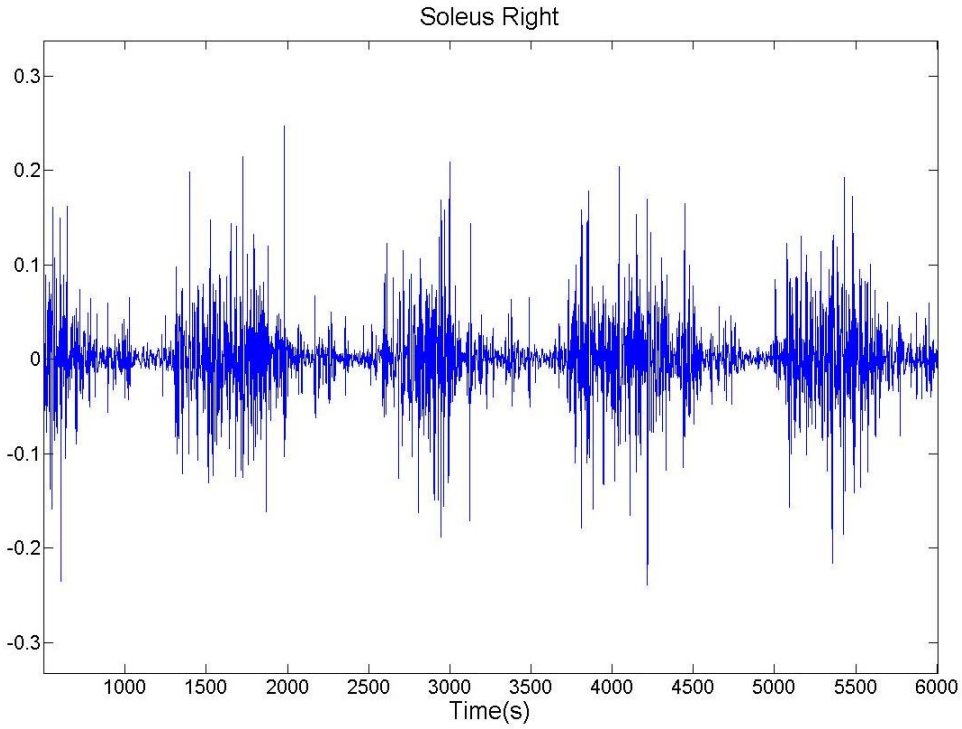


Figure 7.1: Raw signal of Right Soleus.

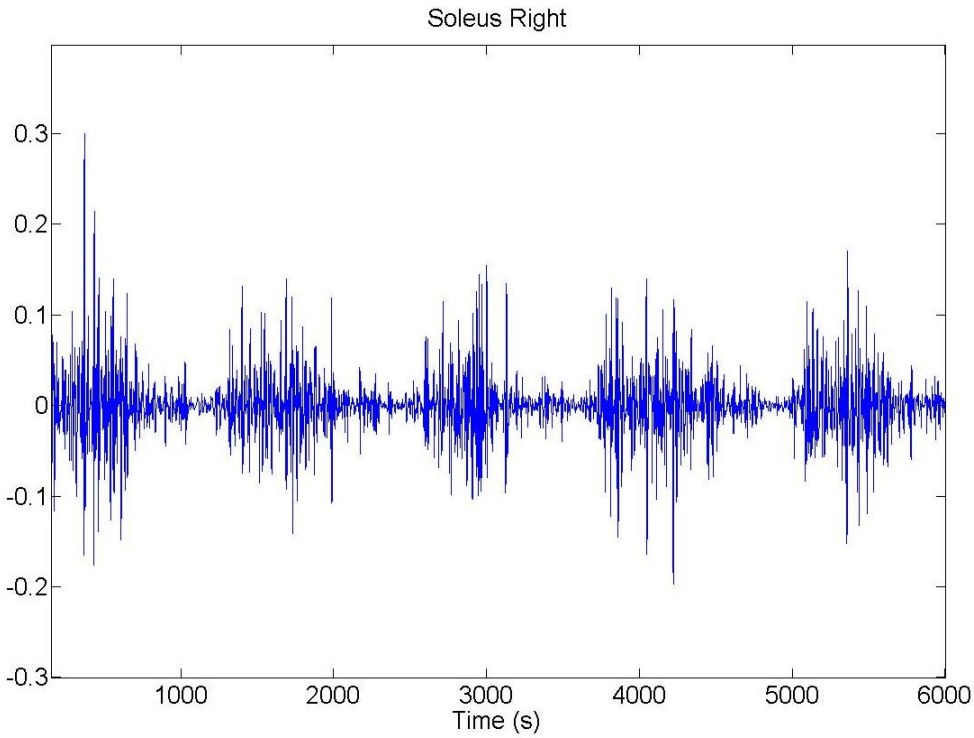


Figure 7.2: First stage of process Band pass filter.

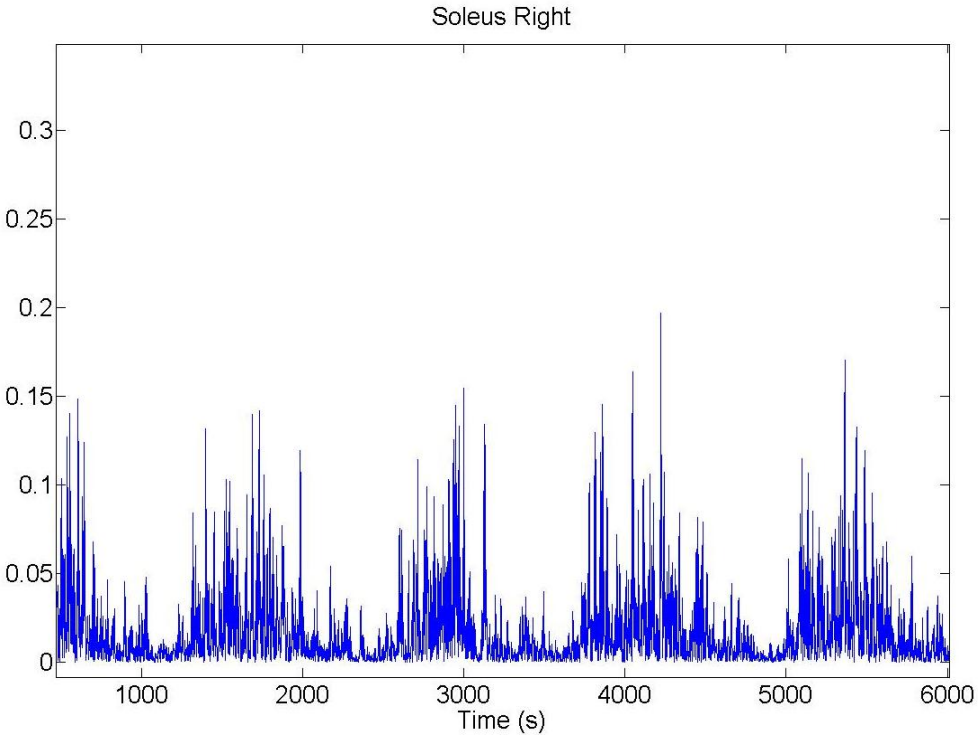


Figure 7.3: Full wave rectifier EMG.

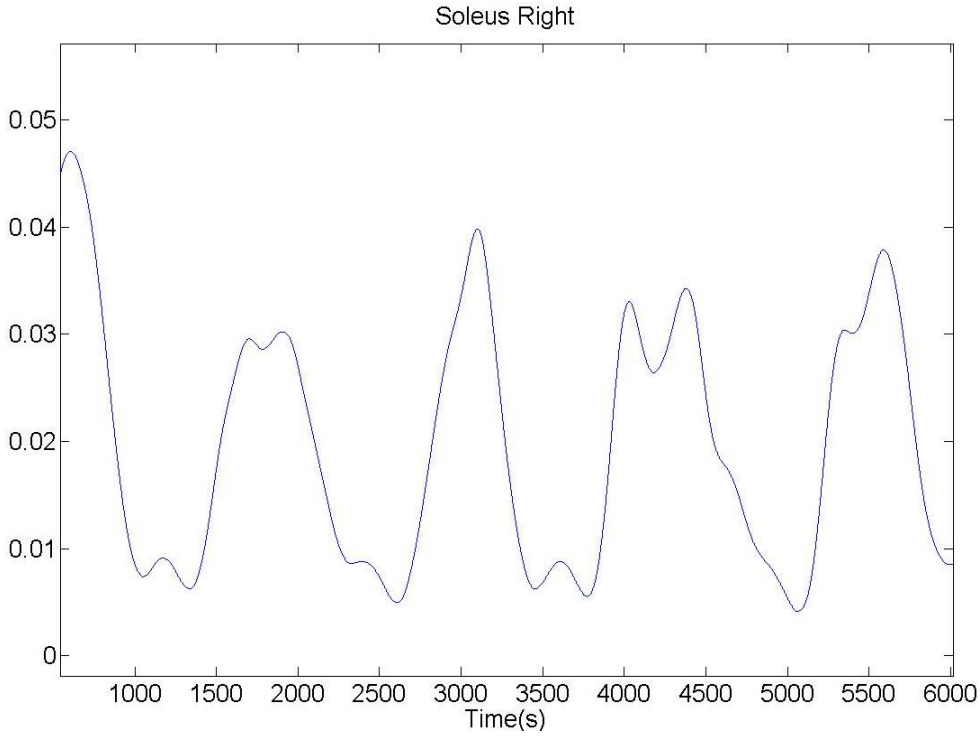


Figure 7.4: Last stage of EMG filtering Low pass filter.

Fscan

Using the Tekscan® software tools, the previously mentioned four areas in each foot were selected manually. Figure 7.5 exemplifies the selection of these areas.

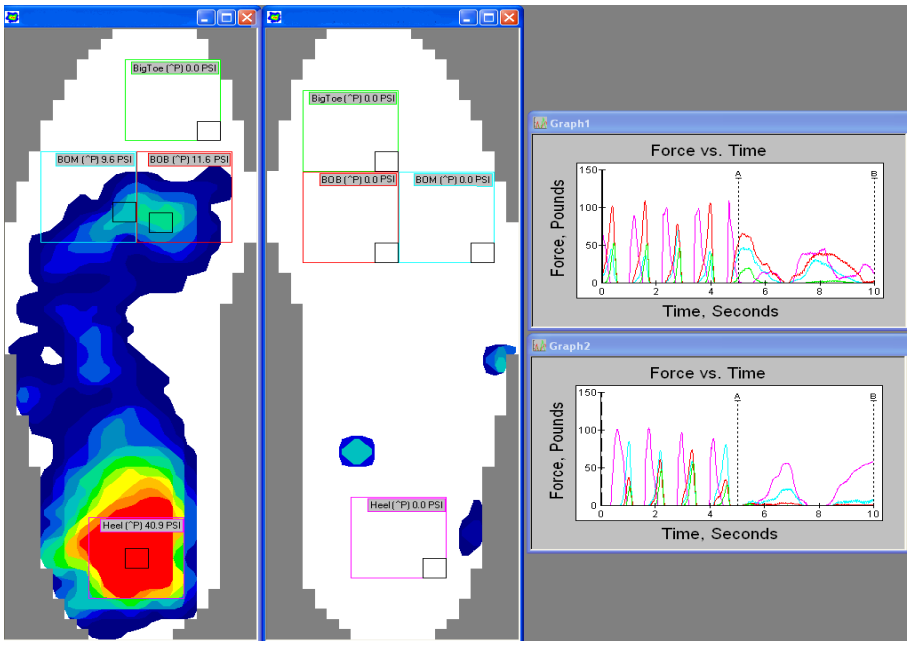


Figure 7.5: This software target the Heel (pink), Big Toe (Green), and Metatarsals one (Red) & two (Blue).

The areas of the boxes were 4cm by 4cm, the position of them were changed to fit the specific size of each participant feet.

An individual excel file was created for each foot. These files contained six columns, first column is the frame number, the second column the time in seconds, and the last four contained the data related to the pressure in each of the four areas given in PSI.

Still at this point the data had to be filtered to eliminate some extra noise. By applying a second order Butterworth filter with a cutoff frequency of 7Hz most of the noise produced by the mechanical parts and bends of the insole and other sources of noise were eliminated.

Figures 7.6a and 7.6b show the enhancement filtered data in comparisons to the raw data from right heel of one of our control group participants.

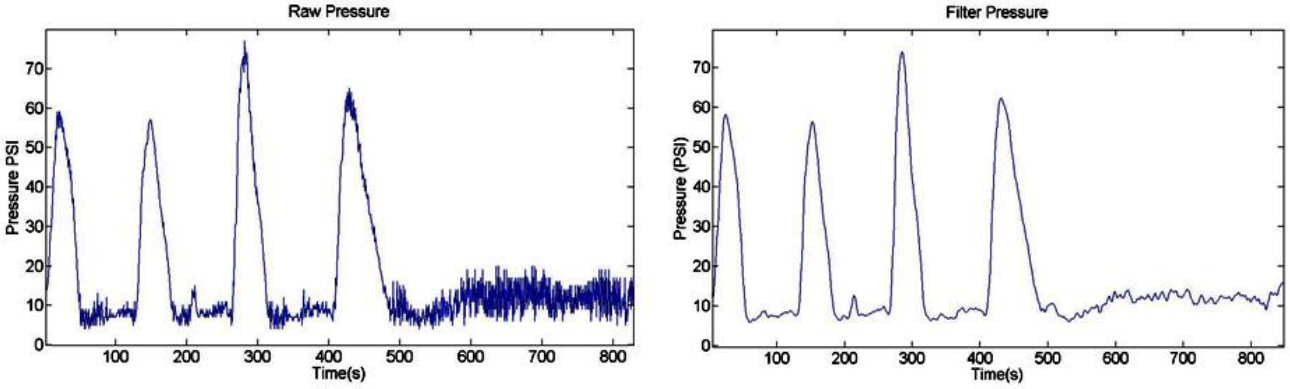


Figure 7.6: Raw data (a) and Filter data (b) from right foot heel of a control group volunteer.

Ground Reaction Force (GRF)

The instrumented treadmill is a precise machine, whose outputs data requires no complex filtering. As in the F-scan the noise produced by the mechanical parts of the treadmill and some other white noise were easily removed by applying a second order Butterworth of a cut off frequency 20 Hz. The following Figures 7.7a and 7.7b illustrate the improvement of the data quality.

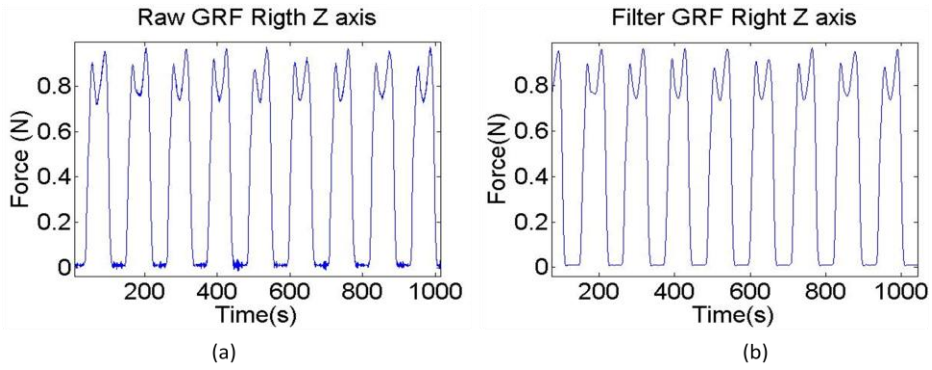


Figure 7.7: Raw data (a) and Filter data (b) from right foot in the vertical axis of a control group volunteer.

All the filter techniques used to process different raw data had as main goal to enhance the data through getting rid of most the noise without affecting the phase and amplitude of the original data. This will provide accurate and detailed information which in a near future can aid medical doctors.

Chapter 8: Feature Extraction

8.1 Data Re-sampling

Since none of the participants (healthy or patient) could repeat precisely and continually each gait cycle at the same length, it was necessary to interpolate each of them at exactly 100 points of data. The mathematical technique of interpolation consists of constructing new data points within the range of a known set of data points [7]. Using the mathematic tool of Matlab "spline" all the data sets were resampled. These gait cycles were extracted by using another method different the interpolation. This was made to corroborate that the significant characteristics of the data (such as the amplitude) were not distorted or contaminated. This method was applied to all the data since it is fast and efficient. Once all the gait cycles were extracted they were averaged, producing a new matrix which is representative of the complete trial (treadmill or overground depending which file was used). This resampling and averaging method were applied to the filtered output data of the systems.

EMG

To properly re-sample the EMG, it was necessary to use the GRF at the Z axis (vertical) to separate the EMG data into the strides. Each muscle needed to activate at a specific time during the gait cycle (this is if the person does not suffer any motor impairment or disease which can affect the proper activation such as "Diabetes" Figure 8.1 shows the proper pattern of activation during the gait cycle) [19].

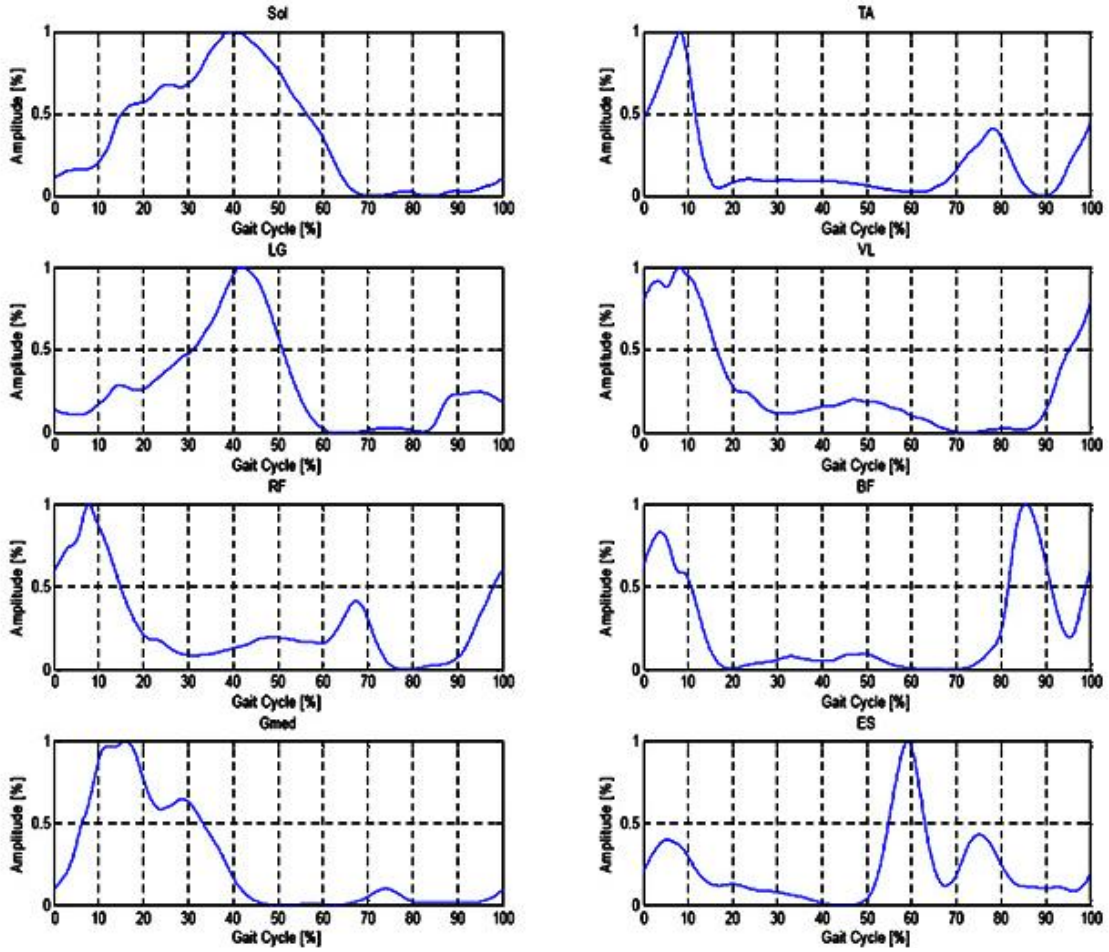


Figure 8.1: Muscle activation during the gait cycle in percentage.

Each muscle was processed by using the same resampling technique. After processing 100 seconds of collected data, each muscle from right and left leg was averaged individually to provide a characteristic matrix and plot of the muscle. Figure 8.2 shows the plot of the characteristic muscle activity during the 100 seconds test over the treadmill.

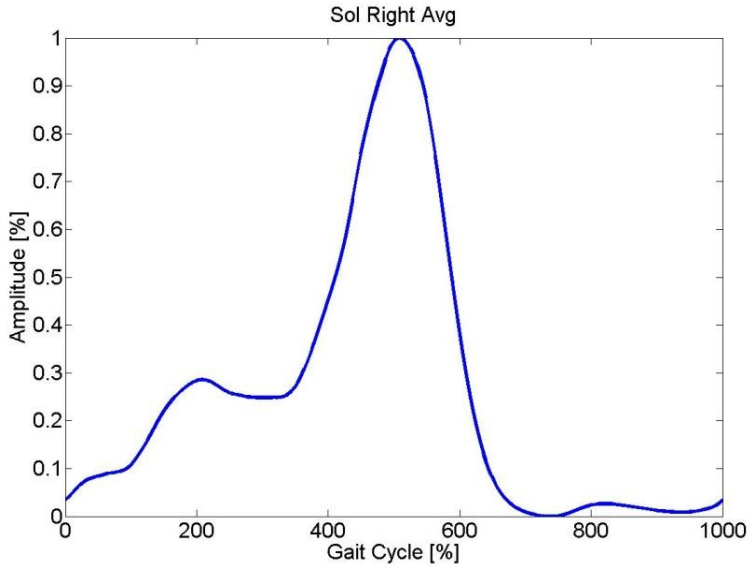


Figure 8.2: Characteristic plot of the right Sol of one volunteer from the control group during the 100 seconds trial.

Once all the members of the control group were processed, all the females and males were averaged into a knowledge base which was used as a reference point to compare in a future the level of impairment. The bigger the population grows the more accurate it will be. Figure 8.3 shows the current knowledge base for males, while Figure 8.4 represents the knowledge base for the female subjects.

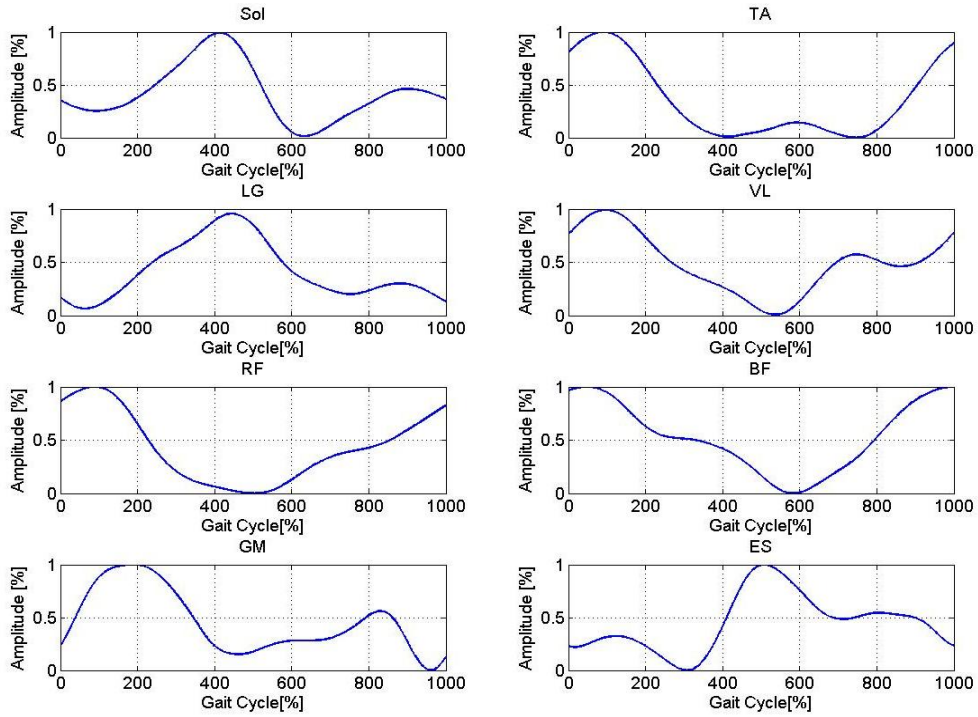


Figure 8.3: EMG Knowledge base of female control group.

