Design of a Telemetric Gait Analysis Insole and 1-D Convolutional Neural Network to Track Postoperative Fracture Rehabilitation

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***Abstract*— Accurate and objective monitoring of a fracture's healing process is both essential to patient quality of care, as well as determination of the chances of nonunion and postoperative intervention. In recent years, due to industrialization, injury rates in developing countries, notably road traffic injuries (RTIs), have drastically increased. This has led to many fracture patients in ill- equipped countries, such as Kenya with only 60 orthopedic surgeons for a population of 36.9 million, not having any rigorous rehabilitation protocol or quality postoperative care. This work focuses on the development of a telemetric gait analysis insole that works in conjunction with a mobile application and convolutional neural network. This technique automates the tedious process of tracking postoperative fracture rehabilitation by analyzing ground reaction forces (GRFs) of patients which correlate well with weight-bearing ability, fracture healing, and delayed union. 4 force-sensitive resistors (FSRs) are placed in the insole under the primary areas for force measurement. An Arduino microcontroller compiles the data and sends it to a Python program via a Bluetooth module. The Python program performs peak analysis on the data to determine the average peak Vertical Ground Reaction Force (VGRF) of the strides to measure if a patient is properly healing. As a further step, we employ a 1D-CNN to differentiate between healed and healing patients to automatically find which patients have nonunions. With these methodologies we are able to automatically diagnose rural patients with nonunions based on only ground reaction force measurements at minimal costs and without an on-site physician.**

Keywords*— *Telemetry, Gait Analysis, Insole, Weight-Bearing, Peak Analysis, Convolutional Neural Network

I. INTRODUCTION

A. Motivation

1) Lower Extremity Injury Prevalence: The economic boom occurring in developing countries comes at the cost of new and challenging problems, including the rapid increase of Road Traffic Injuries (RTIs) with the urbanization of rural areas. There is often a lack of legislation regulating the education of the local population on how to navigate the new infrastructure being constructed in their areas. This results in a higher prevalence of fractures and lower-extremity injuries in developing countries, accounting for more than 1.27 million deaths per year, and more deaths than HIV/AIDS, Tuberculosis, and Malaria combined [1]. However, the number of RTI injuries is more jarring, with 20-50 injured due to RTIs for every RTI related death [2].These 60 million injured patients expected in the next ten years place a significant burden on local, unequipped medical facilities [3]. This problem of exorbitant amounts of injuries is compounded by the lack of qualified specialists and an excessive number of under-qualified physicians referred to as Rural Medical Practitioners (RMPs) who have no formal education. These RMPs tend to over prescribe painkillers, in place of legitimate procedures, taking advantage of their uneducated clientele [4].

2) Delayed-Union and Nonunion: Approximately 5% to 10% of fractures worldwide proceed to nonunion, which is the improper bonding of a fracture (Fig. 1)[5]. This leads to permanent disabilities and a significantly higher use of healthcare resources, which often cannot be provided. Classically, the reasons for delayed-union and nonunion are complications including inadequate reduction, loss of blood supply, and infection, all of which are extremely prevalent in developing areas [6]. A well designed postoperative rehabilitation protocol can be implemented to identify any stagnations in the healing process; however, physicians in rural areas often cannot provide quality postoperative care, leaving their patients without outpatient facilities after surgery.

Fig. 1. X-Ray of a Humeral Nonunion[7]

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3) Benefits of Early Partial Weight-Bearing: Early weight-bearing is often absent from many rural rehabilitation protocols, with "just rest" being prescribed, as that is mistakenly seen as the best way to heal a fracture. However, early partial weight-bearing has been found to improve fracture healing, maintain bone stock and density, and keep the fracture and implants aligned early in the recovery process [8]. This research aims to promote early partial weight-bearing by providing the tools to safely execute the process.

B. Background

1) Telemetric Medicine: Telemetric medicine is a budding subfield of biomedical engineering that allows for patient-doctor communication from ranges of thousands of miles away. This has massive potential in addressing the problem of a lack of qualfied specialists, by giving under-served communities access to the qualfied specialists that they need. Currently telemetric medicine has been limited to first world countries, where elderly and disabled patients who are not capable of traveling to a hospital can be provided with quality care from the comfort of their home. However, current trends have shown rapid increases in the number of smartphones available to rural populations in developing countries due to a decline in phone prices. This has allowed for fast data transmission to these areas, as vaccine reminders and natural disaster alerts have become commonplace. This research takes advantage of this framework by allowing for direct patient to doctor communication over long distances.

