A Wearable Biofeedback Device for Monitoring Tibial Load During Partial Weight-Bearing Walking

Tao Ma, Xun Xu, Zhiwei Chai, Teng Wang, Xiantao Shen, and Tao Sun, *Senior Member, IEEE*

***Abstract*— Patients with tibial fractures are usually advised to follow a partial weight-bearing gait rehabilitation program after surgery to promote bone healing and lower limb functional recovery. Currently, the biofeedback devices used for gait rehabilitation training in fracture patients use ground reaction force (GRF) as the indicator of tibial load. However, an increasing body of research has shown that monitoring GRF alone cannot objectively reflect the load on the lower limb bones during human movement. In this study, a novel biofeedback system was developed utilizing inertial measurement units and custom instrumented insoles. Based on the data collected from experiments, a hybrid approach combining a physics-based model and neural network architectures was used to predict tibial force. Compared to the traditional physics-based algorithm, the physical guided neural networks method showed better predictive performance. The study also found that regardless of the type of weight-bearing walking, the peak tibial force was significantly higher than the peak tibial GRF, and the time at which the peak tibial compression force occurs may not be consistent with the time at which the peak vertical GRF occurs. This further supports the idea that during gait rehabilitation training for patients with tibial fractures, monitoring and providing feedback on the actual tibial force rather than just the GRF is necessary. The developed device is a non-invasive and reliable portable device that can provide audio feedback, providing a viable solution for gait rehabilitation training outside laboratory and helping to optimize patients' rehabilitation treatment strategies.**

***Index Terms*— Tibial force, rehabilitation, partial weight-bearing, machine learning, ambulatory monitoring.**

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I. Introduction

TIBIAL fractures are one of the most common types of fractures in clinical practice, especially among military personnel [1] and sportspeople [2]. After tibial fracture surgery, clinical physicians typically advise patients to follow a partial weight-bearing (PWB) protocol [3]. PWB is defined as a specific weight that patients are allowed to bear on the affected limb during standing and walking with the use of assistive devices [4]. PWB walking can promote fracture healing and lower limb function recovery in patients with lower limb fractures [5], [6], and also reduce the incidence of postoperative complications after fracture surgery [7], [8]. A successful PWB gait is the core of the rehabilitation plan for patients with lower limb fractures [9].

To help patients with tibial fractures achieve correct and effective PWB walking, physical therapists usually use verbal instructions or bathroom scales to improve patient compliance. However, the effectiveness of these methods is not ideal [10], [11]. This is largely due to the fact that PWB gait training is primarily conducted by patients at home or in the community after discharge, and even if patients learn how to properly perform PWB walking in a clinical setting, it remains difficult for them to maintain compliance without effective supervision and guidance post-discharge [8], [11]. Therefore, there is increasing attention being paid to the development of portable biofeedback devices to aid in the gait rehabilitation training of lower limb fracture patients after discharge. With the development of sensing technologies, commercial biofeedback systems have been developed for monitoring and guiding PWB gait training for patients with fractures. For example, Sensistep (Evalan BV, Amsterdam, The Netherlands) [8], OpenGo Science (Moticon GmbH, Munich, Germany) [12], and SmartStep (Andante Medical Devices, Beer Sheva, Israel) [13]. These devices are portable and can continuously collect and monitor ground reaction force (GRF) in patients during PWB gait training in both clinical and home settings, providing real-time feedback and significantly improving patient compliance [14]. However, none of these devices are currently designed for multi-day at-home patient monitoring. Additionally, these devices use the GRF on the sagittal plane as an indicator of the longitudinally compressive force of the tibia (TCF) during walking. In fact, the force on the tibia during walking is mainly caused by muscle forces rather than GRF [15], [16], and recent studies have shown that the peak vertical GRF ($F_{GRF,max}$) during movement does not have a strong correlation with the peak tibial compression force [17], [18]. The timing of $F_{GRF,max}$ does not necessarily coincide with the timing of peak tibial compression force [19], [20]. Therefore, the validity of using only GRF information to guide rehabilitation training for tibial fracture patients is questionable. Guiding patients' gait rehabilitation training solely based on GRF information may lead to overloading of the fracture site. Although the probability of loss of fixation leading to secondary fractures due to overloading is small, overloading and non-loading can both lead to delayed healing [21], [22]. During rehabilitation training for the patient, real-time tibial compression force should be obtained and provided to both the patient and the physician.