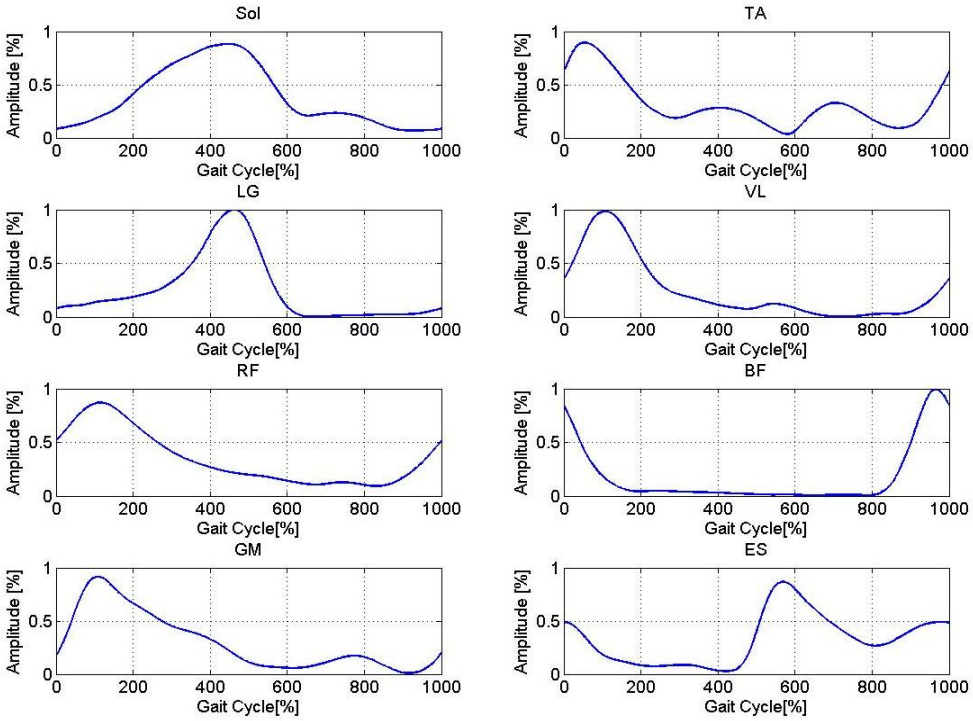


Figure 8.4: EMG Knowledge base of male control group.

Fscan

After the extraction and filtering stage, the next step was to extract the maximum pressure point from the areas of interest. The filter data was also normalized by the relative velocity of the participant. The relative velocity was obtained using the simple formula of $v = \frac{x}{t}$ where 'x' is equal to the stride length and 't' was the time of stride. The stride length was estimated to one meter for all the participants healthy and patients. The time of the strides was obtained by placing a time index at the maximum point of the peak pressure on the heel, and then subtracted from the time index from the previous stride. A new matrix of time was generated and then averaged to obtain a single value for the time. This process was applied individually to the right and left leg, since we know that there is always a difference between them. Simultaneous to the process of obtaining the time, each of the maximum values of pressure was extracted and stored in a matrix tag as the area that was being processed. Before extracting the peak pressure, the data was resampled using the re-interpolation method mentioned at the beginning of this section. To extract the time the data was resample since this would produce a false time.

After all the healthy participants' pressure data was extracted in all the four areas, they were averaged to create a pressure range for to diabetic participants. The following tables provide in detail the pressure data over the treadmill of all of the males and females patients and the range generated by the healthy group.

Table 8.1: Male Diabetic patients average of the max press over the instrumental treadmill and Knowledge base.

	Big Toe		M1		M3		Heel	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
PM01	26.43(08.20)	31.28(07.80)	53.04(06.11)	53.23(08.89)	43.65(08.23)	57.04(10.71)	40.11(07.29)	22.17(05.47)
PM02	121.73(37.18)	145.71(54.90)	69.54(08.49)	65.26(27.29)	59.53(13.83)	134.23(21.03)	49.57(14.00)	59.82(12.54)
PM03	119.58(15.85)	107.59(40.15)	96.35(12.04)	38.90(06.90)	74.33(11.34)	165.47(35.49)	89.15(11.51)	42.39(07.91)
PM04	79.30(16.93)	70.57(28.04)	73.08(20.96)	65.18(19.16)	62.58(08.37)	27.78(04.84)	39.16(09.47)	28.95(06.00)
PM05	136.17(21.31)	192.03(39.39)	74.10(14.91)	34.94(16.55)	116.17(24.29	134.10(41.15)	105.33(33.86)	189.58(41.22)

Healthy Participants

	Big Toe	M1	M3	Heel
mean/std	**56.20 / 25.20**	**65.19 / 18.61**	**48.67 / 20.30**	**64.50 /15.99**
minimum	**22.08**	**39.94**	**17.26**	**42.66**
maximum	**126.56**	**102.16**	**95.34**	**95.31**

Table 8.2: Female Diabetic patients average of the max press over the instrumental treadmill and Knowledge base.

	Big Toe		M1		M3		Heel	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
FDM01	49.00(15.18)	103.18(44.84)	37.22(8.34)	80.40(16.12)	33.10(8.72)	64.52(15.89)	30.52(13.03)	29.95(9.36)
FDM02	85.81(25.66)	46.53(21.69)	107.07(9.76)	86.15(12.31)	79.39(17.45)	68.52(15.41)	37.43(9.62)	20.05(5.96)
FDM03	216.82(82.67)	44.39(14.39)	62.90(17.02)	40.81(18.05)	78.22(28.15)	62.05(28.59)	117.25(33.29)	146.11(64.28)
FDM04	20.24(6.45)	38.35(15.57)	74.71(24.66)	78.60(27.13)	34.80(9.97)	52.42(39.56)	36.33(6.08)	42.31(10.31)
FDM05	35.99(2.98)	33.54(4.48)	34.76(2.85)	25.44(5.12)	21.38(6.16)	22.29(5.44)	23.16(5.83)	22.33(5.43)
FDM06	75.65(31.60)	96.81(52.05)	48.49(5.78)	95.19(14.83)	51.76(6.51)	86.03(15.48)	35.05(13.03)	46.71(20.25)
FDM07	168.58(26.93)	26.07(10.41)	102.16(23.	37.49(6.70)	51.32(14.39)	29.95(8.38)	78.05(22.95)	67.03(13.19)
FDM08	64.04(22.94)	46.96(8.93)	113.77(15.03)	126.42(15.87)	73.19(13.36)	71.52(10.94)	47.11(7.19)	43.66(6.58)
FDM09	194.80(65.42)	41.66(10.14)	206.93(38.53)	40.14(7.11)	321.47(49.99)	52.45(10.55)	179.55(33.88)	65.77(13.61)

Healthy Participants

	Big Toe	M1	M3	Heel
mean/std	**39.49 / 19.60**	**49.45/ 29.28**	**45.57 / 10.21**	**38.54/ 13.26**
minimum	**13.32**	**7.70**	**30.03**	**18.19**
maximum	**78.11**	**105.96**	**63.61**	**60.78**

The overground trials were averaged to produce characteristic tables which represent the four areas. Due the robust information collected over the ground, some of the trials were disregard if the data was overwhelmed by too much noise. As in the trial over the treadmill,

another knowledge base for female and male was produced out of the average from the control group. The following tables represent in detailed the pressure information of the male and female patients and range of magnitudes provide by the knowledge base.

Table 8.3: Male Diabetic patients average of the max press over ground and Knowledge base.

	Big Toe		**M1**		**M3**		**Heel**	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
PM01	36.90(7.45)	41.08(7.91)	71.82(19.64)	61.00(16.86)	65.94(2.96)	56.70(17.01)	58.53(20.39)	39.40(11.54)
PM02	145.61(27.31)	152.39(12.43)	80.54(6.92)	77.30(4.63)	161.02(15.45)	160.02(21.89)	61.97(3.23)	62.50(1.69)
PM03	179.60(8.04)	98.44(20.72)	123.36(13.59)	50.02(7.89)	94.54(14.15)	100.42(14.72)	106.66(14.18)	58.88(8.84)
PM04	129.24(27.42)	67.69(13.79)	92.55(5.79)	62.19(4.69)	86.42(22.41)	74.03(07.55)	92.79(4.92)	64.39(2.27)
PM05	162.52(4.74)	203.11(29.90)	54.42(5.23)	29.08(9.35)	118.63(5.17)	159.78(11.82)	98.30(14.35)	201.70(38.57)

Healthy Participants

	Big Toe	**M1**	**M3**	**Heel**
mean/std	**55.42 /29.29**	**67.93 / 26.44**	**61.22 / 30.70**	**83.74 / 23.67**
Minimum	**14.78**	**31.83**	**20.14**	**55.37**
Maximum	**125.97**	**145.24**	**121.55**	**139.21**

Table 8.4: Female Diabetic patients average of the max press over ground and Knowledge base.

	Big Toe		**M1**		**M3**		**Heel**	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
FDM01	24.41(2.33)	70.367(13.48)	36.71(10.76)	57.68(16.27)	46.12(14.09)	61.85(9.18)	51.62(15.53)	68.67(25.81)
FDM02	47.99(9.11)	13.53(2.65)	78.14(24.09)	78.18(24.43)	86.75(23.03)	70.45(12.90)	84.14(1.85)	54.43(3.21)
FDM03	121.66(45.34)	21.03(6.37)	75.65(12.80)	68.67(13.99)	110.43(9.35)	107.48(27.22)	211.75(27.811)	246.38(22.16)
FDM04	100.00(40.24)	217.80(50.19)	163.24(74.35)	191.19(58.84)	97.81(40.37)	92.29(39.19)	83.05(15.81)	116.44(18.27)
FDM05	30.78(3.45)	37.15(7.46)	39.24(6.01)	54.45(13.72)	36.39(4.56)	47.78(11.40)	64.45(8.79)	54.89(13.63)
FDM06	39.72(10.48)	36.47(11.80)	64.37(12.32)	112.07(29.97)	66.84(13.55)	112.76(28.24)	68.41(5.11)	106.52(3.50)
FDM07	78.97(18.93)	41.82(8.25)	68.08(19.20)	41.63(11.57)	55.00(6.57)	36.11(10.68)	101.0(26.85)	64.60(12.42)
FDM08	32.27(8.33)	30.33(2.53)	81.32(22.02)	103.71(26.01)	58.55(15.28)	60.16(15.58)	61.42(10.11)	62.35(6.64)
FDM09	254.46(38.98)	52.02(3.03)	219.22(17.67)	44.13(1.22)	352.45(40.48)	65.27(4.55)	227.12(5.35)	77.28(2.79)

Healthy Participants

	Big Toe	**M1**	**M3**	**Heel**
mean/std	**58.44 / 42.20**	**58.36 / 22.09**	**42.49 / 15.88**	**50.48 / 20.41**
minimum	**9.66**	**31.36**	**18.30**	**30.17**
maximum	**132.06**	**103.33**	**64.23**	**94.55**

GRF

The GRF data was resampled once the filtering stage was completed, as well as the data from the other systems. A matrix was created for each force (Anterior posterior, medio-lateral, and vertical) from the entire stride. The next step was to extract the most significant characteristics of these matrixes to create a vector and plot representative trial. A knowledge base was built for the Vertical, Medio-lateral, and Anterior posterior GRF (for both male and female). For each of the knowledge base, an average of the left and right leg of all the healthy participants was performed. As a result of this technique, we produced a matrix and a representative plot (figure 8.5) for the GRF knowledge base.

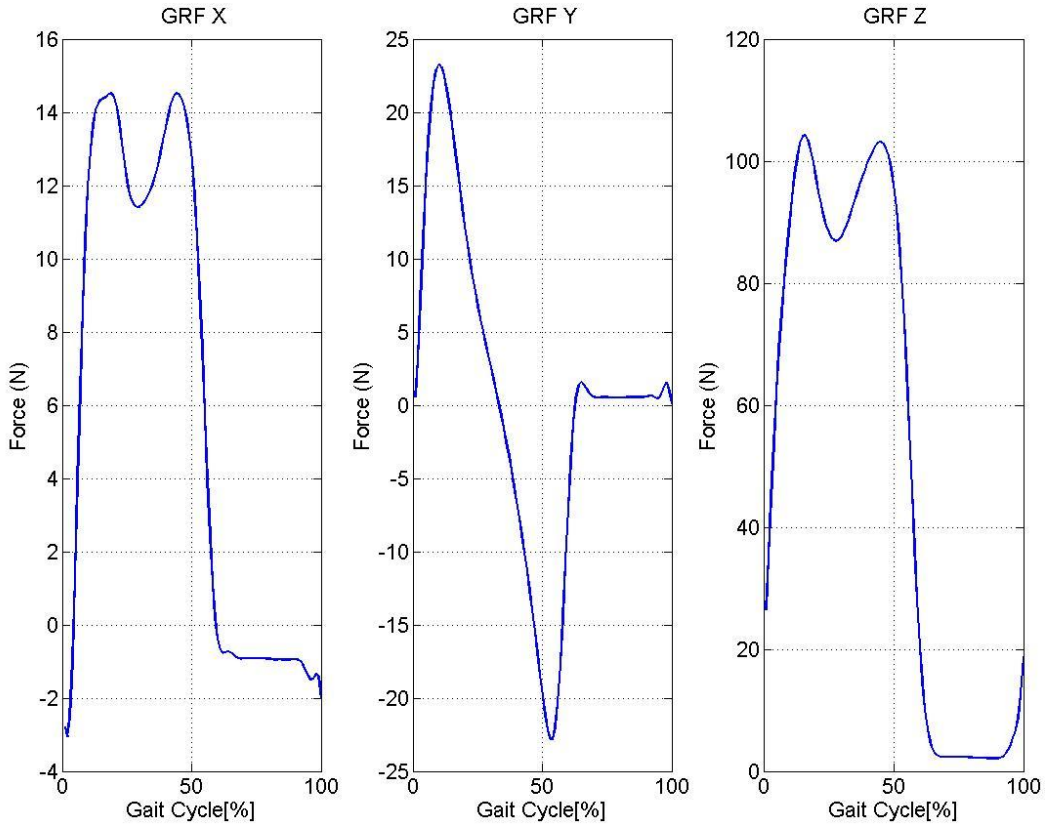


Figure 8.5: Male GRF Knowledge base, for Mediolateral (FX), anterioposterior (FY), and vertical (FZ).

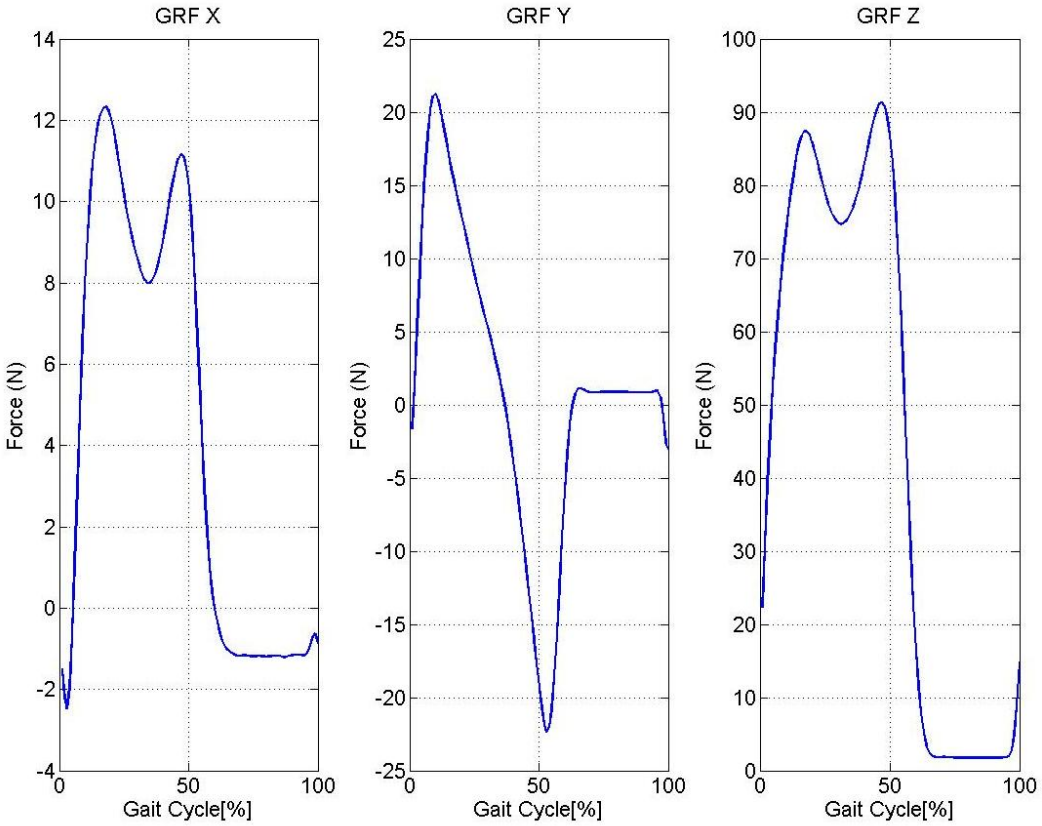


Figure 8.6: Female GRF Knowledge base, for Mediolateral (FX), anterioposterior (FY), and vertical (FZ).

Chapter 9: Discussion

Study Case of Diabetes FP01

Subject is a 56 year old female who was diagnosed with diabetes type 2 five years ago. From her visit to the study (06/20/2011) her glucose level (fasting) was 260 mg/dL. She is being medicated with 14 units of insulin per day at the evening. She is not being diagnosed with any type of peripheral neuropathy. As mentioned in chapter 6 she walked a 100 seconds over the treadmill while the three systems were collecting simultaneously her data.

Figure 9.1 illustrates the GRF pattern in the different planes of the FP01 in comparison to our knowledge base built from the six healthy participants.

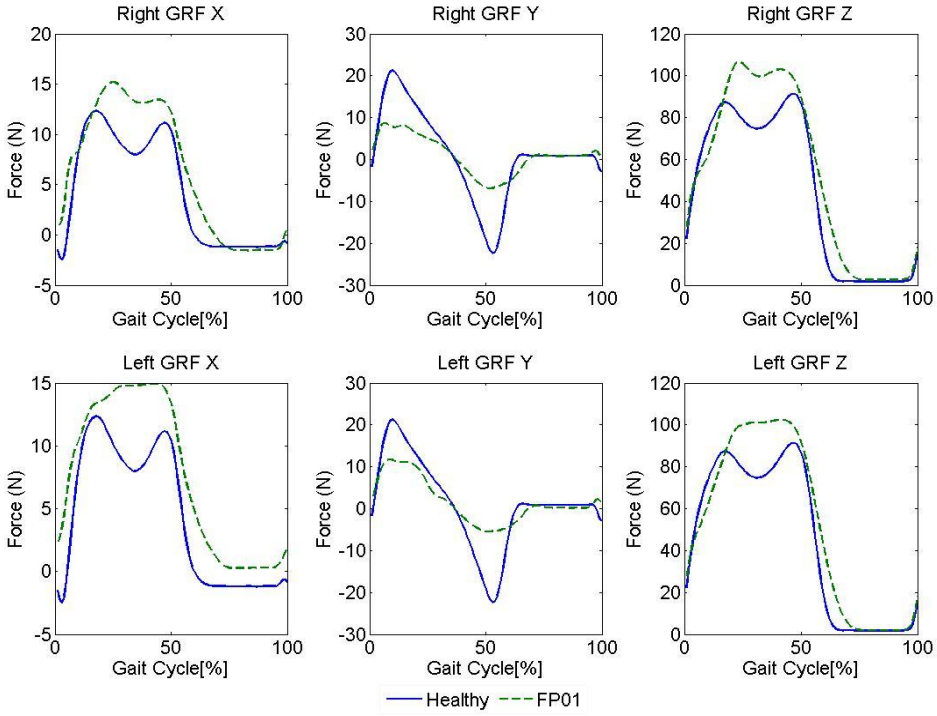


Figure 9.1: GRF patter during the gait cycle for FP01 (Green dash) in the Mediolateral, anterioposterior , and vertical in comparison to control group (blue). Note: both data were normalized by the body weight.

The average speed of the control group was .92 m/s, while the speed of FP01 .69 m/s for right and .70 m/s for left. The low speed during the trial is reflected in the output shapes. In the vertical (Z axis) plane the characteristic 'M' shape is more 'n' due to the slow speed, but still in amplitude it is 20 Newtons higher than the knowledge base. In the medial lateral plane, the magnitude is lower with respect to the knowledge base, since the speed is significantly slower. As found by Paula M.H. Akashi and Robert van Deusre in the vertical force of the right side there is the characteristic low peak consequence of the delay in the LG.

Figures 9.2 and 9.3 show the pattern of muscle activation during the gait cycle, in the right and left leg, respectively. These figures show the comparison between our knowledge base and patient FP01.

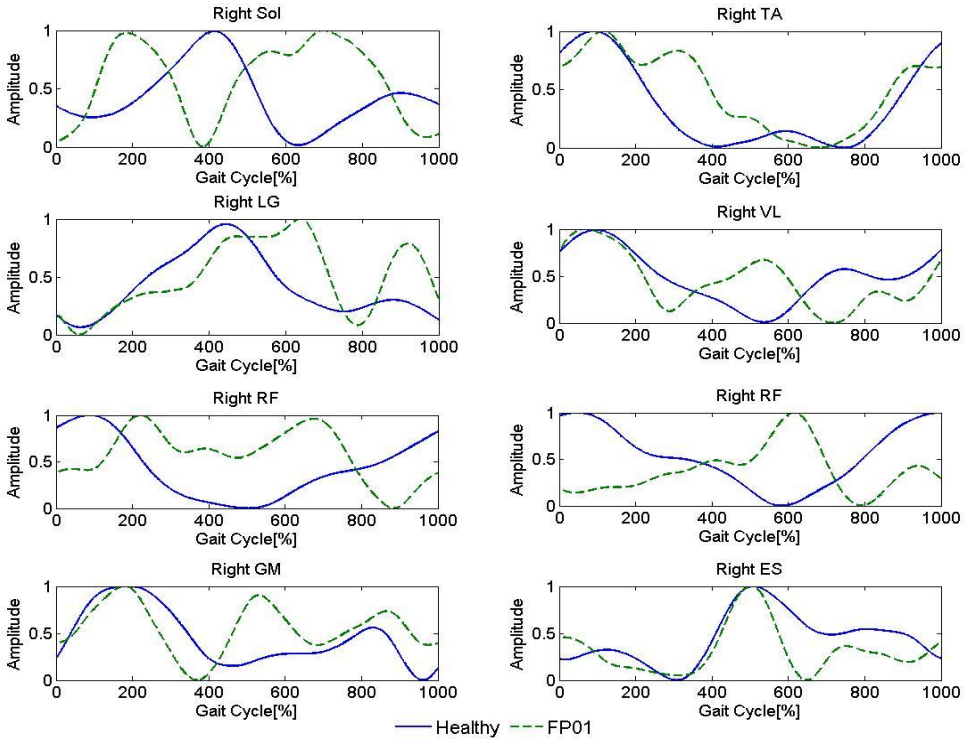


Figure 9.2: EMG activation pattern in the right leg, during the gait cycle for, FP01 (Green dash) in comparison to control group (blue).