2) Review of Gait Analytics Systems: Currently a majority of gait analysis is performed in two specific methods: a laboratory with force plates and 3-D motion tracking or in a doctor's office with a clinician making visual observations. The first method is extremely expensive and provides highly specialized and unnecessary data points while the second method is very subjective and is often not repeatable over several trials and patient visits. The benefits of insole-based gait analytics have been identified as an cheap and accurate alternative to laboratory and clinician-based gait analysis. Gait analysis systems measure a range of data types including foot angle, stride distance, step distance, step count, cadence, and speed [9]. Accelerometers are used for stride length and velocity, gyroscopes are used for orientation, flex-sensors are used for plantar and dorsi-flexion, electric field sensors are used for height above the floor, and finally force-sensitive resistors are used for force parameters which is the focus of this work[10].

3) Weight-Bearing Ability: Weight-bearing ability of the afflicted limb has been shown to greatly correlate with radiological evidence of fracture union and overall healing (Fig. 2) [5]. According to a study by S. Morshed, 84% of patients indicated that weight-bearing ability was the most important clinical criteria for diagnosis of delayed union and nonunion. Despite weight-bearing ability being the most critical factor in the diagnosis of nonunion, it is not often used due to the subjectivity of clinical observation and patient feedback being very unreliable and incomparable over the long term. This research presents an objective method to track weight-bearing ability, and allows for repeatability- crucial in the tracking of a patient's rehabilitation protocol.

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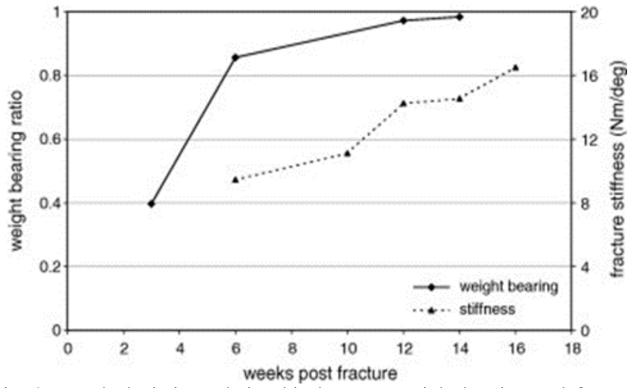

Fig. 2. Graph depicting relationship between weight-bearing and fracture healing [11]

4) Ground Reaction Force and Biomechanics: The method utilized to measure weight-bearing ability is the temporospatial gait parameter known as vertical ground reaction force (VGRF). In biomechanics, it is defined as the force exerted by the ground on the body, when in contact with the ground. Research has also suggested that ground reaction forces correlate well with callus mineralization and, more importantly, weight-bearing [12]. Therefore, an increase in ground reaction force indicates increased healing for the patient. While weight-bearing is subjective, ground reaction force measurements provide healthcare providers with a singular statistic that can be stored and automatically processed by computers in a setting where human involvement is scarce and valuable. The VGRF graph (Fig.3) displays the active peak, the point of greatest force in the gait cycle, which is the target statistic the insole aims to measure.

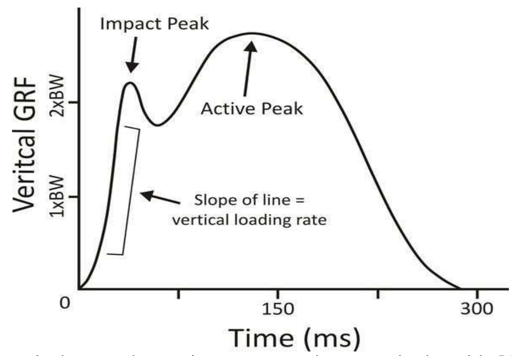

Fig. 3. Vertical Ground Reaction Force graph over a single stride [13]

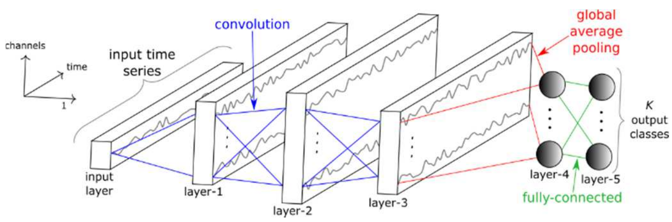

Fig. 4. 1-D CNN architecture for time series classification [14]

5) Review of 1-D Convolutional Neural Network and Time-Series Classification: For further analysis of a patient's gait patterns we utilized a 1-Dimensional Convolutional