To obtain the internal load of the tibia, the field of orthopedics usually uses either invasive or non-invasive measurement methods. In vivo measurement methods involve measuring the stress or strain on the fixation devices implanted inside the body of the fracture patient [23], [24]. However, the fracture site will bear some load after the lower limb is subjected to external loads, which will affect the deformation of the fixation device. Therefore, the measured TCF is not accurate [25]. In vitro measurement methods typically use optical motion capture (OMC) systems and force plates (FP) to collect patient biomechanical data, and then calculate TCF using a musculoskeletal model [25], [26]. Although these systems have high measurement accuracy and the calculated TCF is more accurate, OMC and FP are bulky, expensive, and have complex usage procedures, and this method can only be implemented in the laboratory [27]. To continuously monitor lower limb loading of the human body in daily life, many researchers use wearable devices such as pressure sensitive insoles and inertial measurement units (IMUs) to estimate the bone load of lower limbs [28], [29]. However, low-quality sensor data and limited data dimensions make it difficult for wearable sensors to achieve the desired effect in monitoring lower limb loading [30]. In recent years, machine learning (ML) has become a promising method to overcome the shortcomings of wearable devices in terms of measurement accuracy and data computation [31]. Matijevich et al. [32] first proposed a method to estimate peak tibial forces during running by combining wearable sensor signals and ML. Subsequently, Elstub et al. [33] combined IMUs and pressure-sensing insoles with the Lasso algorithm to more accurately estimate peak tibial forces during running compared to traditional physics-based algorithms. However, they only predicted discrete data such as peak tibial forces during running, and the traditional ML algorithm, Lasso, is not suitable for providing real-time predictions based on in-situ data [34]. For tibial fracture patients, real-time estimation of the load on the fracture site and obtaining the tibial load curve during PWB walking is beneficial [11].

Currently, there is no wearable device available in orthopedics that can monitor and provide real-time feedback on tibial load for PWB gait training in fracture patients. In response to the limitations of previous devices that could only monitor and provide feedback on patient GRF, the present study developed a new portable biofeedback device for collecting, monitoring, and providing feedback on tibial force information during gait rehabilitation training for lower leg fracture patients. By using a combination of physics-based models and neural network architectures, we obtained better prediction results than the traditional physics-based algorithm. The design and development of this system can help physicians and patients understand the real tibial load during PWB walking, which can optimize the rehabilitation strategy for lower limb fracture patients and reduce the risk of overloading during rehabilitation training.

II. Methods

A. Participants

To account for potential safety issues, 15 healthy volunteers (12 men and 3 women; mean age ± SD, 27.6 ± 2.41 years; height, 172.63 ± 4.58cm; weight, 73.26 ± 10.90kg) were recruited for this study. All subjects had no history of lower limb surgery, were able to walk normally without reliance on walking aids, and had sufficient upper limb strength to use crutches. Prior to testing, all participants provided written informed consent, and the study was approved by the Ethics Committee and Institutional Review Board of Wuhan Children's Hospital.

B. System Description

The biofeedback system designed in this study consists of a pair of customized instrumented shoe, two IMUs and a microcontroller. As shown in Fig. 1, two 3-axis force sensors (Jinghe Sensor, Bengbu, China) were attached to the sole under heel and metatarsal area of each instrumented shoe. Compared with pressure sensitive insoles, which can only collect the vertical component of the GRF, the instrumented shoe can measure the three-dimensional (3D) GRF during walking, and the measurement accuracy is higher [35]. The force sensor had a measurement accuracy of 0.1N and a sampling period of 10ms. Two IMUs (WitMotion, Shenzhen, China) were affixed to the foot and calf by double-sided tape as shown in Fig. 2(a, b). Previous studies have indicated that accurate estimation of GRF is crucial for obtaining tibial force measurements [32], [33], which is why we chose instrumented shoes with higher measurement accuracy sensors instead of pressure sensitive insoles. IMUs transmitted 3-axis acceleration and 3-axis angular velocity information to the microcontroller via Bluetooth, with an attitude measurement accuracy of 0.2° and an acquisition period of 5ms. The microcontroller included a digital transmitter, a speaker, an RS485 to TTL converter, and a Raspberry Pi Zero. The Raspberry Pi Zero processed the data from the force sensors and IMUs in real time to obtain the vertical GRF and TCF of the affected limb, and controlled the speaker to provide audio feedback.