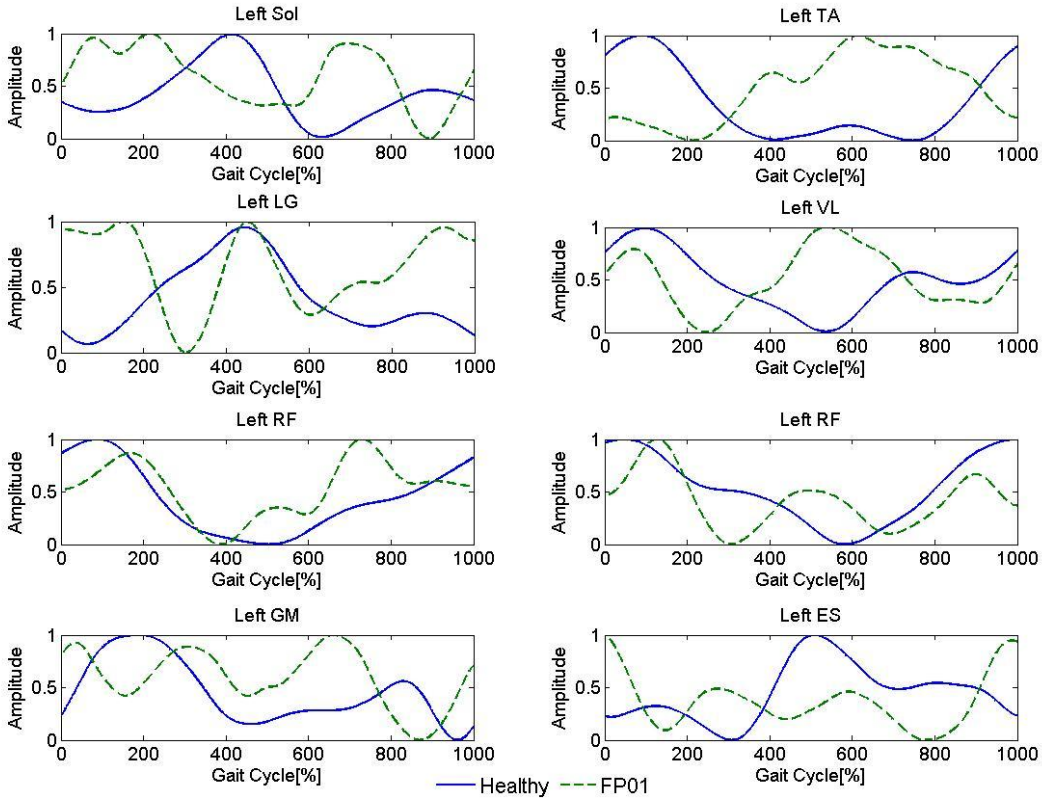


Figure 9.3: EMG activation pattern in the left leg, during the gait cycle for, FP01 (Green) in comparison to control group (blue).

The muscle activation in the right LG and left VL show a similar delay found by Paula M.H Akashi and colleagues. Both of the Soleus show an early activation which can be associated to a drop foot case, commonly found in diabetic patients. Other muscles such as TA-right, GM-right, and ES-right are activated at their proper time. The left side muscles show a difference in the activation time. This could be an indicator of PN.

Table 9.1 represents the average of the pressure in foot sole, over the treadmill, in the target areas of Heel, Metatarsals 1 & 3, and Big toe. The table below represents the range of

pressure provided by the minimum and maximum value of the average of the control group. For each of the targeted areas there is range.

Table 9.1: PF01 average of the max press over the instrumental treadmill and Knowledge base.

	Big Toe		M1		M3		Heel	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
FDM01	49.00(15.18)	103.18(44.84)	37.22(8.34)	80.40(16.12)	33.10(8.72)	64.52(15.89)	30.52(13.03)	29.95(9.36)

Healthy Participants

	Big Toe	M1	M3	Heel
mean/std	**39.49 / 19.60**	**49.45 / 29.28**	**45.57 / 10.21**	**38.54 / 13.26**
Minimum	**13.32**	**7.70**	**30.03**	**18.19**
Maximum	**78.11**	**105.96**	**63.61**	**60.78**

The most affected areas were left Big toe, and left metatarsal one. The rest of the areas were in the range of the knowledge base. Table 9.2 represents the average pressure of the five trials over the ground on the different areas, of interest.

Table 9.2: FP01 average of the max press over ground and Knowledge base.

	Big Toe		M1		M3		Heel	
Patients	Right	Left	Right	Left	Right	Left	Right	Left
FDM01	24.41(2.33)	70.367(13.48)	36.71(10.76)	57.68(16.27)	46.12(14.09)	61.85(9.18)	51.62(15.53)	68.67(25.81)

Healthy Participants

	Big Toe	M1	M3	Heel
mean/std	**58.44 / 42.20**	**58.36 / 22.09**	**42.49 / 15.88**	**50.48 / 20.41**
minimum	**9.66**	**31.36**	**18.30**	**30.17**
maximum	**132.06**	**103.33**	**64.23**	**94.55**

As expected the same areas with higher pressure were the big toe and metatarsal one.

SW Monofilament

The feeling sensation of FP01 was tested using a set of monofilaments (4-g/4.31, 10-g /5.07, and 10-g /5.07). These were the results obtained.

- 4-g/4.31

Failed to sense in right metatarsal 3, 5, and heel in the. Also, failed to sense left big toe, in metatarsal 3, 5, and heel.

- 10-g /5.07

Failed to sense in the left big toe and left hell.

- 300-r/6.56

Did not fail to sense any area.

Over view FP01

(A) GRF

In the vertical plane and medio-lateral, FP01 shows a bigger magnitude with respect to the control group data, especially in the left side. In the right vertical plane there is second low peak characteristic of the diabetic patients due to a delay in the LG.

(B) EMG

As mentioned from the literature, the GL and VL showed a delay in the activation during the gait cycle. The muscles of the right leg although some irregularities they were activated at the proper time. The group of muscles in the left leg showed irregularities during the activation during the gait cycle.

(C) Pressure in the Foot sole

Even though there is a difference in magnitude between the trial overground and over the treadmill, in both trials there were irregular high pressures in the left big toe and left metatarsal one.

All three systems found irregular details which can be associated to diabetic neuropathy in the left lower extremity of FP01. Within the results of the monofilament test, it was also found that areas with low sensitivity have higher pressure.

Chapter 10: Conclusions, Outcomes and Claims of the Research

Background

There was an extensive investigation of parameter which are associated to the development of peripheral neuropathy such as irregular high pressure in the foot sole, irregular muscle activation during the gait cycle, and irregular high magnitude in the ground reaction force in three different axis.

Objective

The objective was to develop an efficient and reliable measurement of foot ulceration will provide the required sensory feedback for the brain plasticity.

Outcomes of this research

By implementing the technique of multiple sensors, this investigation successfully found motor irregularities that might indicate the development of PN in diabetic patients with type 2 diabetes using three sensor systems. The data collected from one sensor system supported and validated the information from the other sensor and vice versa. As in the study case of FP01 all three sensor systems confirmed that her left lower extremity had irregular muscular activation (such delay in the GL), high pressure (in big toe and metatarsal 1), and strong GFR (in the X and Z plane). PF01 was also tested using the SW monofilaments in the same areas with less feeling sensation at the same areas with highest pressure found using the Fscan. This system could not provide a diagnosed of whether a diabetic patient has developed or not PN, but it can provide reliable and accurate data to medical doctor.

Claims of this research

[1] It is possible to obtain a reliable and efficient measurement of the diabetic foot by the use of this innovative technique .

[2] The data collected using multiple sensors sources can provide measurements which can be used for feedback compensatory strategies.

[3] The data collected over the ground and/or over the treadmill can provide reliable information to monitor the diabetic foot.

Chapter 11: Future Work

- For future work, it will be necessary to increase the size of the population of patients and healthy participants.
- Healthy patients need to have closer anthropomorphic similarities to the patients. During the overground trials it is necessary to establish a specific distance, this will enhance the accuracy of the calculation of the speed.
- Incorporate a third group to the investigation, with a population of diabetic patients with history of diabetic ulceration.
- Since there are a set of knowledge base, the next step will be to implement an intelligent algorithm to establish the difference between the control group and diabetic patients. At the same time this can also be use to classify the level of severity of the PN.
- Pressure data can enhance by replacing the insole system with a pressure sensor mat.

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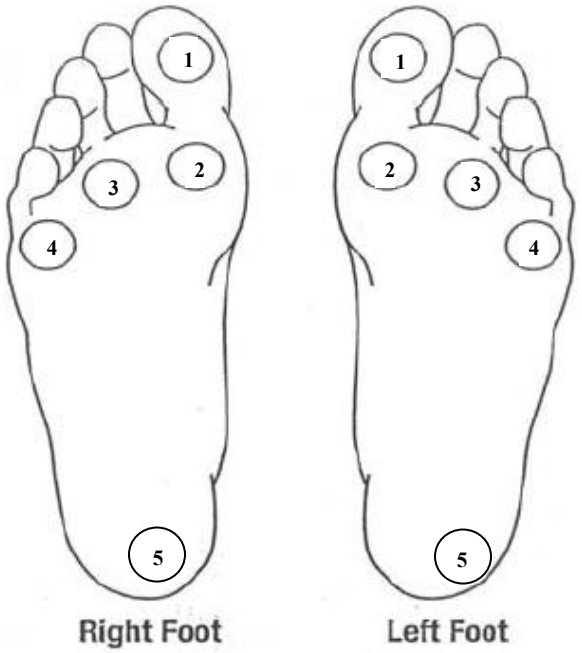
Appendix (experimental results without interpretations)

Semmes – Weinstein Monofilament Testing Results Sheet

Name: _____ Gender: _____ Age: _____



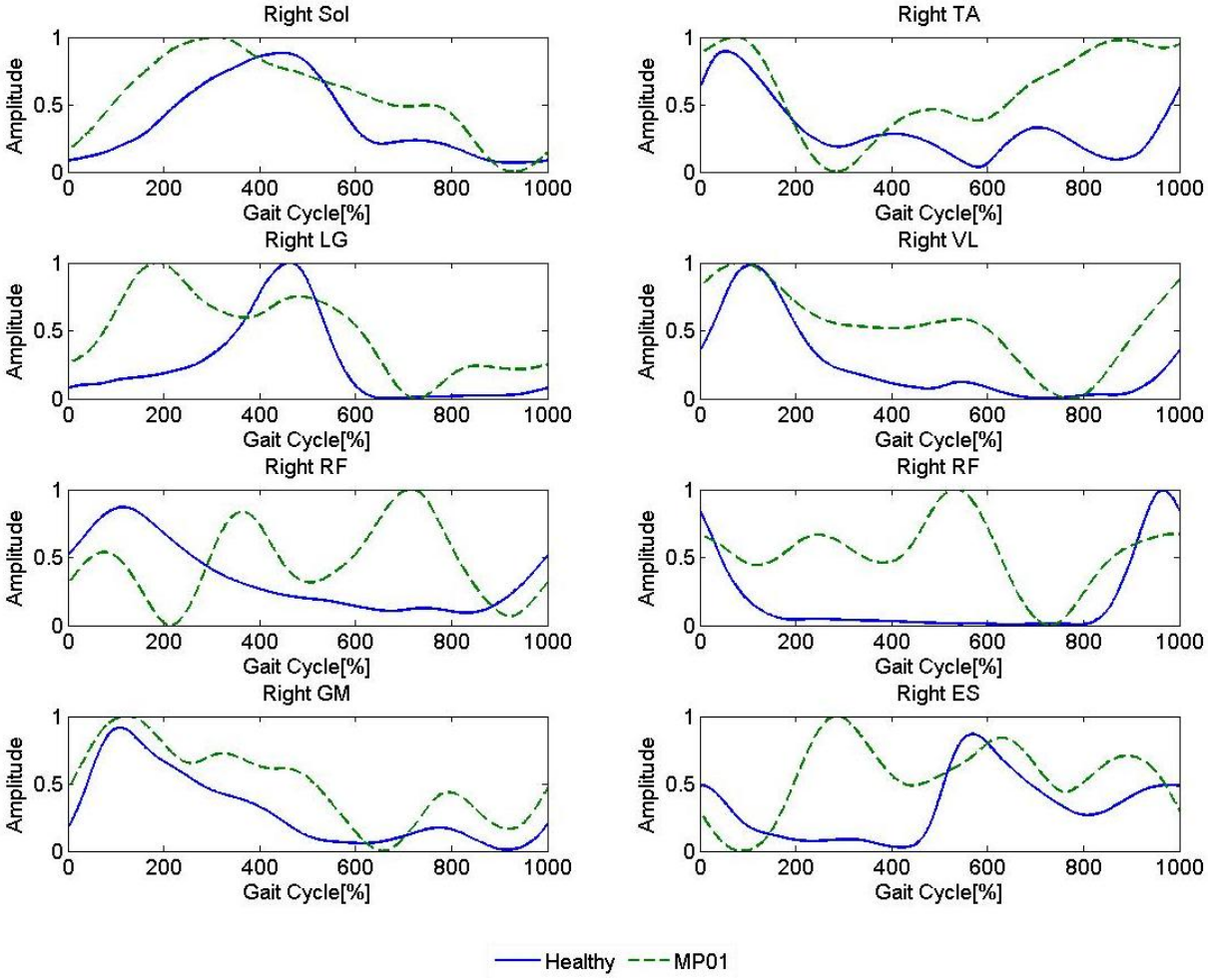
- Bow the 10-g MF at a designated site, and ask the patient, “Do you feel it touch you – yes or no?”
- Repeat testing twice at each site and randomly include a “sham” application in which the 10-g MF is not applied. There will be a total of three applications at each site, one of which does not touch the skin.
- Protective sensation is considered to be present if the patient correctly answers two or more of the three applications, one of which was a sham.
- If the patient correctly answers only one or none of the three applications, return and retest that site.
- The patient is considered to have insensate feet if they fail on retesting at just one or more sites on either foot.

10-g/5.07 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						
2.83 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						

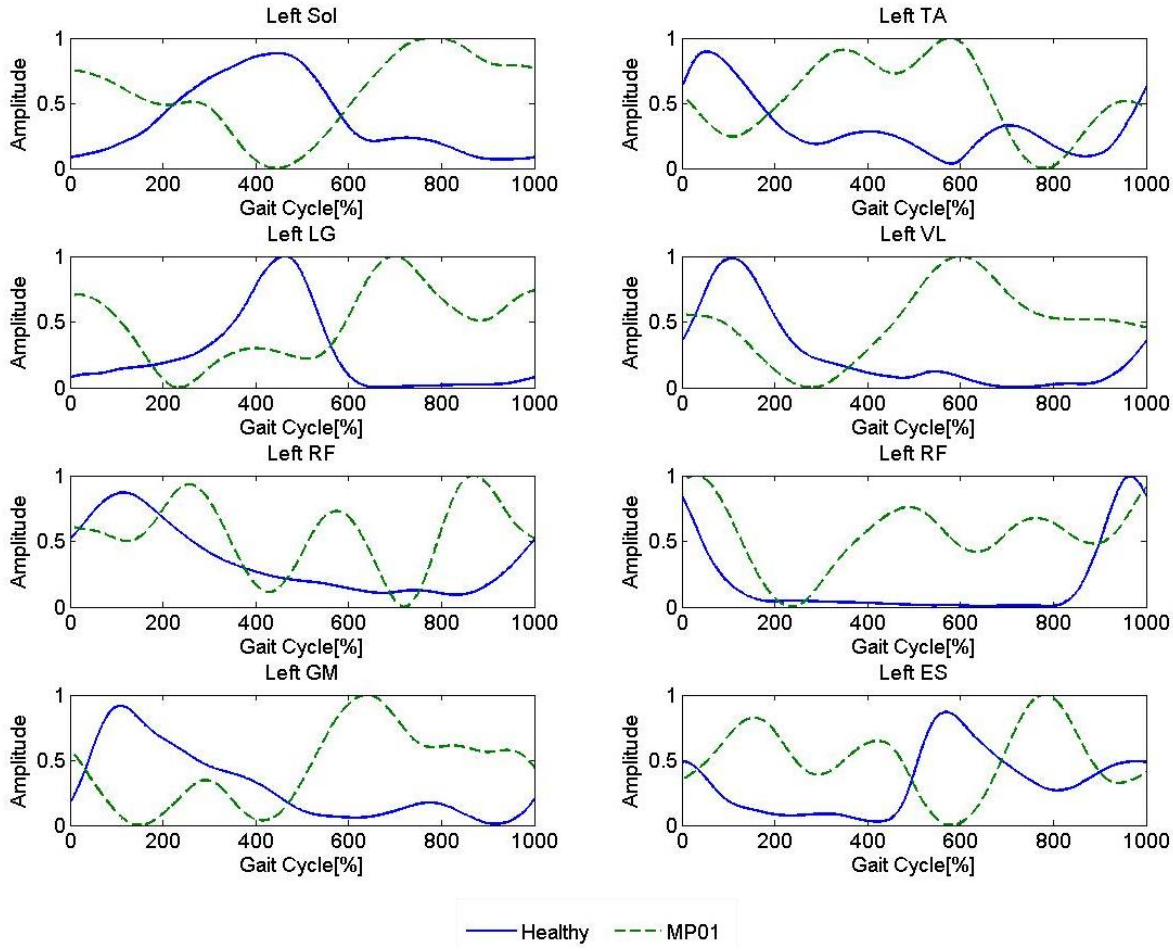
3.61 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						
4.31 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						
4.56 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						
6.65 SW Monofilament Test Results							
		Right			Left		
		1st	2nd	Sham	1st	2nd	sham
1	Great Toe						
2	1st metatarsal						
3	3rd metatarsal						
4	5th metatarsal						
5	Heel						

Note:

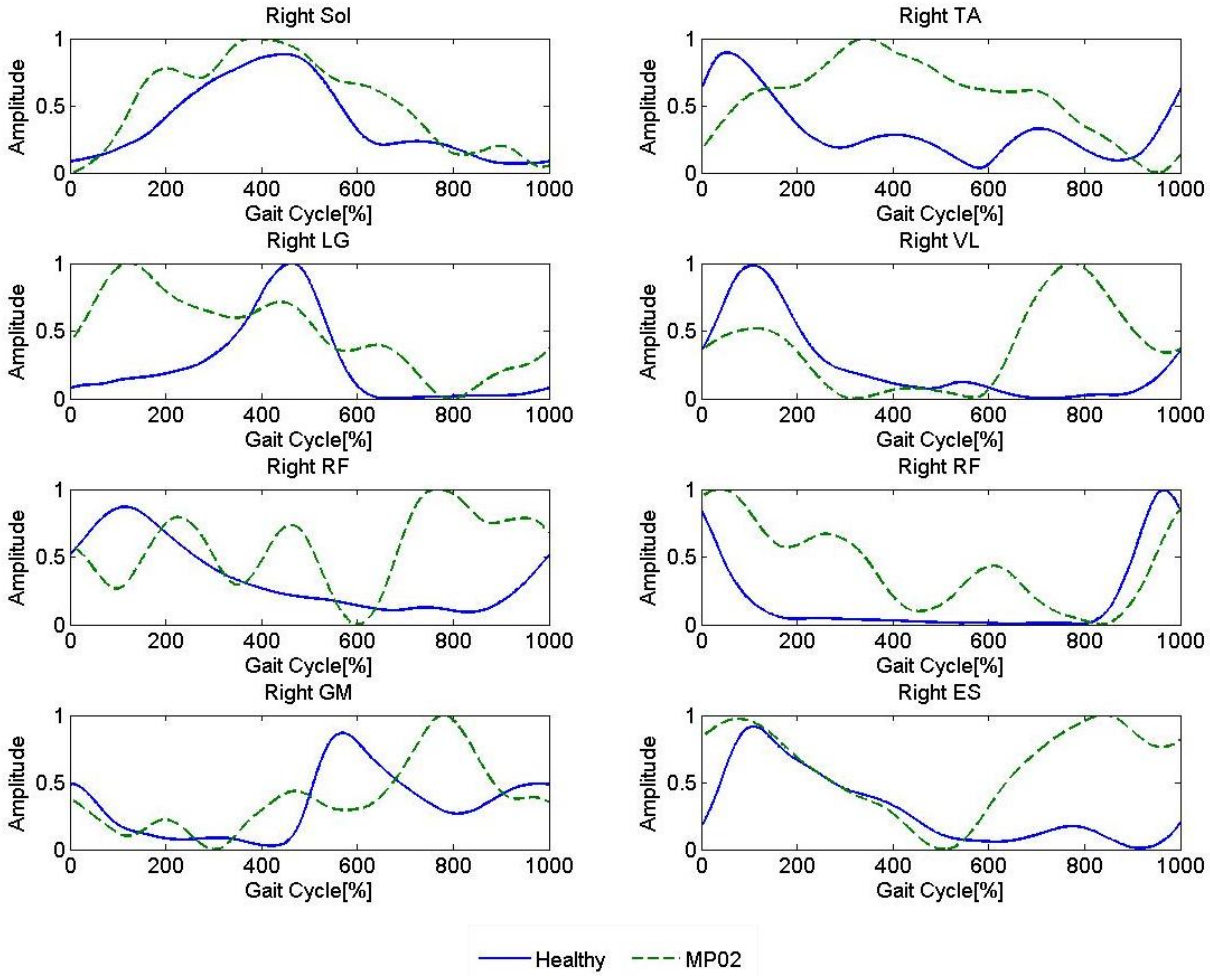
- Normal: 2.83, 3.61, 4.31
- Protective: 4.56, 5.07
- Severe insensitive: 6.65