Neural Network (CNN) that was designed for the use case of time series classification. Traditionally, CNNs have been used for imaging classification (2-D), and have more recently transitioned to speech and time series classification(1-D) [14]. In this work a time series is defined as a sequence of univariate data points indexed in the order of time such as the VGRF values depicted in Fig. 3. Time series such as ECG values are some of the most common datatypes in medical research with 1-D CNNs being utilized on ECGs extensively [15]. The CNN architecture utilized in this work is the Omni-scale CNN (OS-CNN) which is novel in that the model treats the identification of the kernel size as a learning process rather than a hyper-parameter [16]. An input time-series is passed through three convolution layers that learn weights, then a global average pooling layer that down samples, and then a fully-connected layer for classification (Fig. 4.).

II. Materials and Insole Design

A. Insole Design Criteria

The insole was chosen as the primary data acquisition device due to the low relative cost in comparison to force plates. Force plates are traditionally used in gait analysis but are not viable due to their extremely high cost. The insole was also designed to be less than 300 grams, as any heavier weight has been found to greatly alter gait parameters, resulting in inaccurate data [10]. Small, individual sensors were used in place of larger sensors, minimizing hysteresis and inaccuracy in measurements across multiple trials.

B. Force-Sensitive Resistors and Placement

The insole uses 4 force-sensitive resistors (FSRs) which utilize polymer-thick film technology and provide a resistance differential based on the force exerted. Polymer-thick film sensors are constructed by the deposition of several dielectric layers via a screen-printing process, making them extremely cheap and lightweight compared to their capacitive sensor counterparts. To maximize cost efficiency, 4 locations on the sole of the foot, which were identified via a pedobarograph (Fig. 5) to have the greatest concentration of force, are where the FSRs would be placed. The locations on the sole of the foot determined to have the greatest concentrations of force were under the big toe, metatarsal head I, metatarsal head V, and the heel [17].

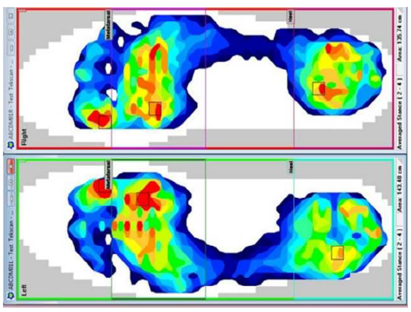

Fig. 5. Pedobarograph representing areas of highest force concentration [18]

C. Hardware Structure and Data Pathway

The data from the FSRs is then sent to a Velcro strap ankle-mounted Arduino Nano microcontroller. The Arduino microcontroller compiles the data and uses a Bluetooth module to send the data via Bluetooth low energy signals (Fig. 6). In gait analysis, wireless technology is heavily utilized and beneficial as wired technology greatly affects the target gait parameters, resulting in nonrepresentative data. The data is then received by the data analytics software, which is written in the Python programming language.

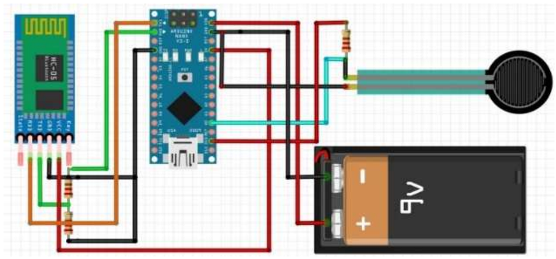

Fig. 6. Insole hardware wiring including an Arduino Nano and HC-O6 Bluetooth Module

III. Data Analysis Software

A. Python Code and Peak Analysis

The Python program performs peak analysis to acquire the active loading peak of the ground reaction force. Table 1 is an example of an acquired raw dataset in newtons that requires peak analysis. Each data point in Table 1 is taken every 30 milliseconds from the insole and is stored in the table. Fig. 7 is a plot of the data in Table 1 and depicts how peak analysis functions. The red point in each step represents the active loading peak or the max VGRF for that step. An algorithm included within the code performs this process by defining a step as an array of non-zero digits separated by zeroes, where the largest value in that array is extracted and tagged as the VGRF of that individual step. When analyzed intuitively, the non-zero digits are the instances when the foot is in contact with the ground, while the zero digits are when the foot is in the air, providing no data to the force sensors. To provide robust and accurate data, the program is designed to average the VGRF value over multiple strides (N>6) during the trial, as to negate any outlying force values. 6 strides were chosen as it is the minimum value of steps needed to provide representative gait analysis data including ground reaction force [19].

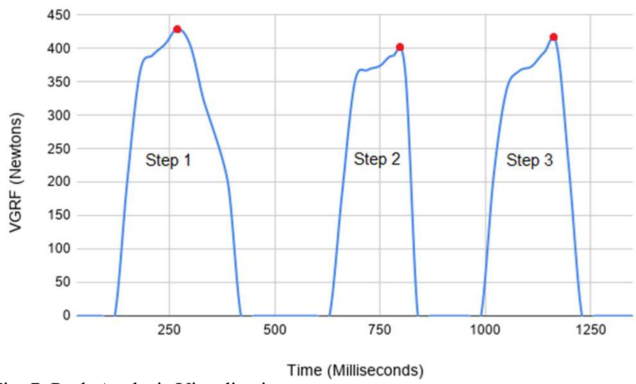

Fig. 7. Peak Analysis Visualization

Table 1. Consecutive VGRF Values (Newtons) Acquired from Insole (Left to Right and Top to Bottom)

0	0	0	0
203.2	364.8	389.6	406.4
429.2	403.2	324.8	194.4
0	0	0	0
183.2	348.8	367.2	373.6
388.4	364.8	0	0
0	0	0	0
208.8	336.0	365.6	372.8
393.6	404.0	212.8	0

B. Smartphone Application

To provide patient-centered care, a mobile app was developed through the program MIT App Inventor that provides the patient with data and communication tools that allows for proper management of their injury (Fig 8). The application includes access to the cloud database, a graph of weekly values, and emailing functionality. The design is focused on simplicity of use and upon initialization of the app, the user is shown a welcome screen in which they can visit their history or begin a test. Patient history includes a table and graph of weekly data to aid patients in visualization of the healing progress of their fracture. To perform automatic risk analysis, the application tags patients with stagnation or reversal of VGRF as high risk and tags patients with increases in VGRF as low risk. Testing is done over individual IP servers in order to protect privacy and connect with the API database.

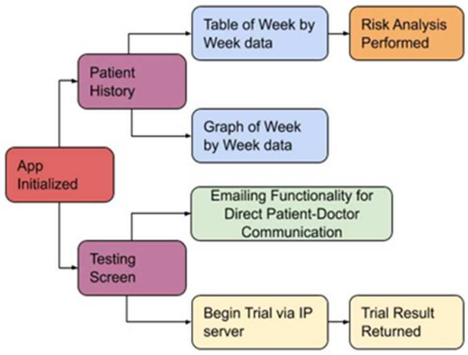

Fig. 8. Mobile Application Initialization Pathway

C. 1-D CNN for State of Healing Classification

In addition to peak analysis which determines progression of healing, we also developed a neural network for the purpose of state of healing classification. The neural network provides more clinically relevant data than simple peak analysis.

1) Data Collection: For this work, we used the ground reaction force dataset known as GaitRec [20]. The dataset was collected by Austrian Workers' Compensation Board (AUVA) who have been using GRF assessments to treat fracture patients for more than two decades. Data was recorded by asking patients and healthy controls to walk unassisted for approximately 10m with two embed force plates. Each patient would walk for 10 total trials and would revisit every week until a medical professional deemed the fracture as healed. Three GRF signals were extracted (vertical, anterior-posterior, and medio-lateral) as well as center of pressure (COP). For the purpose of this work we used solely the vertical GRF values as they have been shown to correspond the greatest with fracture healing status [12].

2) Preprocsseing: The patients were also separated into classes based on their type if injury (hip, knee, ankle, and calcaneus). Previous research has aimed to differentiate the injury classes via machine learning, but the aim of this research is to classify based on state of healing so the calcaneus class was chosen to reduce variability among patients [20]. Among calcaneus patients, subjects with left side injury and both legs injured were excluded as well as patients that had large gaps in rehabilitation timeline. The two classes in our research were patients on their final day of rehabilitation when they were deemed as healed vs patients throughout the remainder of the healing process. This allowed us to classify patients based on their state of healing which was determined by the doctor on-site.