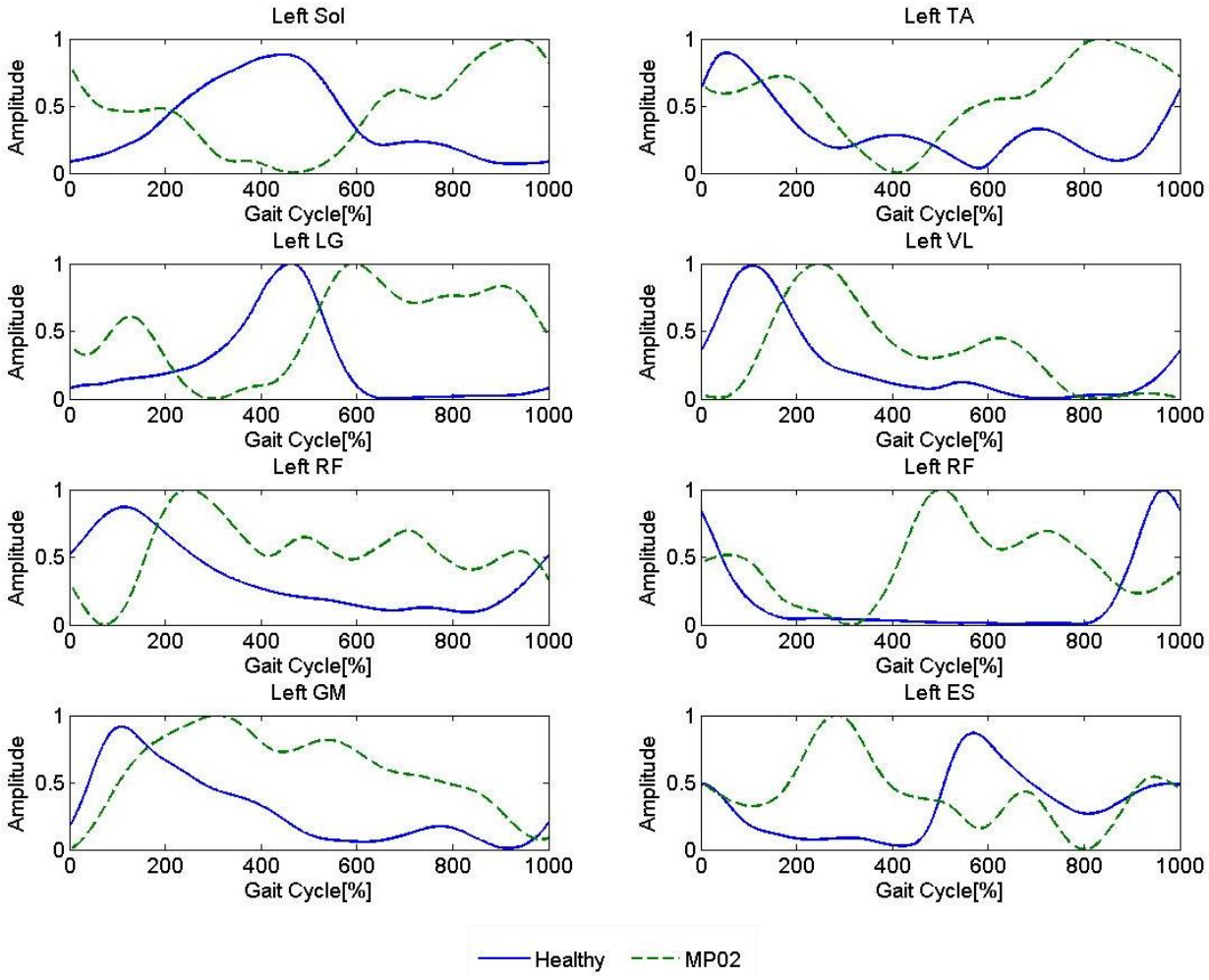
Right leg EMG pattern of MP01 in comparison to Knowledge Base



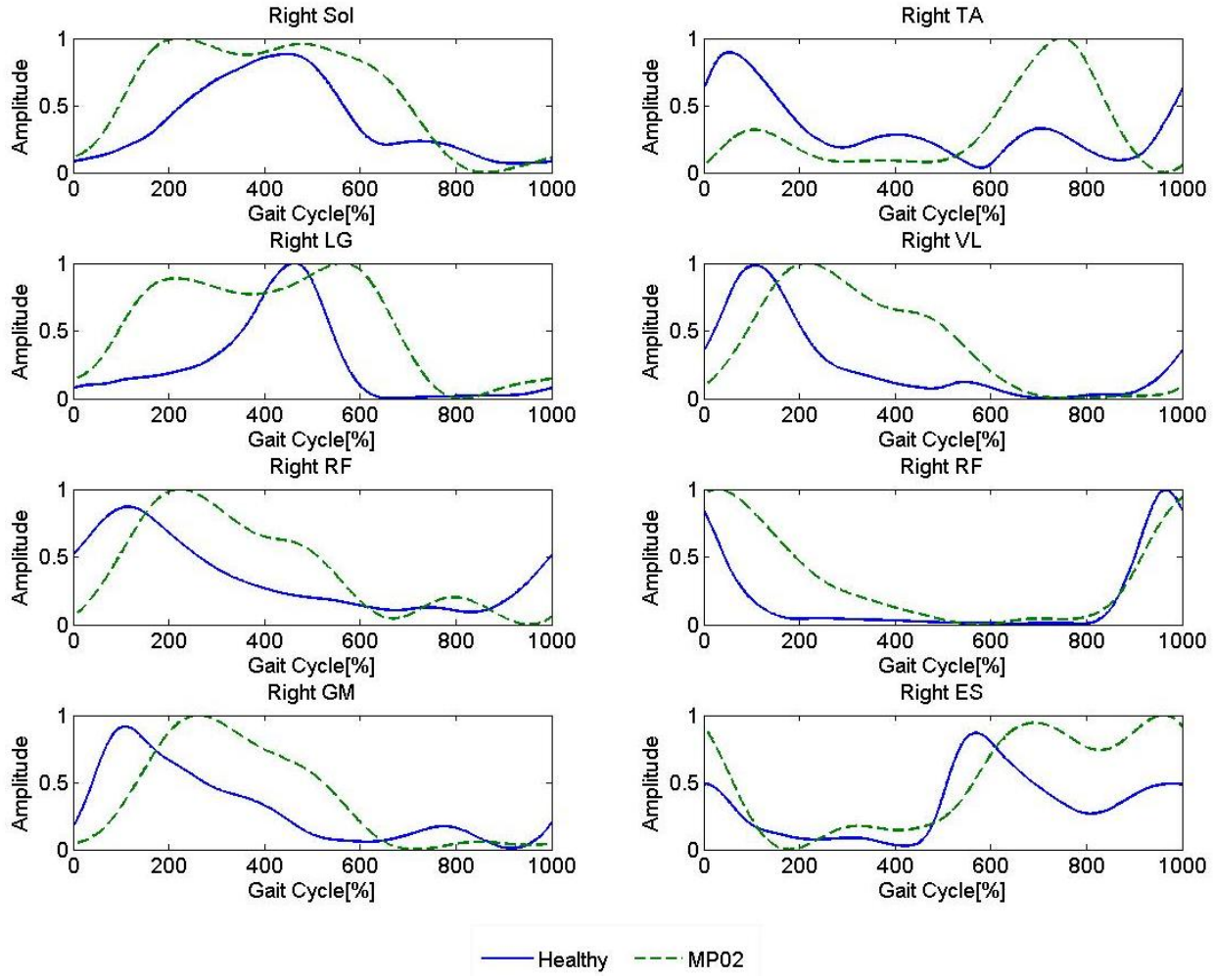
Left leg EMG pattern of MP01 in comparison to Knowledge Base



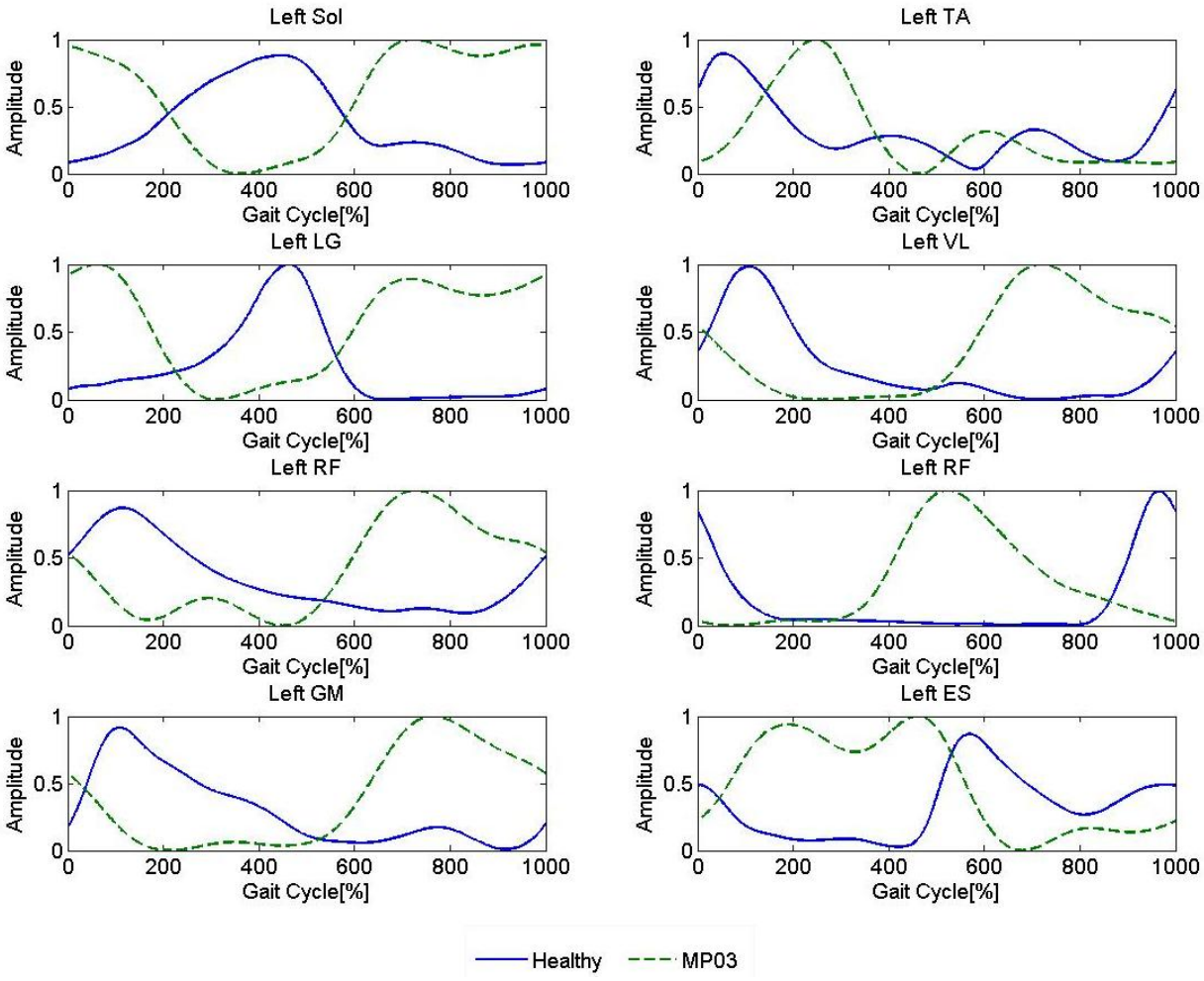
Right leg EMG pattern of MP02 in comparison to Knowledge Base



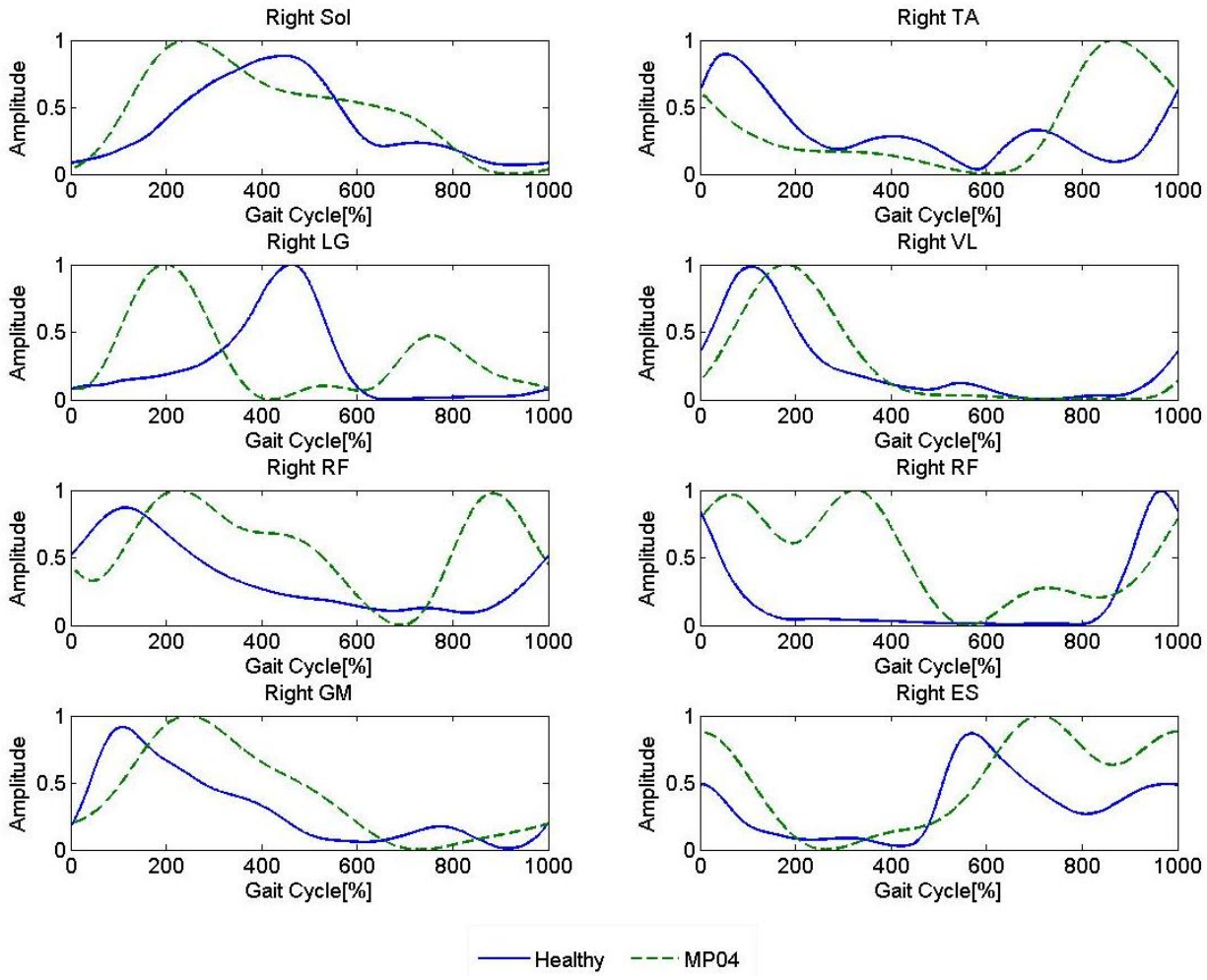
Left leg EMG pattern of MP02 in comparison to Knowledge Base



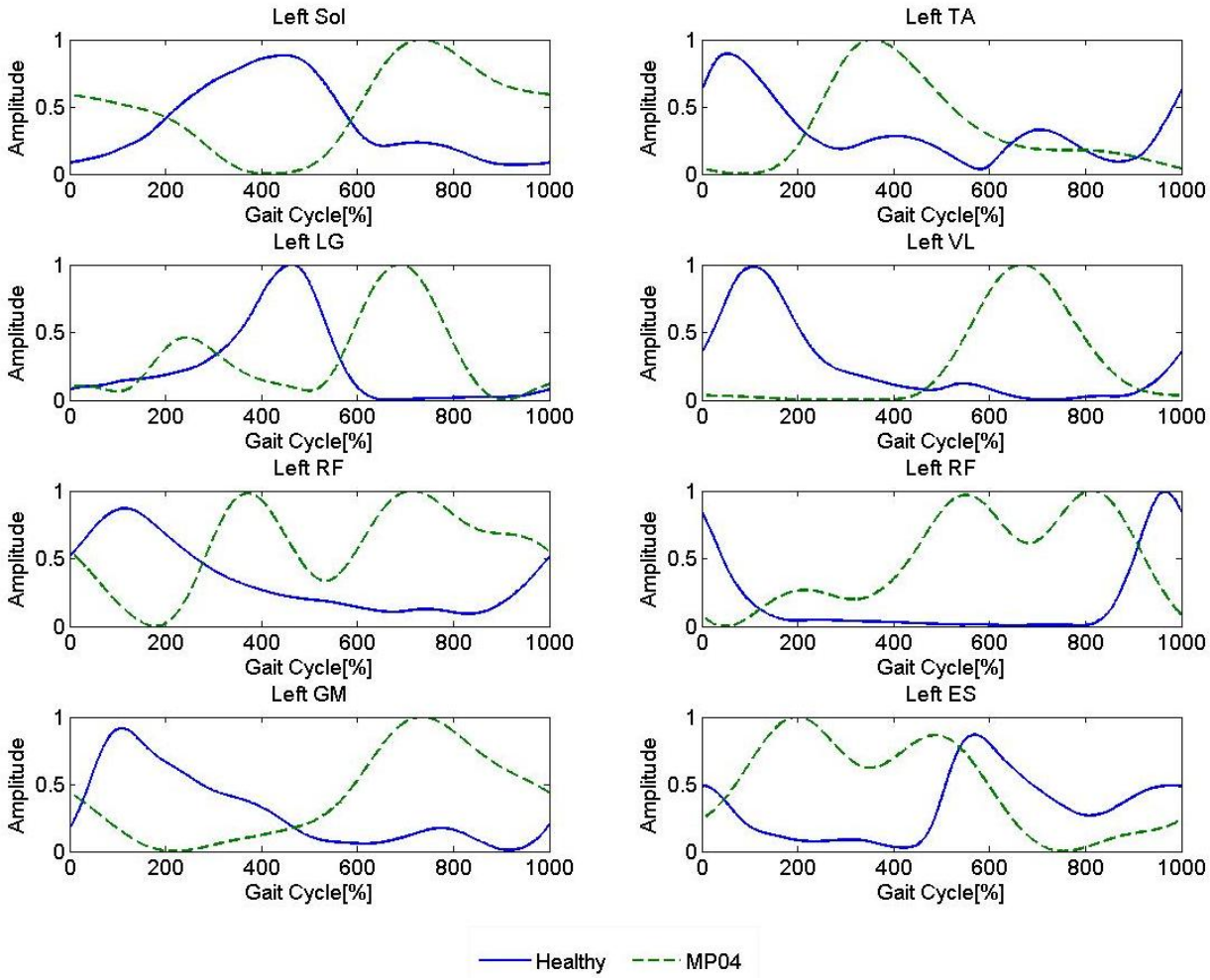
Right leg EMG pattern of MP03 in comparison to Knowledge Base



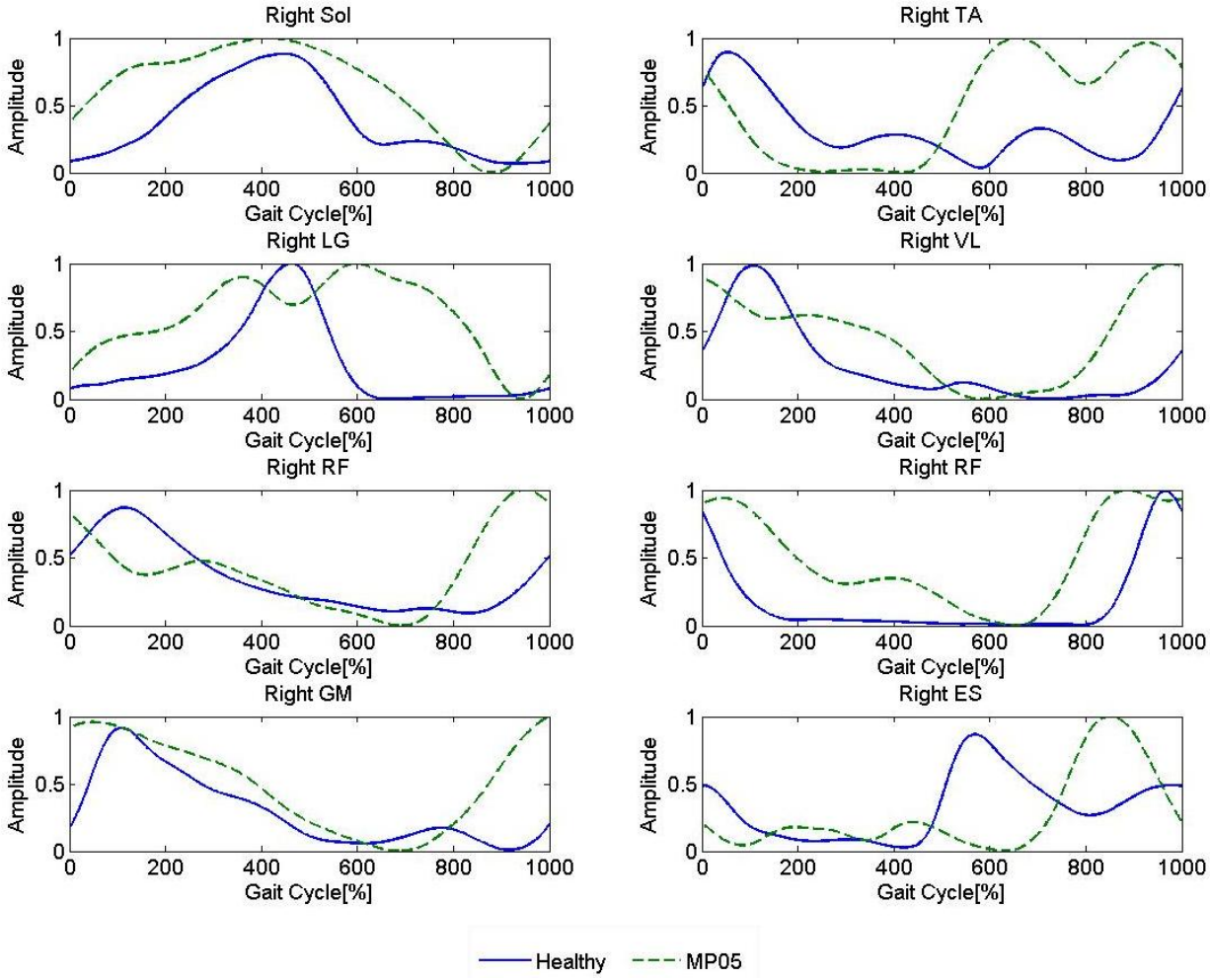
Left leg EMG pattern of MP03 in comparison to Knowledge Base



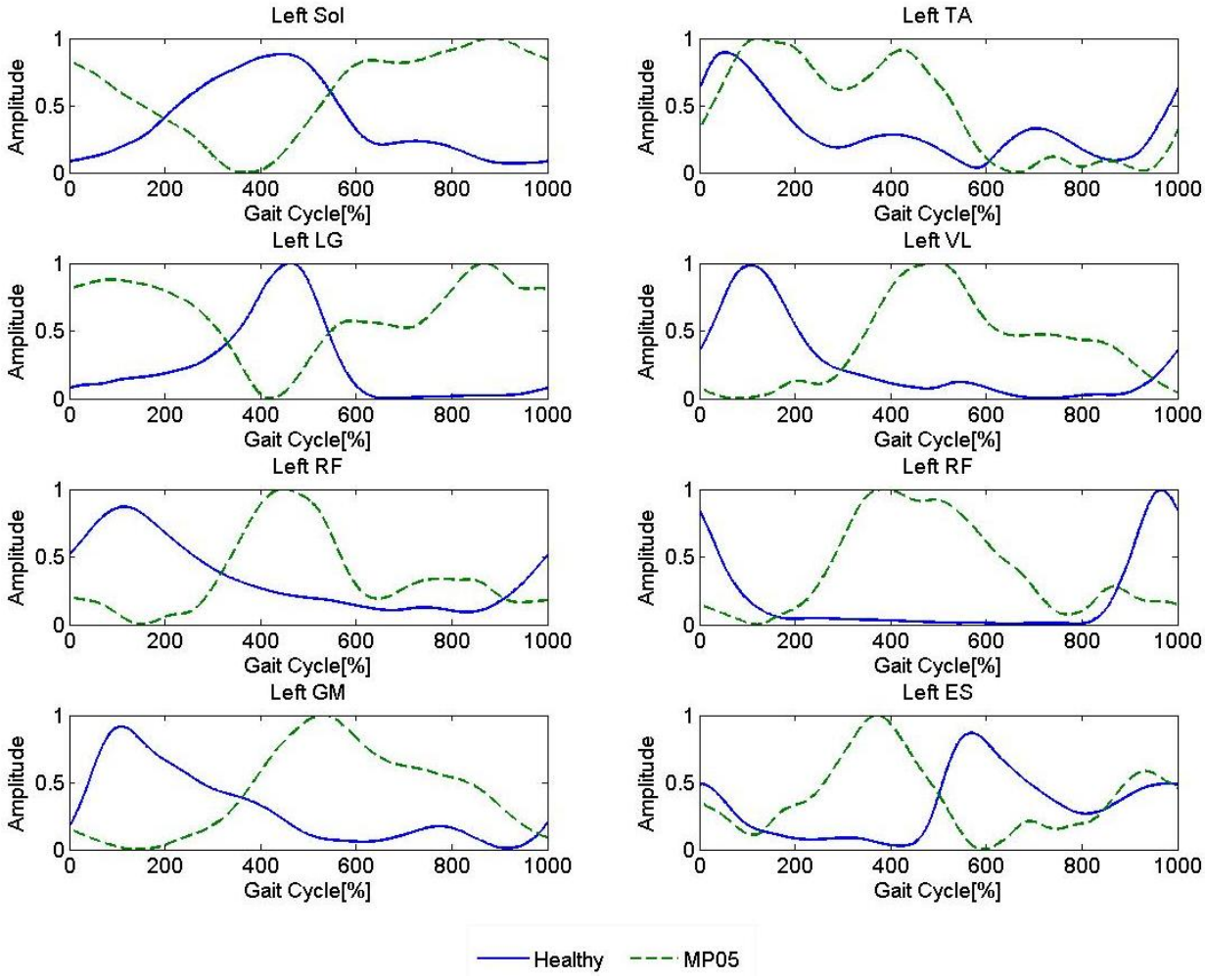
Right leg EMG pattern of MP04 in comparison to Knowledge Base