3) OS-CNN Model Development and Testing:

a) Input Size: The GaitRec dataset included processed data that is optimized for machine learning and neural network development. This processed data was filtered via a 2nd order low-pass Butterworth filter that was time normalized to 101 time-steps. This time normalization is significant as it creates a fixed input size of 101 points which the CNN model requires. Without this time normalization the time-series input sizes would differ greatly due to the patient self-selected pace.

b) Network Architecture: Pytorch, a python-based machine learning framework was utilized in conjunction with the OS-CNN [16]. The OS-CNN as previously mentioned, treats kernel size as an aspect of the learning process rather than the traditional method of manually searching for the ideal kernel size as a hyper-parameter. The model consists of three convolution layers. In the first two convolution layers, kernel size is a variable defined as a prime number from 1 to N. This allows the model to find and extract the ideal Kernel size for the model. In the final convolution layer, the kernel sizes are only one and two as to cover all possible integers. In traditional CNNs the pooling layer is placed after each convolution layer, but in this model a global average pooling is utilized after multiple convolution layers. Pooling is utilized in CNNs to down sample features and reduce dimensionality as to increase the robustness of a model and reduce overfitting. Finally, a fully connected layer is used as a classifier to choose labels based on the features extracted by the model.

IV. Results and Discussion

A. Hysteresis and Quality Analysis of Insole

FSRs are rarely used in biomedical devices, as consistency and accuracy are one of the most important criteria for success, and FSRs have classically been more susceptible to inaccuracies. An experiment was designed to test the quality of the insole, the extent of hysteresis and the inaccuracy of the sensor over time. Hysteresis or deviation is the inaccuracy of a sensor's indicated values from actual values which occurs in all sensors and is accounted for. The graph (Fig. 9) plots sensor hysteresis against hours of use under the stress from weight that simulates human locomotion. The control was a singular unoptimized FSR, and it was compared to the insole designed with optimized FSRs by placement, size, and resistance. The graph below shows clear reductions in the amount of hysteresis for the optimized and designed insole. A 2-Sample T-Test for the final hysteresis values was performed with 30 trials, using a significance value of a=.05. The test results in a p-value of 0.021 indicating statistical significance.

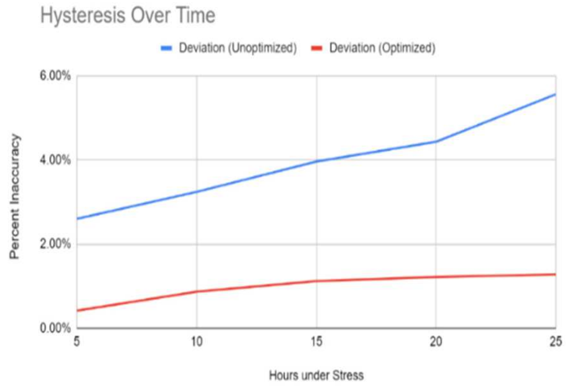

Fig. 9. Hysteresis or inaccuracy overtime: optimized vs unoptimized sensor

B. OS-CNN Performance Evaluation

For performance evaluation we utilized the cross-validation technique of a train test split with a 80:20 ratio and a balanced dataset of 50% fractured patients and 50% healed patients. As a baseline to compare the performance of the OS-CNN model we tested the dataset on a Support Vector Machine Model which achieved a 36.78% accuracy. When tested with an epoch hyperparameter value of 200 the OS-CNN model achieved an accuracy of 88.76% which is comparable with clinical observations.

V. Conclusion and Future Work

A. Conclusion and Real-World Application

This work addresses a commonly overlooked lapse in the healthcare system of a significant portion of the world's population. The addressed issue of increased road traffic injuries will continue to exponentially grow in coming years. Novel solutions for the proper healthcare and rehabilitation of these injuries will be required to maintain a high quality of life for those afflicted. The hardware utilized is optimized for the specific use-case of a rural and low-income setting in conjunction with a software application designed to utilize the overdeveloped sector of communications technology in developing countries with many rural villagers owning smartphones. The convolutional neural network aspect of this work is a step towards noninvasive, cheap, and automatic verification of a healed fracture site that could save lives and monetary capital in terms of travel to hospitals, doctor fees, and medical equipment that would most benefit the poorest among us.

B. Future Work

1) CNN-LSTM and Data Collection: With Convolutional Neural Networks with Long Short Term Memory and the application of more advanced neural network models, the accuracy on this dataset could be vastly improved as this dataset has not been explored extensively in this context. The hardware in this work could also increase the accuracy of the models because a downside of neural networks is the vast amount of data needed to train and create an accurate model [21]. The data that is collected in the field from this work could contibute to gait analysis databases and therefore increase accuracies.

2) Other Gait Disorders: Research has shown that other common disorders such as Parkinson's Disease and Cerebral Palsy have clear lower-extremity gait related symptoms [22][23]. The systems and hardware implemented in this work can be adapted to other gait related disorders such as the ones mentioned. As the modern hospital moves more towards the patient's home, telemetric medicine will become more commonplace with medical devices such as the one presented in this work becoming heavily utilized.

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