Left leg EMG pattern of MP04 in comparison to Knowledge Base



Right leg EMG pattern of MP05 in comparison to Knowledge Base



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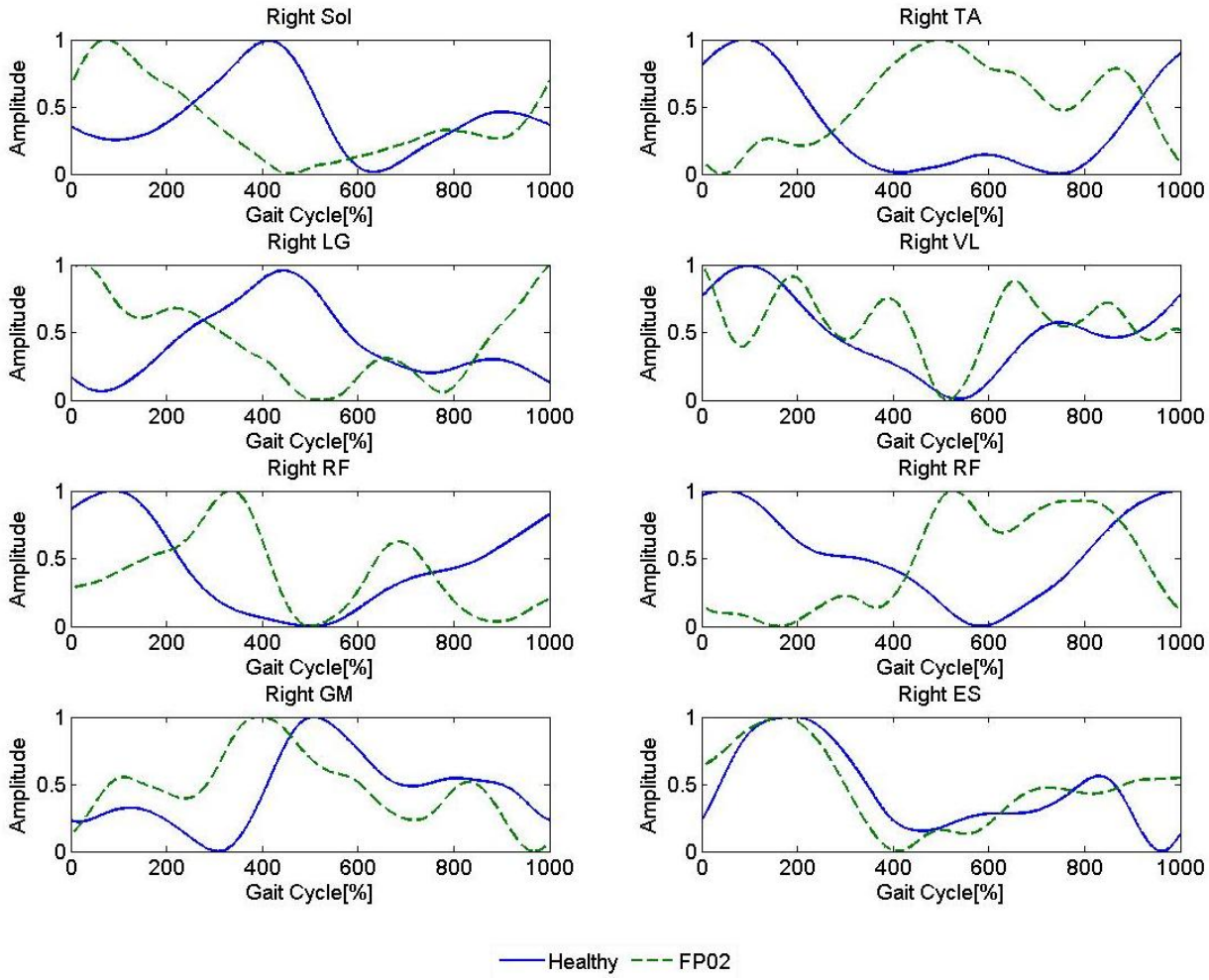
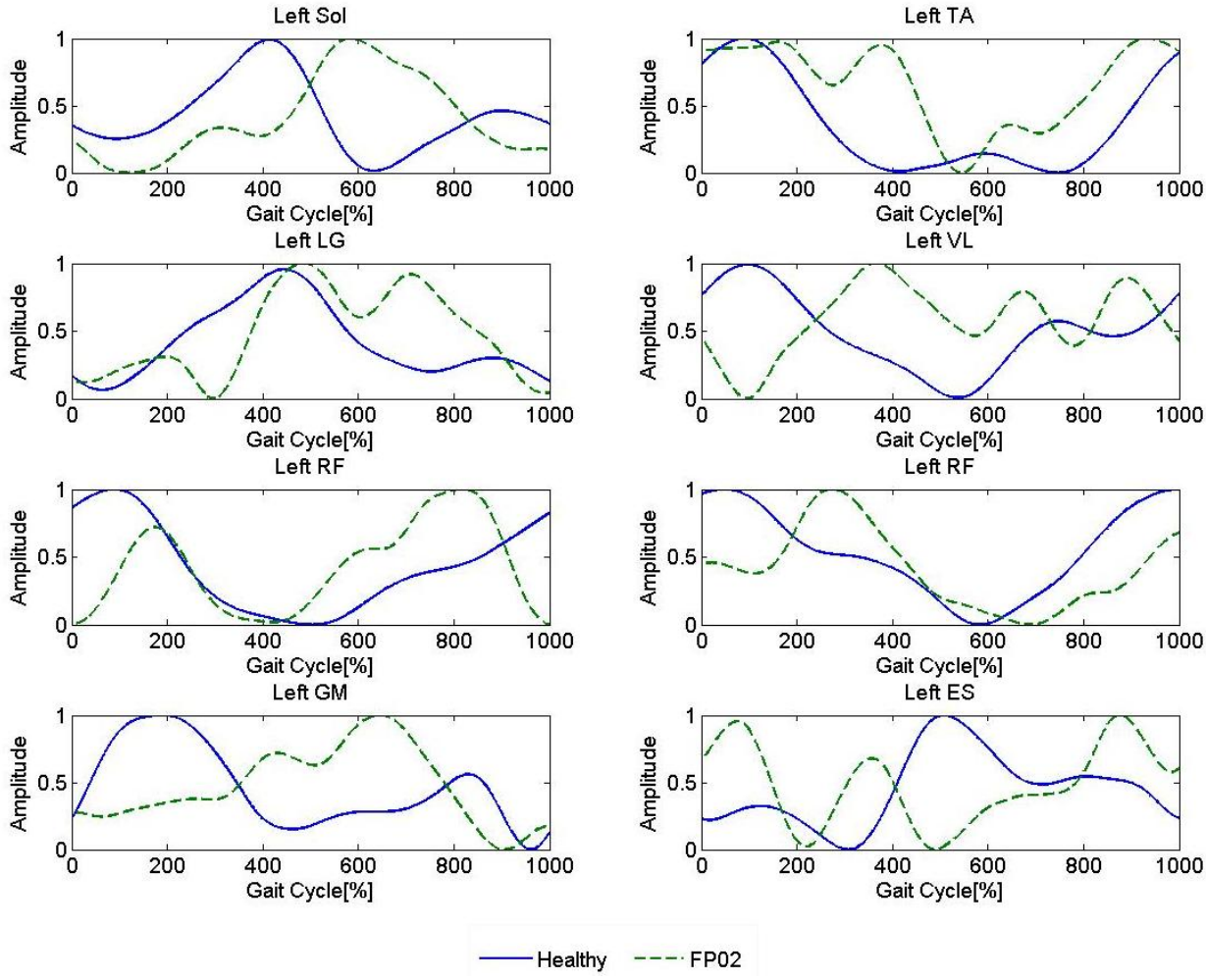
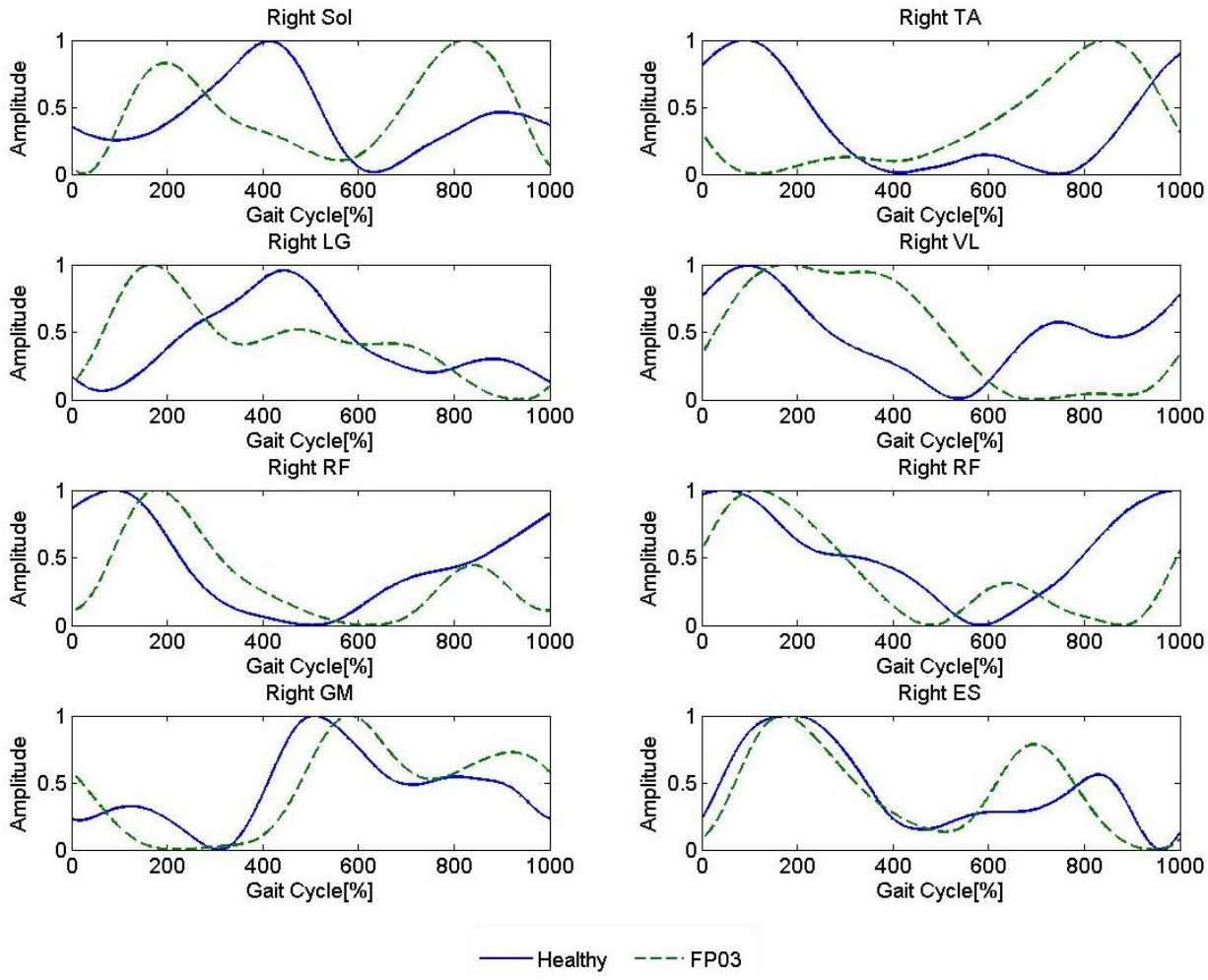


Right leg EMG pattern of FP02 in comparison to Knowledge Base



Left leg EMG pattern of FP02 in comparison to Knowledge Base



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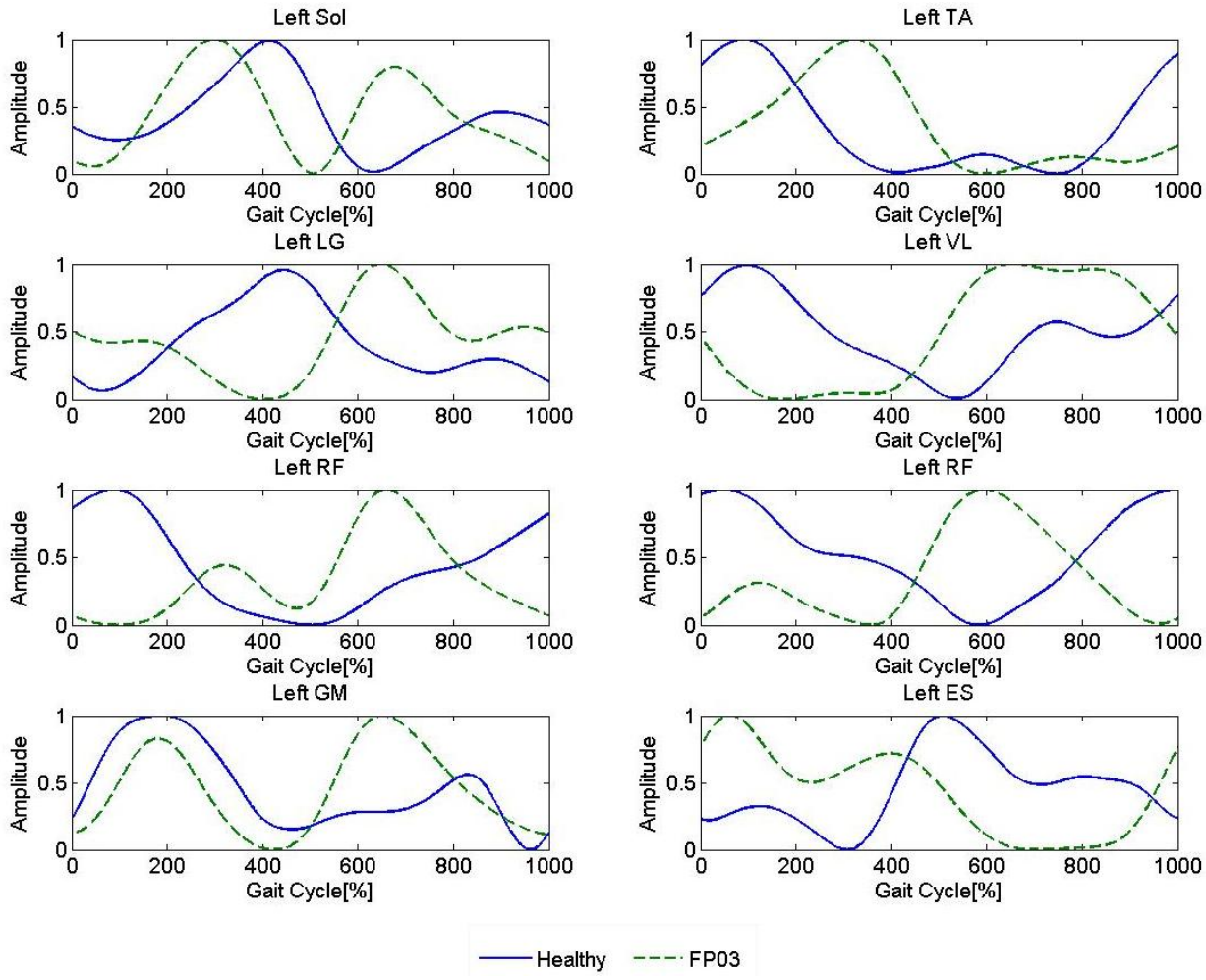
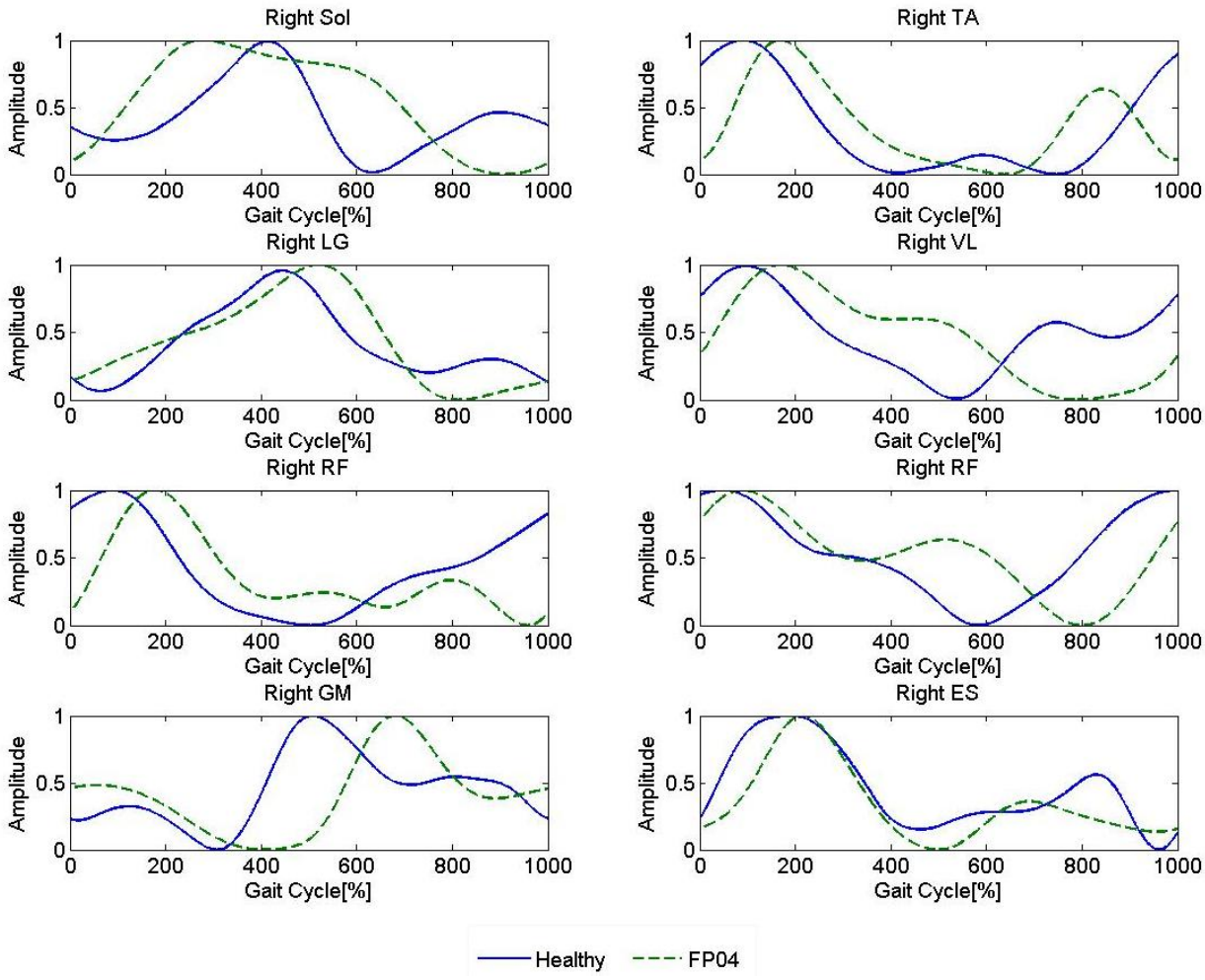


Left leg EMG pattern of FP03 in comparison to Knowledge Base



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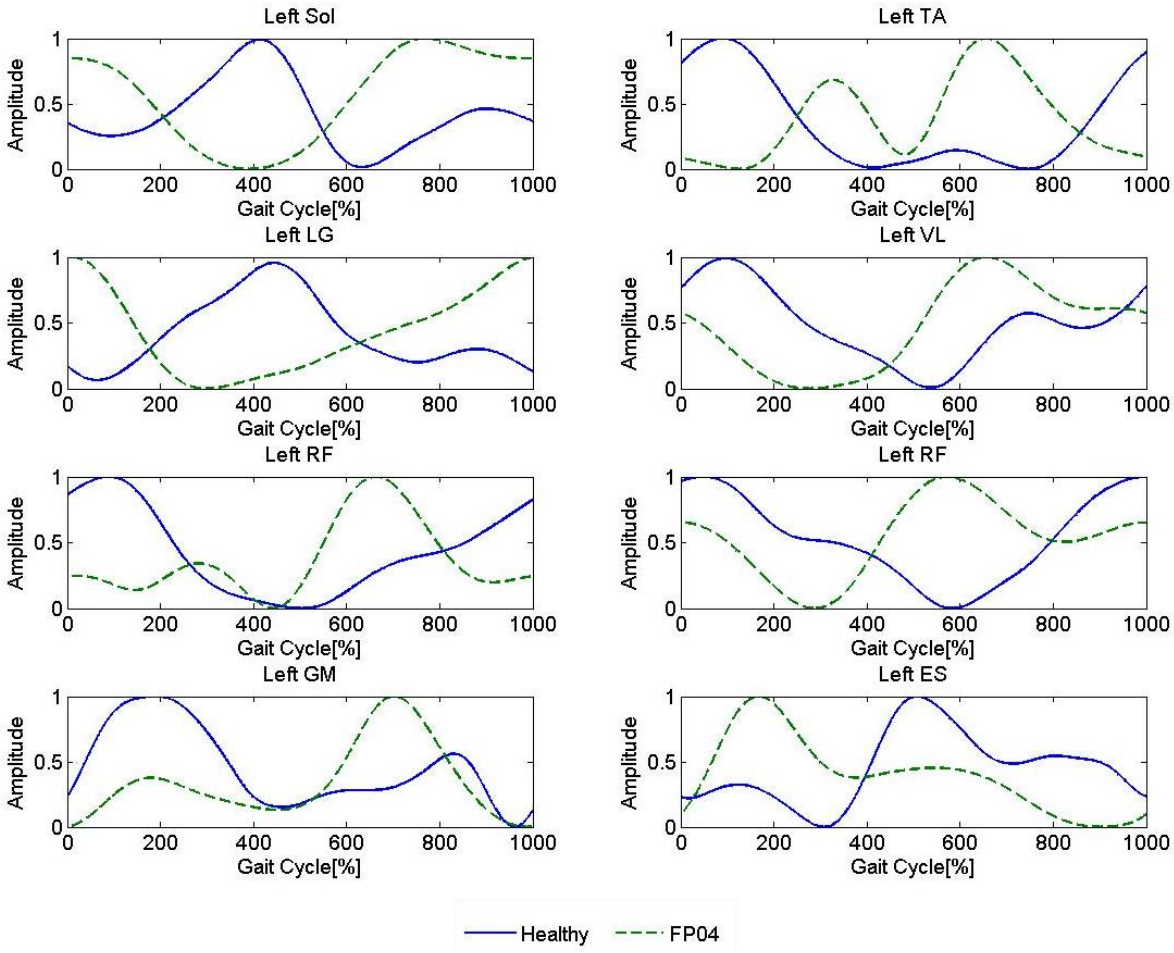

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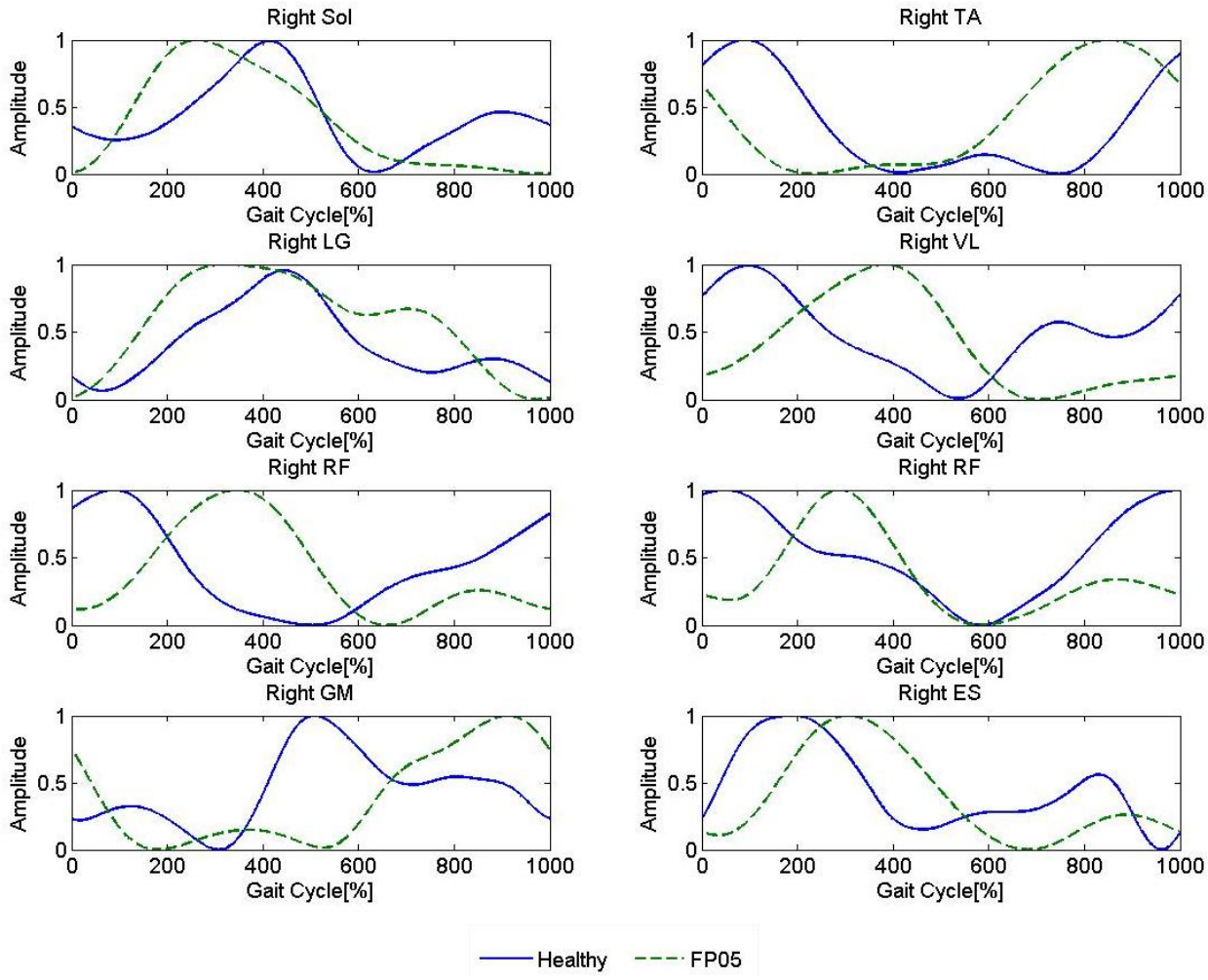

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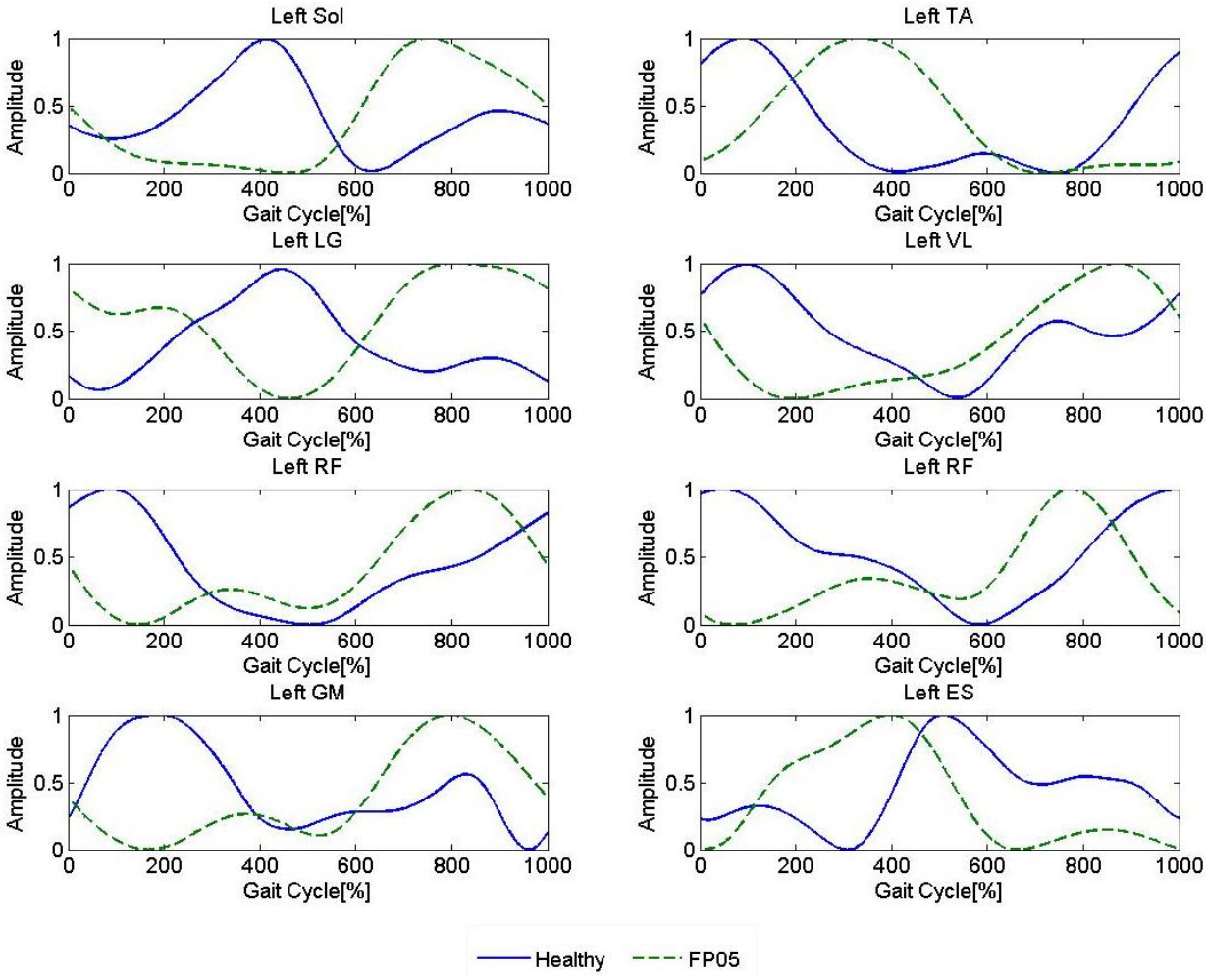
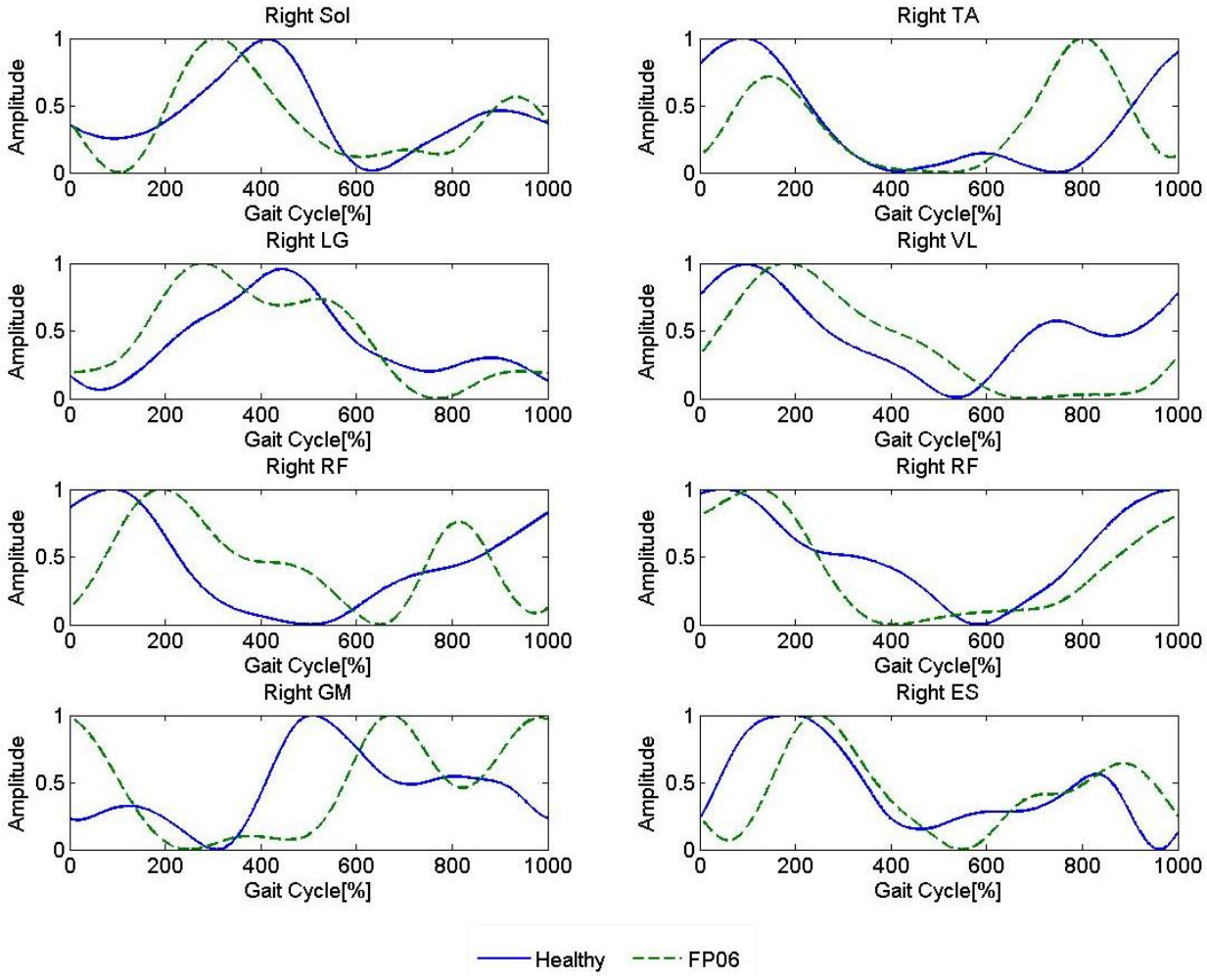
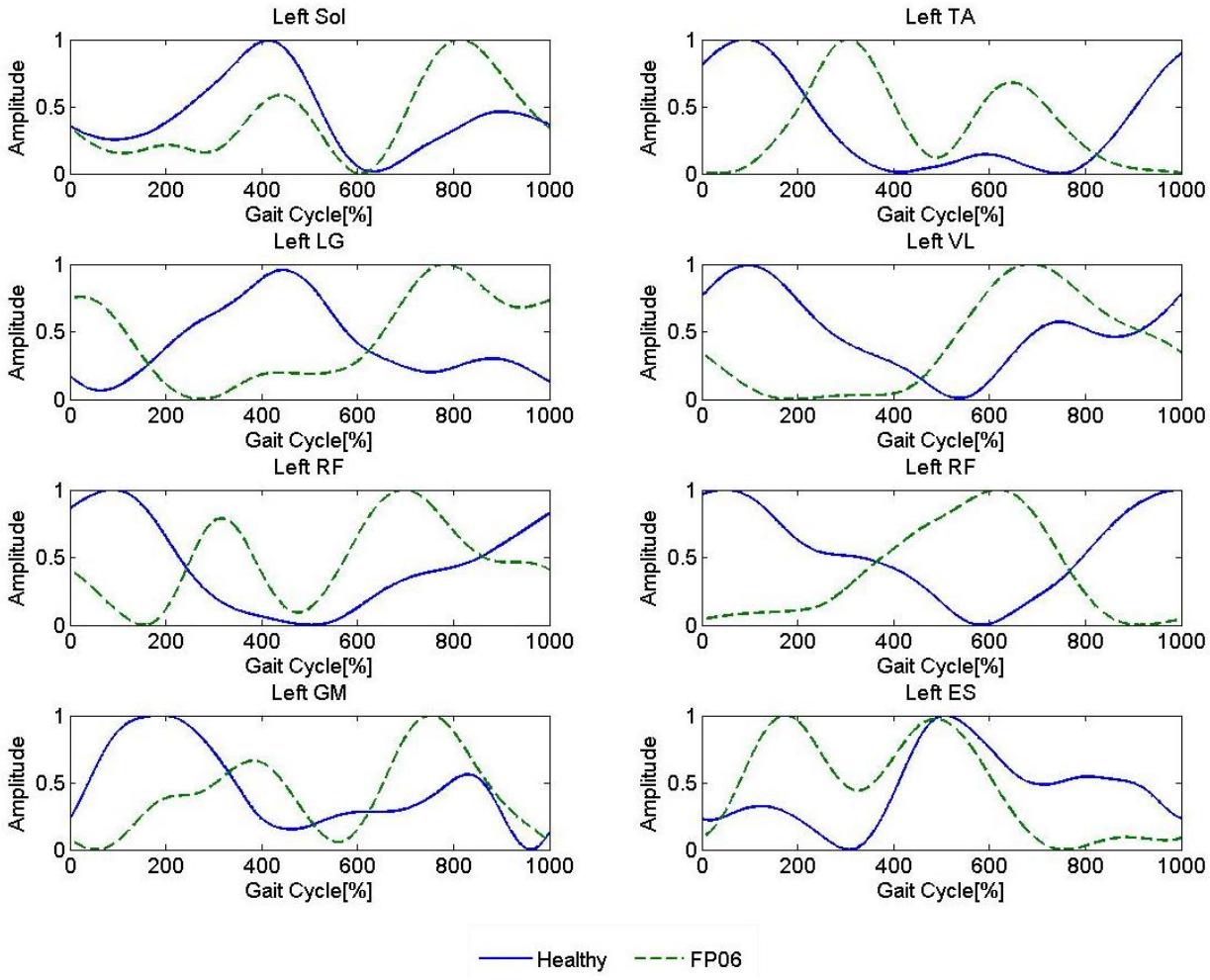


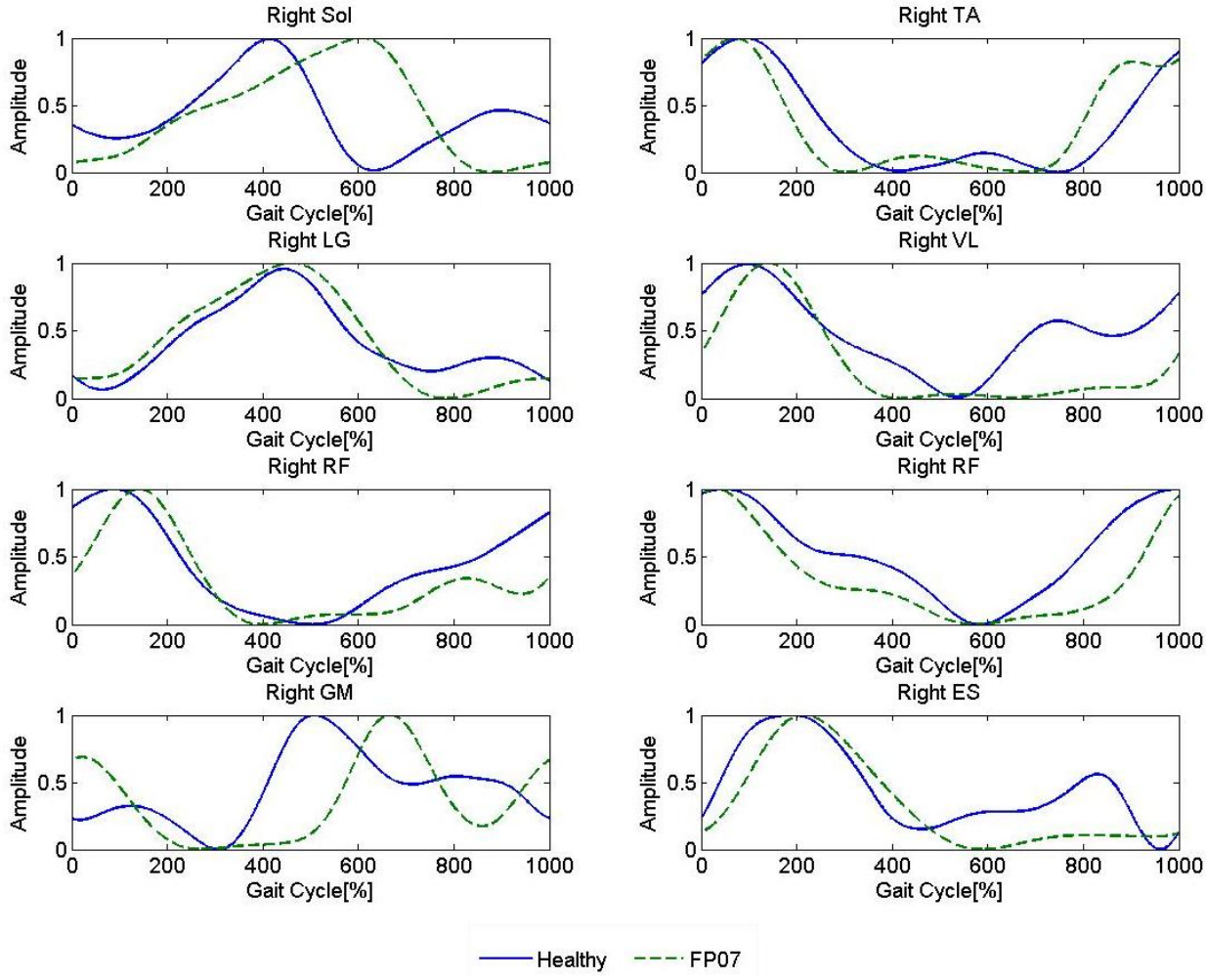
Left leg EMG pattern of FP05 in comparison to Knowledge Base



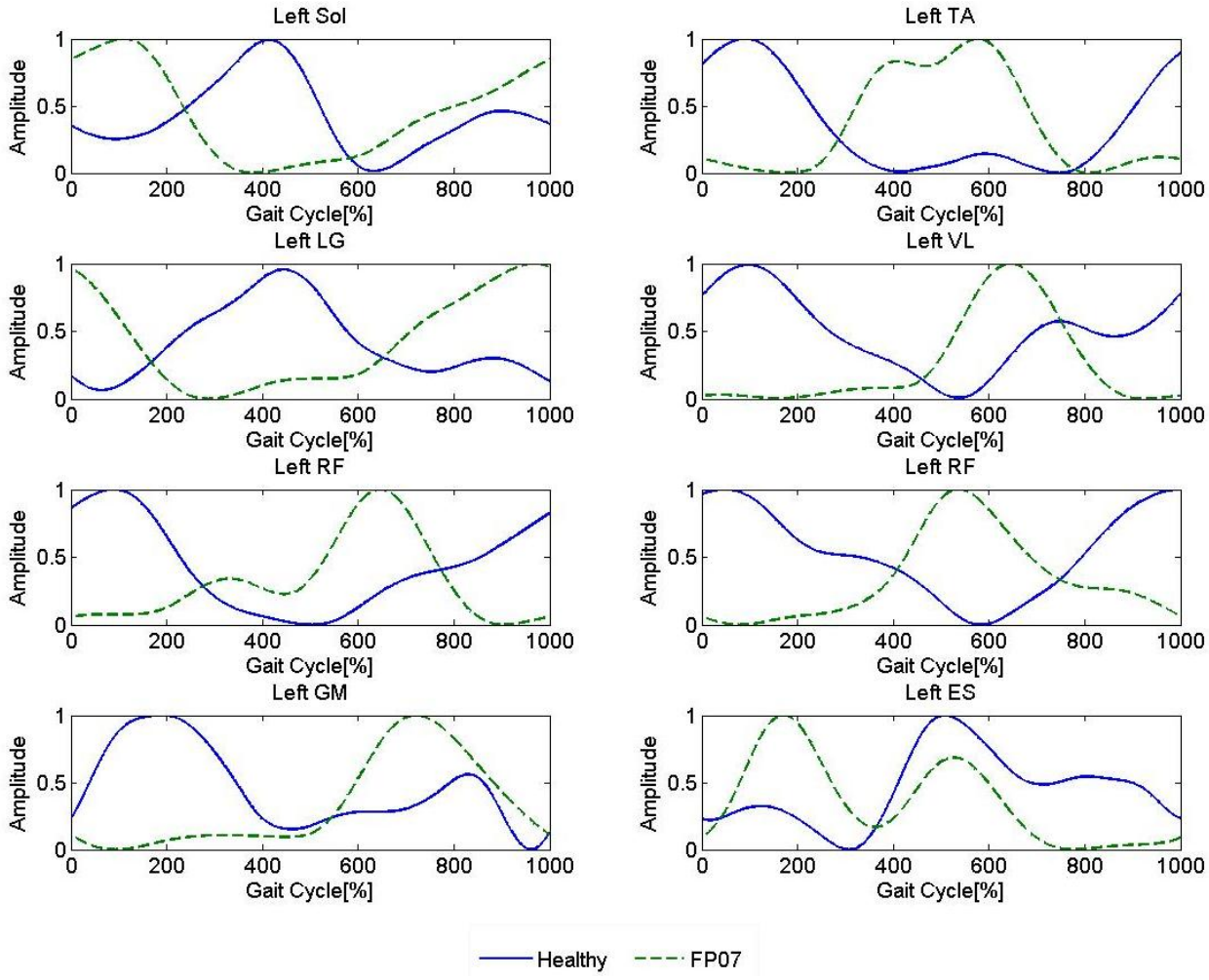
Right leg EMG pattern of FP06 in comparison to Knowledge Base



Left leg EMG pattern of FP06 in comparison to Knowledge Base



Right leg EMG pattern of FP07 in comparison to Knowledge Base



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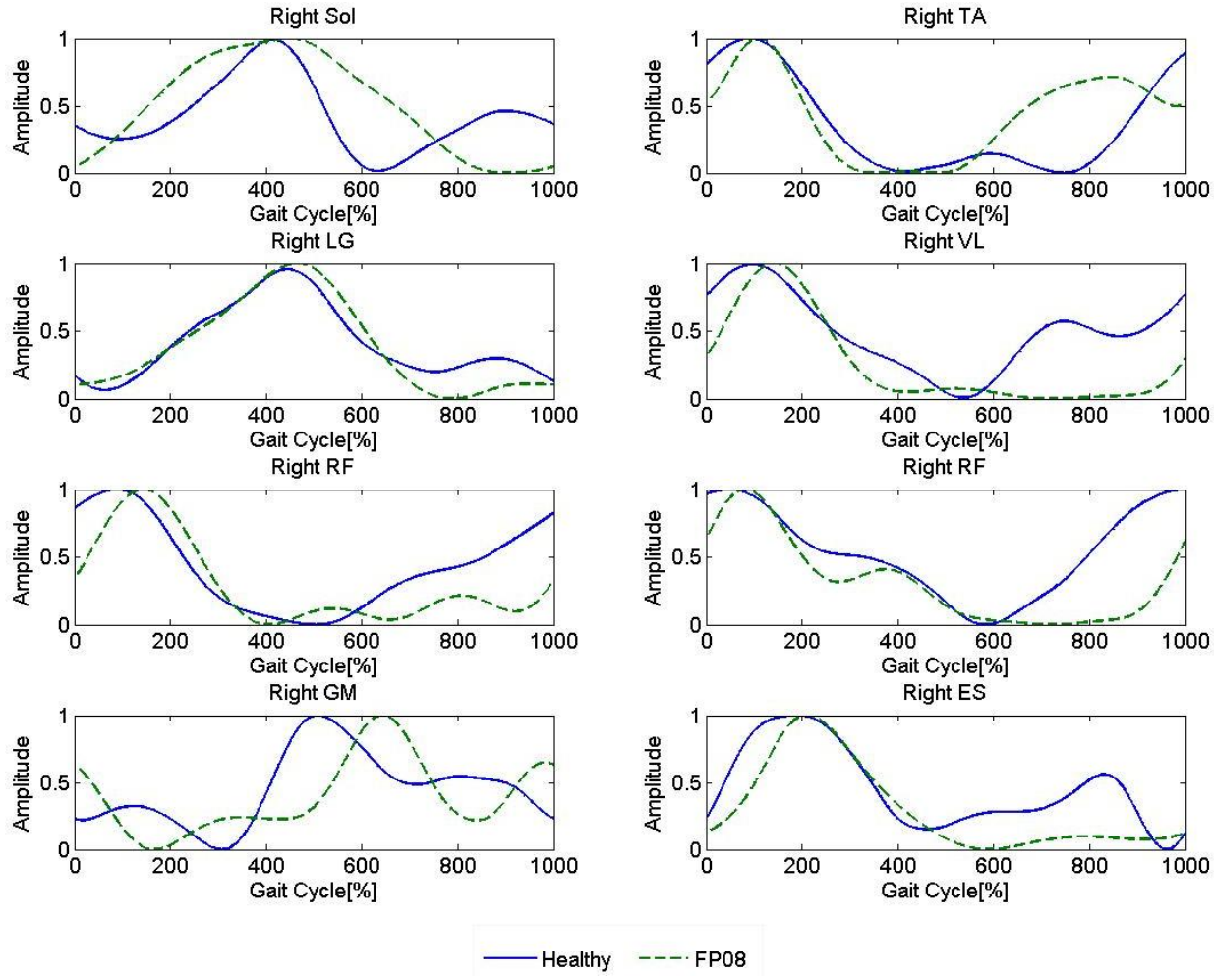
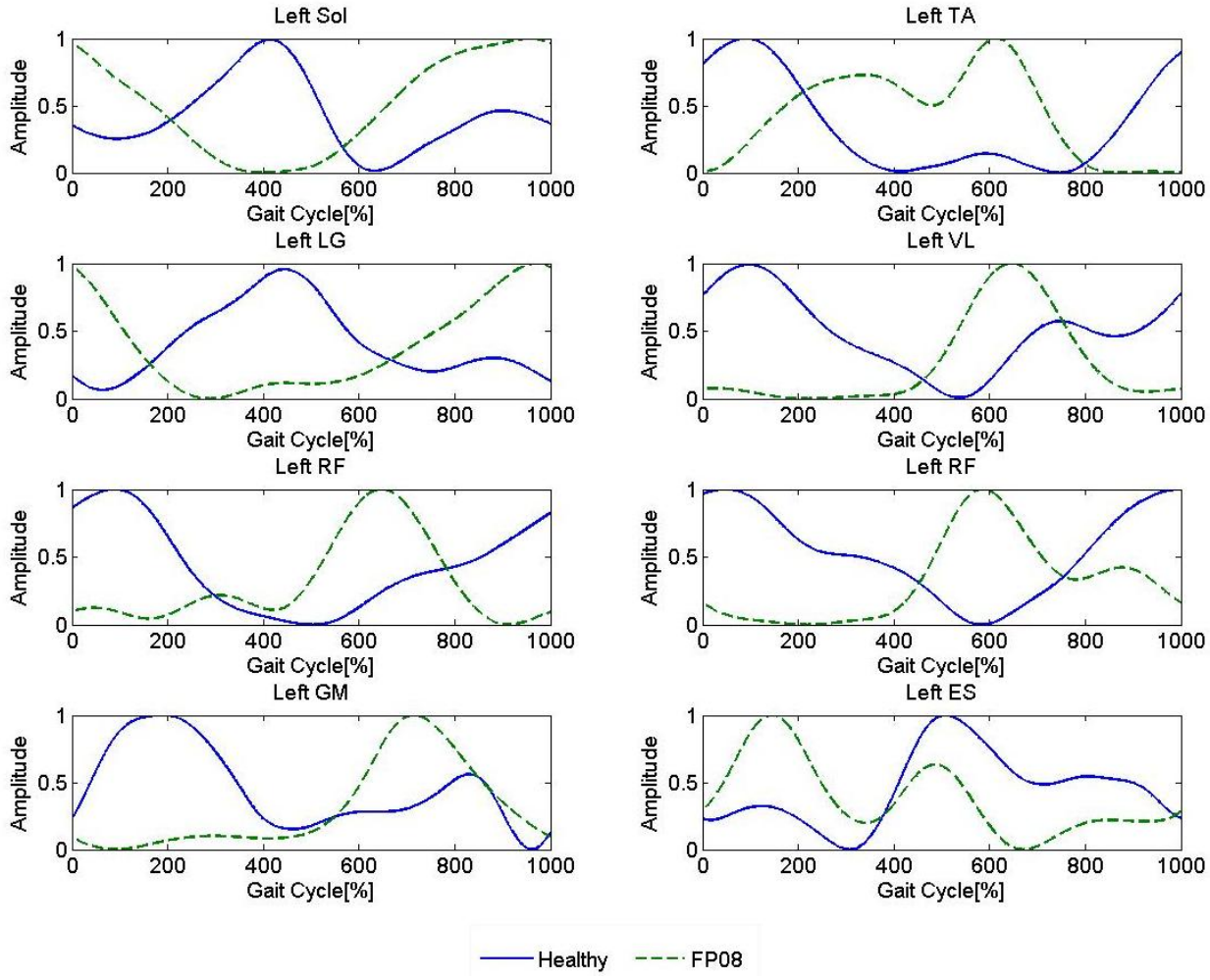


Right leg EMG pattern of FP08 in comparison to Knowledge Base



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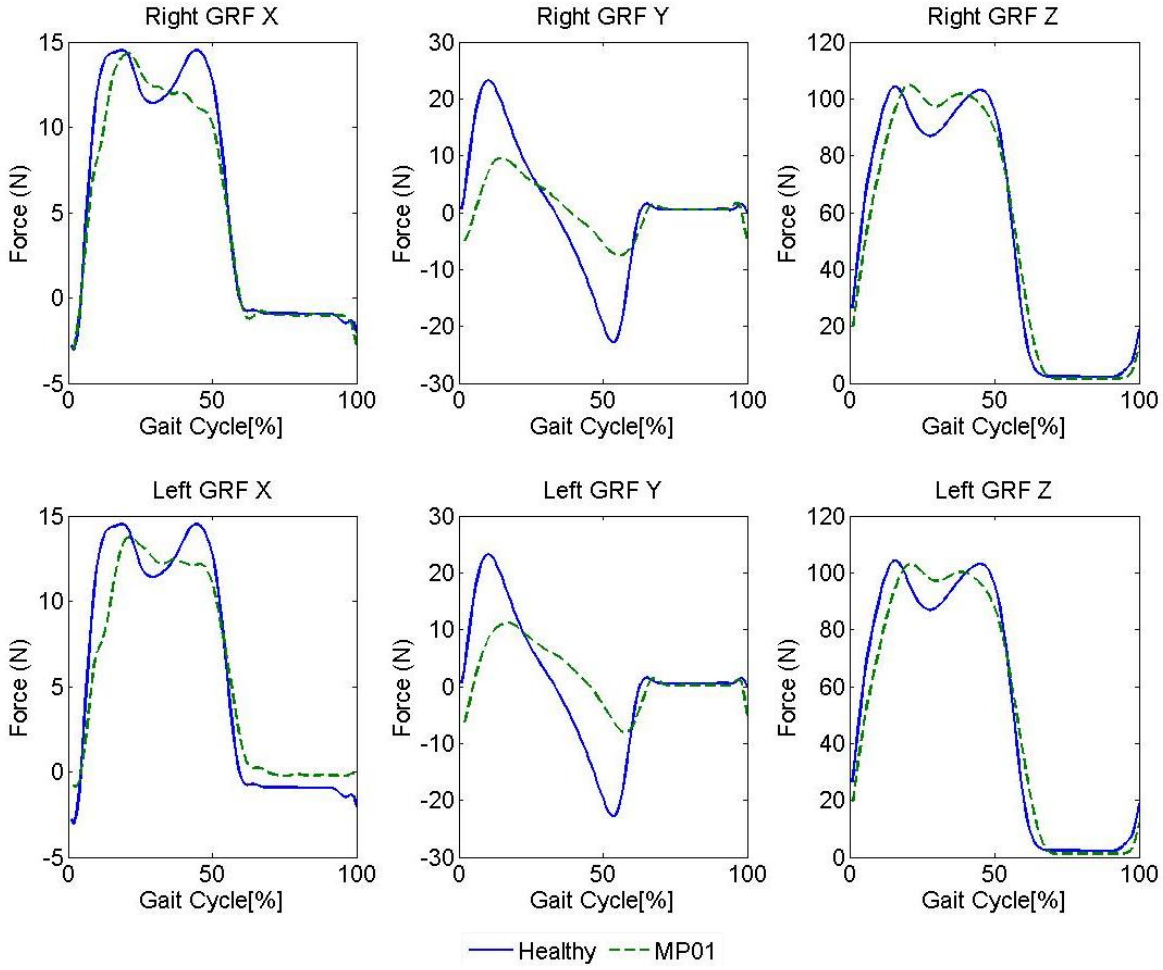
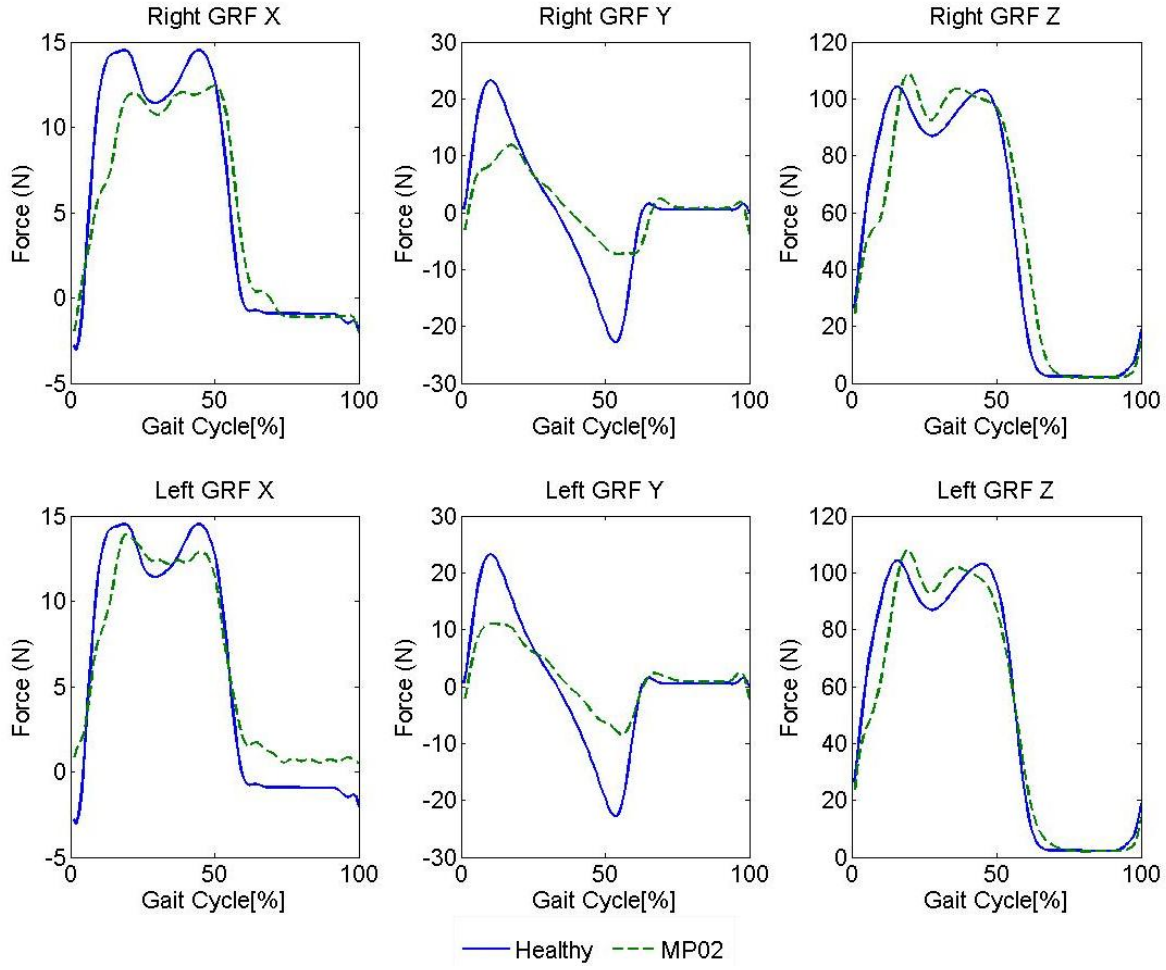


GRF pattern of MP01 in comparison to Knowledge Base



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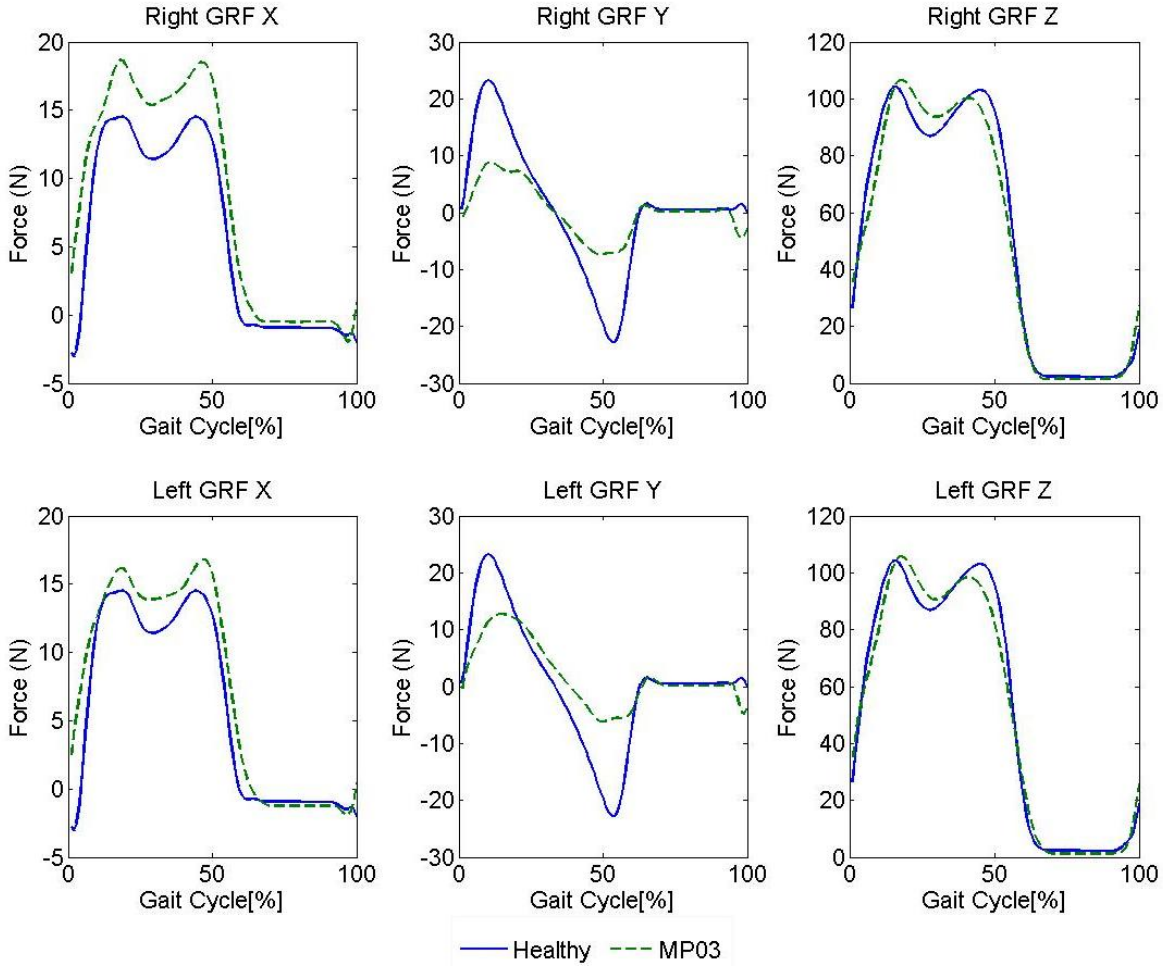

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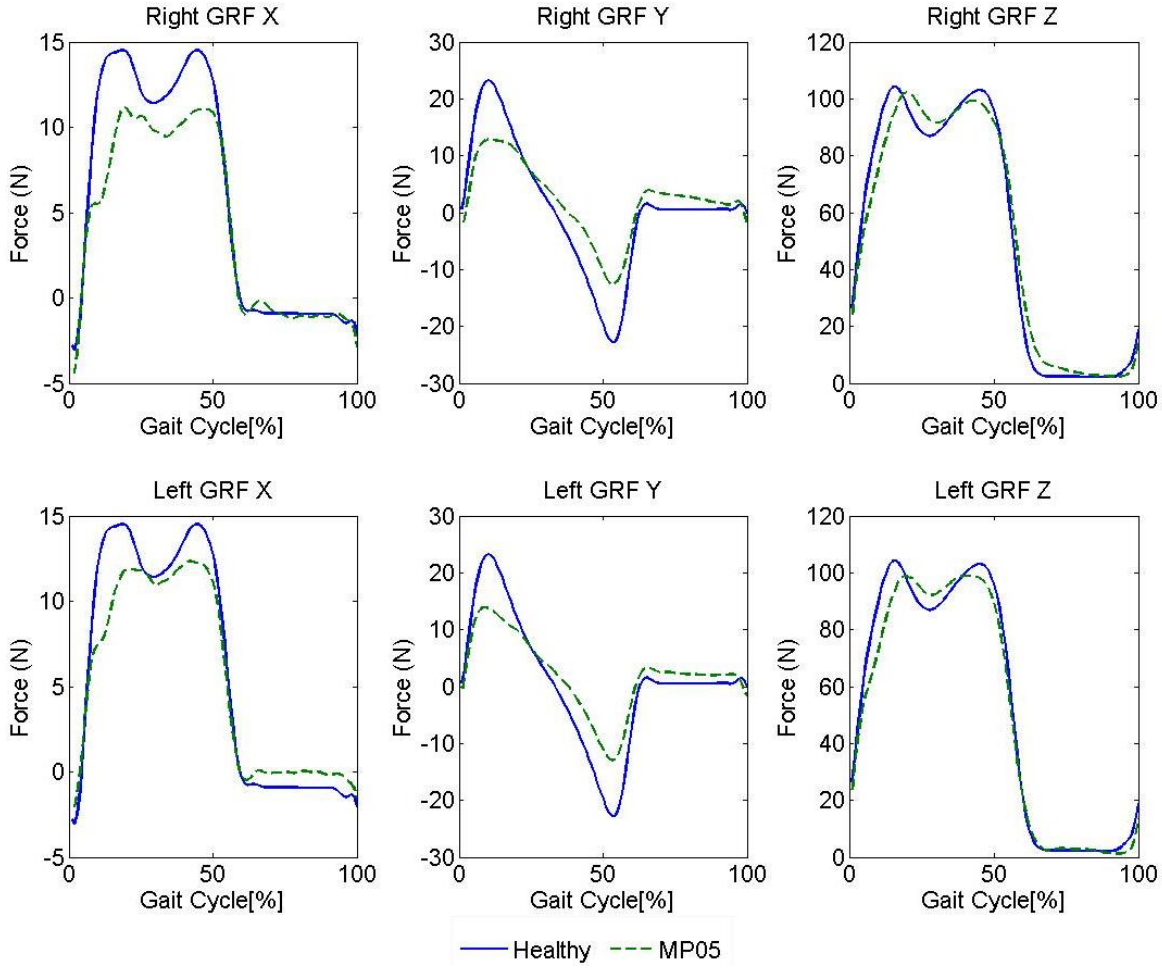

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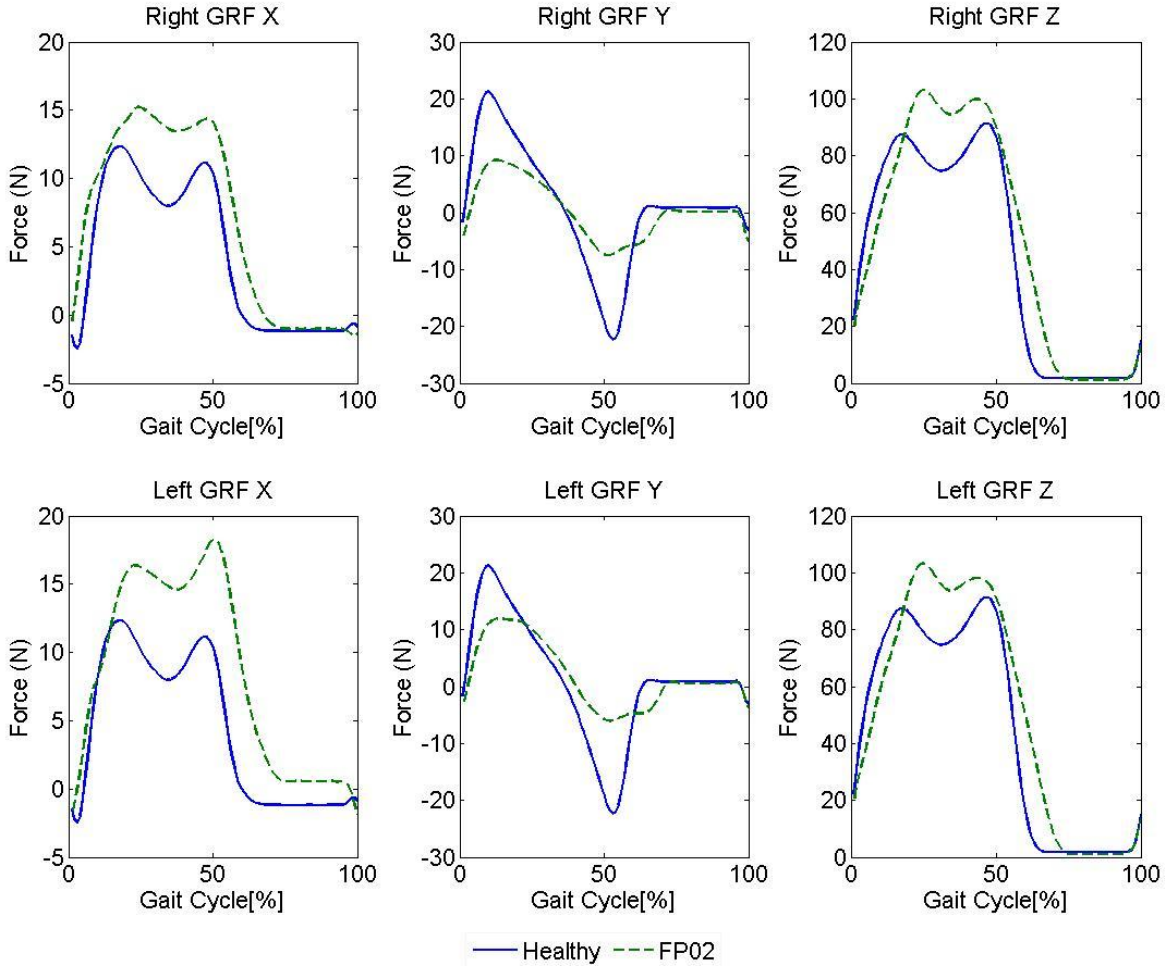

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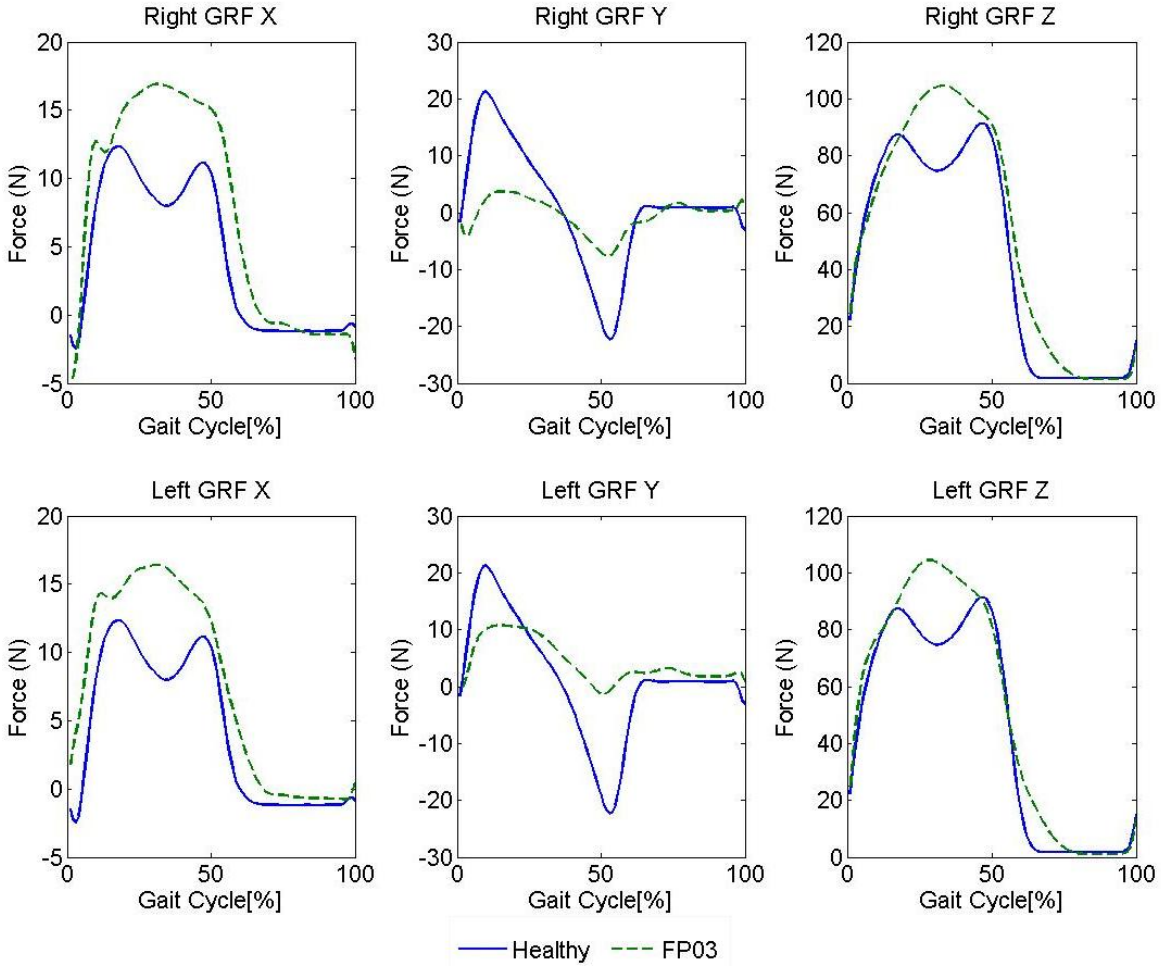

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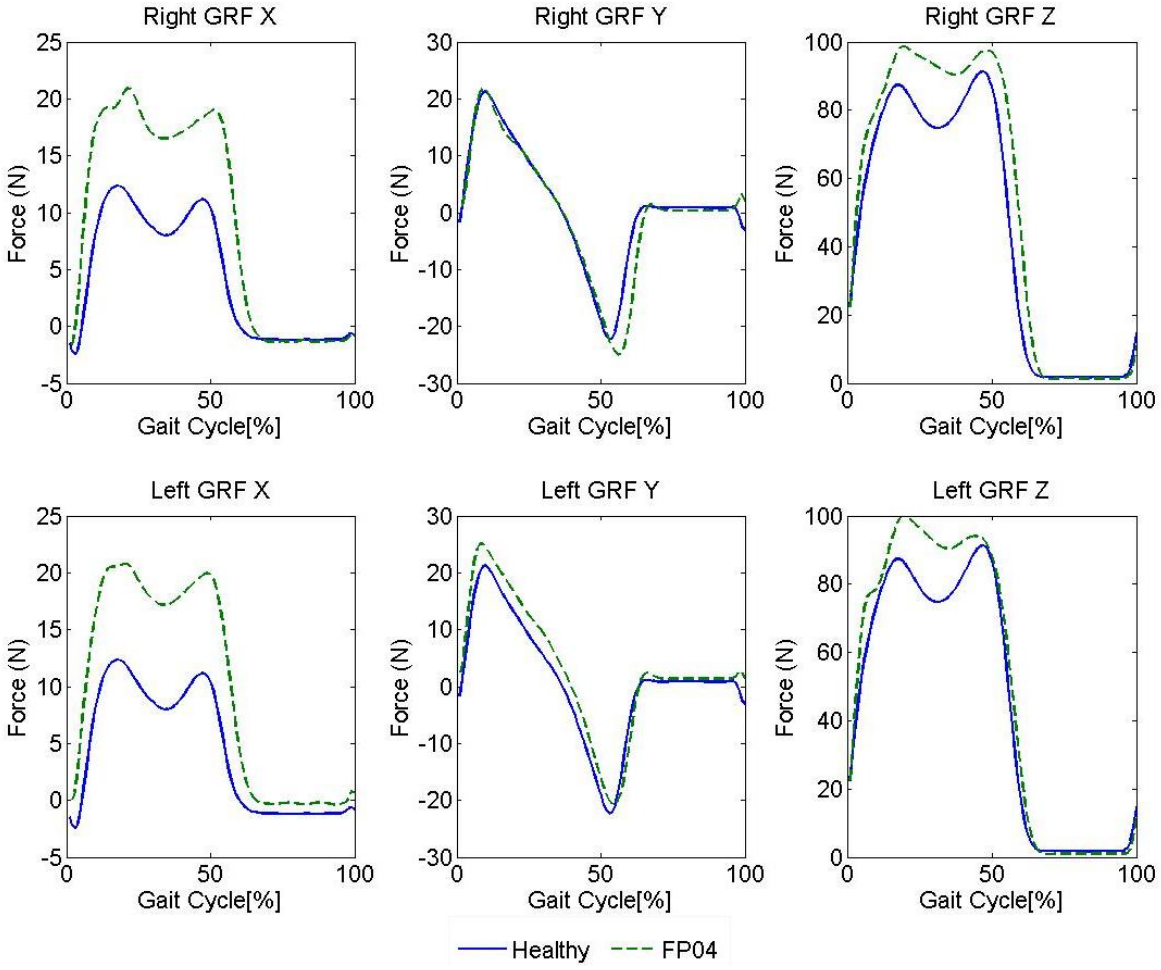

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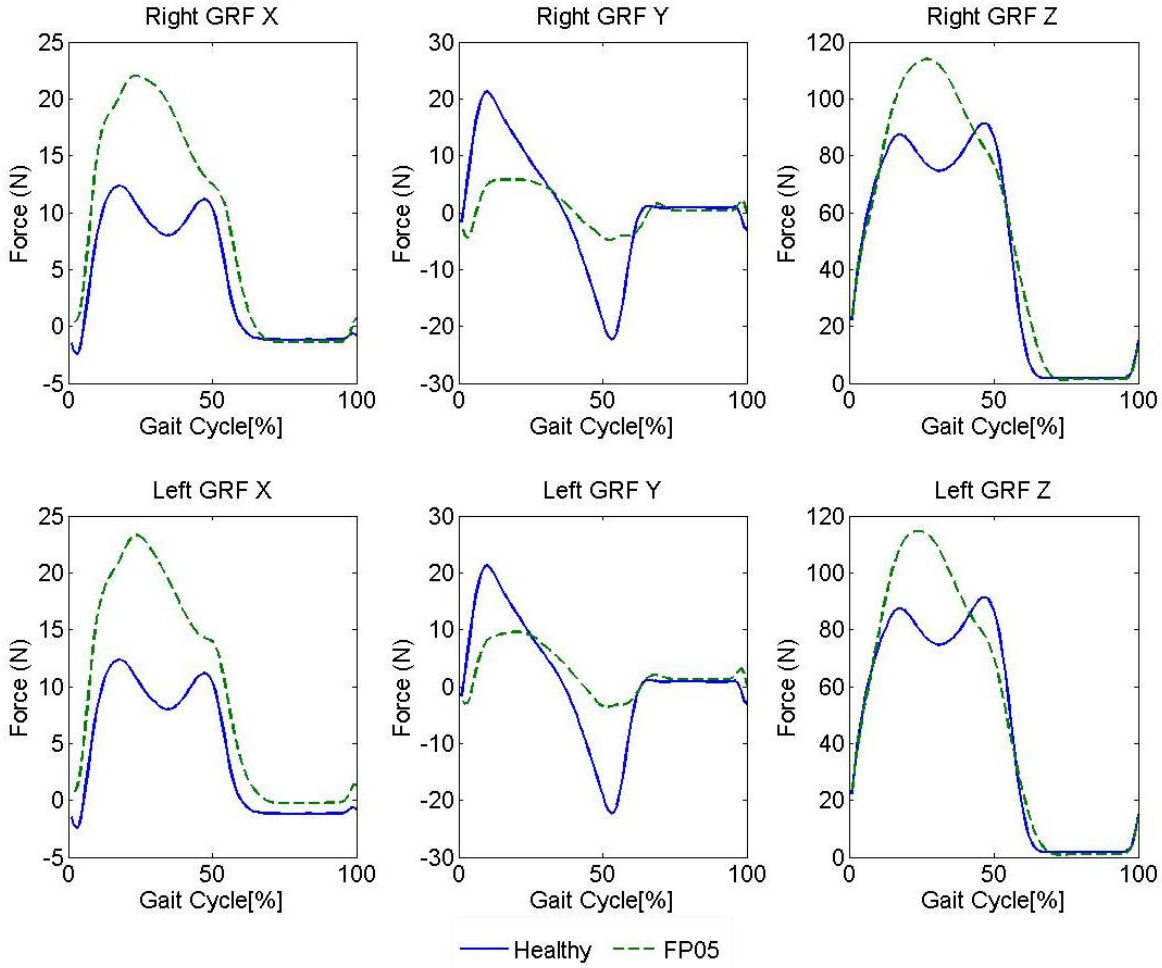

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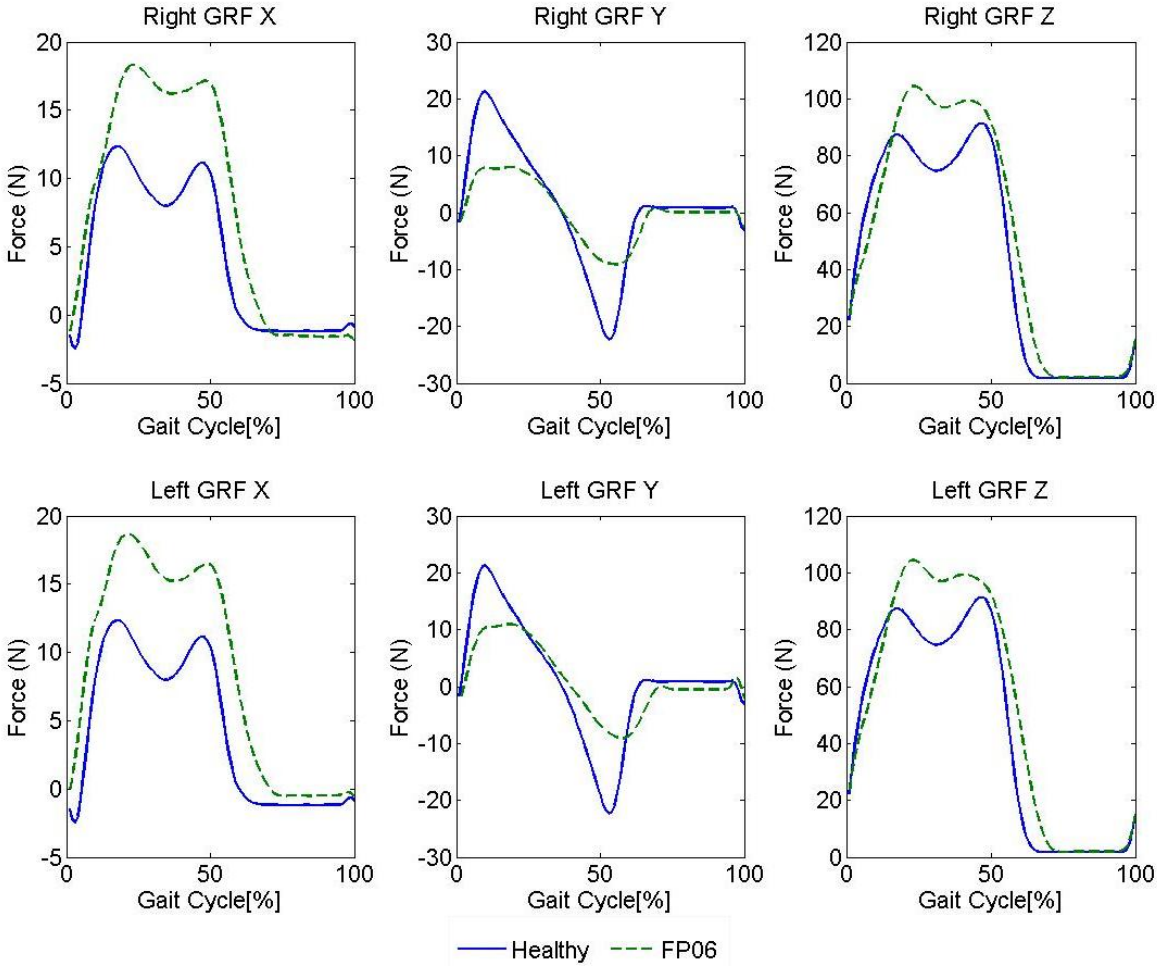

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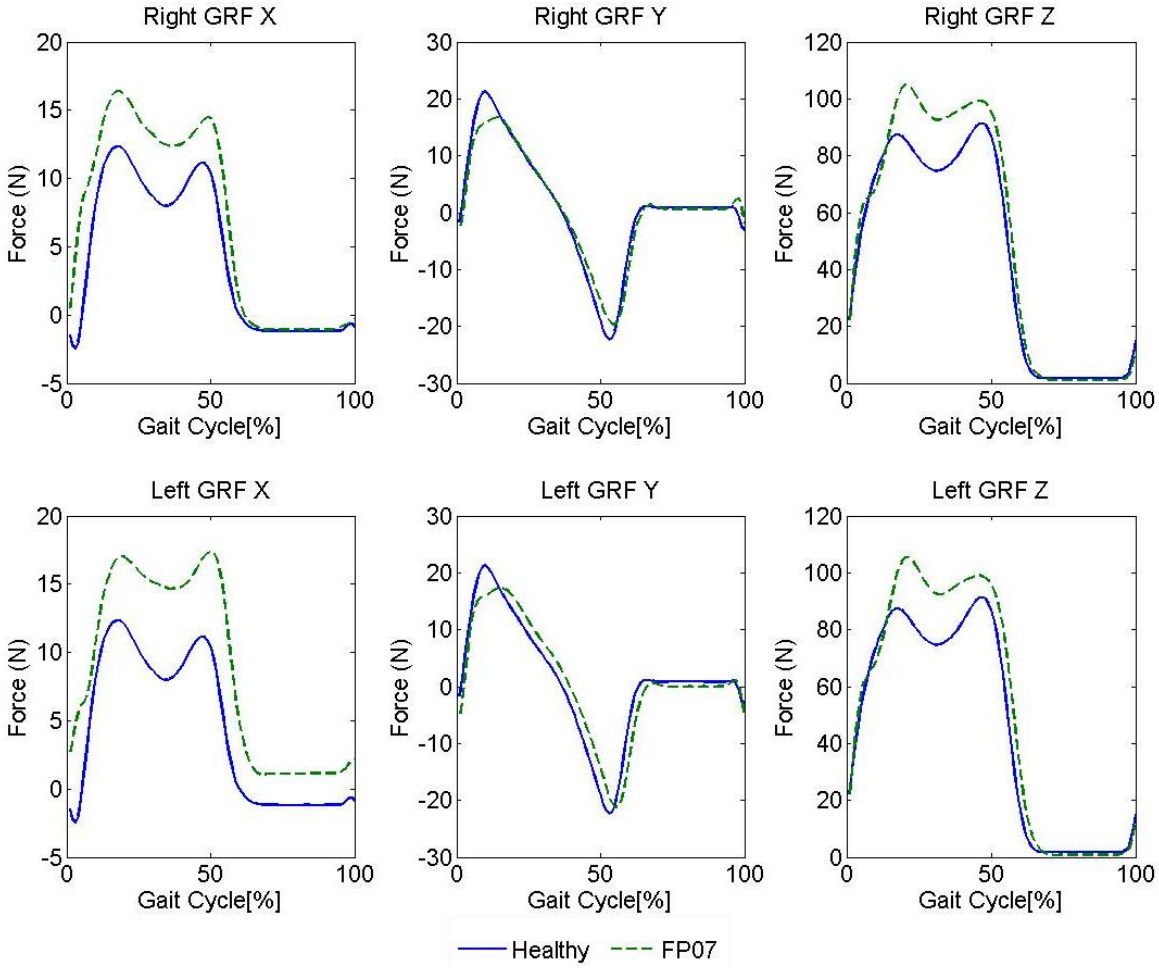

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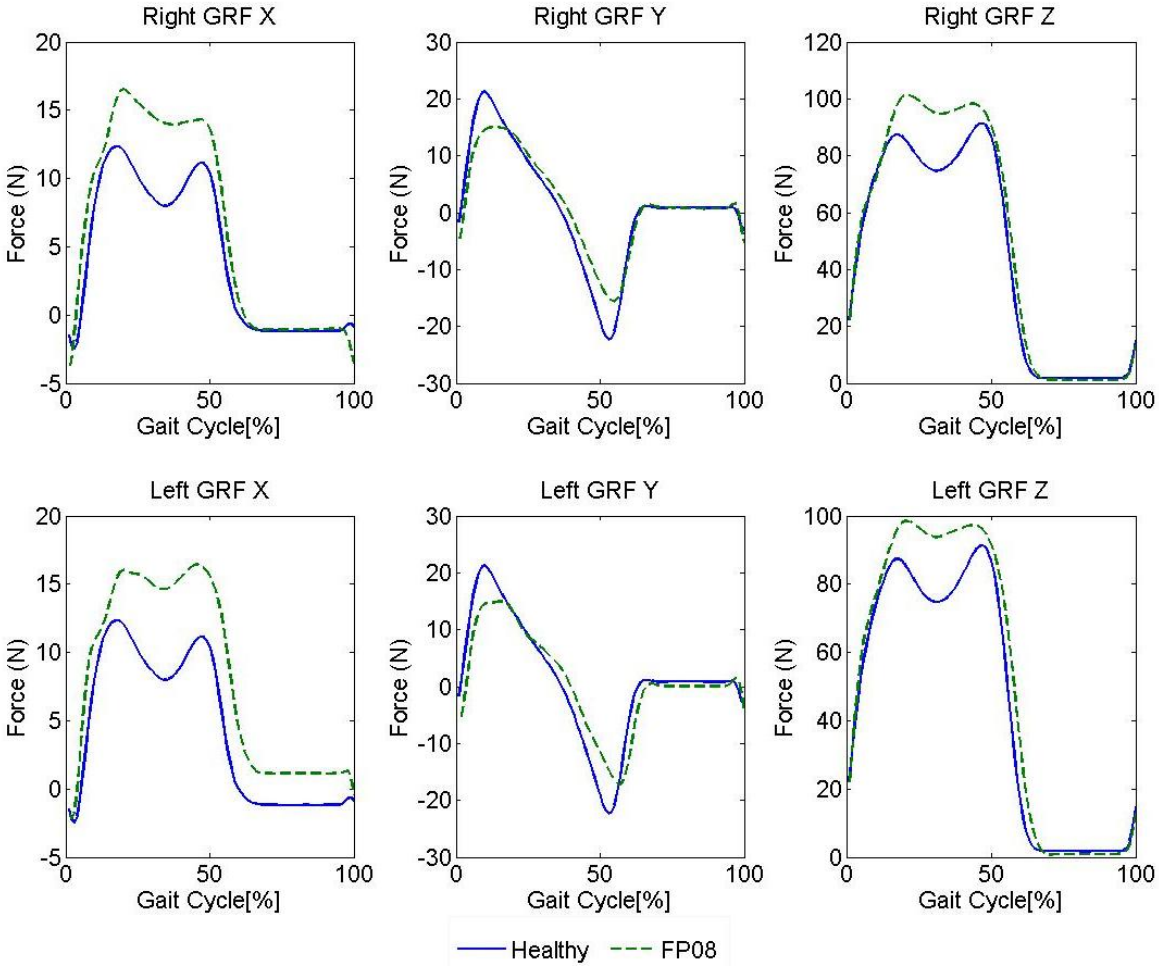

GRF pattern of FP08 in comparison to Knowledge Base

Vita

Came to the University of Texas at El Paso (UTEP) in 2003 after finished all elementary studies in Chihuahua Mexico from where is his home town. In bachelor he worked as teacher assistant for the department of Physics under the supervision of Dr. Jorge Lopez and Dr. Miguel Castro-Collins. At 2009 he completed satisfactorily the bachelor degree in Electrical Engineering. Right after he finished his degree, in the fall of the same year, he was accepted in the Masters program of Electrical at UTEP. Under the supervision of Dr. Thompson Sarkodie-Gyan, he is currently working in LIMA and Human Motion Labs on his thesis "The experimental quantification of the Diabetic foot". He is expecting to obtain his master degree on December 2011 and start working in the industry.