C. Partial Weight-Bearing Gait Training Method

This study referred to the most commonly used rehabilitation training program in orthopedic rehabilitation [22], [36]. Two days prior to the experimental testing, four target loads were determined based on the weight of each subject, namely 25%, 50%, 75%, and 100% of their body weight. Subsequently, the subjects randomly selected one leg as the affected

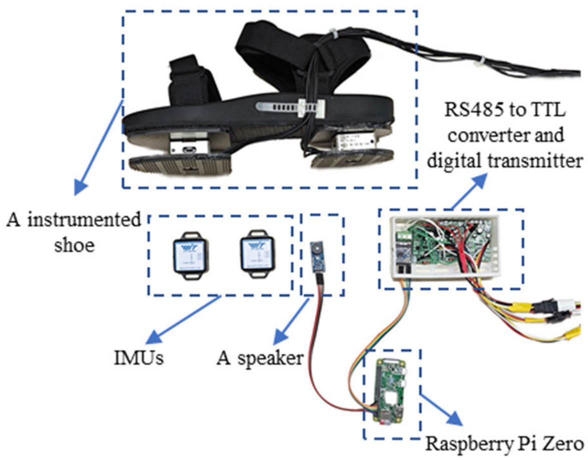

Fig. 1. Hardware of biofeedback system.

limb, and were instructed by the researchers to perform 3-point gait crutch walking. Due to the current limitations in theory and technology, subjects are unable to receive accurate feedback on tibial force during walking. Therefore, according to the traditional training regimen, the subjects wore the biofeedback device to practice using crutches to control the peak vertical GRF of the affected leg during walking to reach the target load.

The biofeedback device obtained the vertical GRF during walking through an IMU and two 3-axis force sensors installed on the foot. Firstly, the orientation of the 3-axis force sensors in the navigation coordinate system was determined through attitude calculation based on the velocity and acceleration information provided by the IMU [37]. Subsequently, a three-dimensional ground reaction force equation, as shown in (1), was established.

$$\boldsymbol{F}_{GRF} = \boldsymbol{R}_{\mathrm{b}}^{\mathrm{n}} \cdot (\boldsymbol{F}_{\text{heel}} + \boldsymbol{F}_{\text{toe}}) \tag{1}$$

where $\boldsymbol{R}_{\mathrm{b}}^{\mathrm{n}}$ represents the attitude matrix of the IMU from the IMU coordinate system to the navigation coordinate system, while $\boldsymbol{F}_{\text{heel}}$ and $\boldsymbol{F}_{\text{toe}}$ denote the measured values of the 3-axis force sensors on the forefoot and heel, respectively. $\boldsymbol{F}_{GRF}$ represents the GRF in all three directions during walking. Compared to the traditional method of using pressure insoles, this approach has been demonstrated to yield results that are more consistent with data obtained from force plates [35], [38].

As shown in Fig. 2(c), a subject wore the biofeedback device and used crutches for PWB training. The sensing system gave an audible feedback when the peak vertical GRF exceeded the pre-set target load during the walking training. At the end of each gait cycle, the system emitted an alert sound when it detected that the maximum values of the peak vertical GRF are below the minimum value specified by the physician. Subjects were required to perform three types of PWB gait training using crutches (25% PWB, 50% PWB, and 75% PWB) and slow walking training without crutches (FWB) for 30 minutes for 2 days in the lab.

D. Data Collection

On the day of data collection, 26 retro-reflective markers were placed on each subject's body. During walking, the marker trajectories were recorded with 8-camera motion capture system (Nokov, Beijing, China) at 200 Hz, and two force plates (Bertec, Ohio, USA) embedded in the walkway were used to collect 3D GRF during walking. The sampling frequency for 3D GRF was 1000 Hz. After wearing instrumented shoes and IMUs, subjects performed 25%, 50%, and 75% PWB crutch walking on the walkway at self-selected speeds, and then walked naturally at a slow speed (0.8m/s $\pm$ 10%) without crutches. During the experiment, the error between the peak vertical GRF of the affected limb and the target load was acceptable within 5% of body weight, and at least 10 complete gait cycles were recorded for each load level. The signals from the wearable sensors were synchronized with those from the motion capture cameras and force plates.

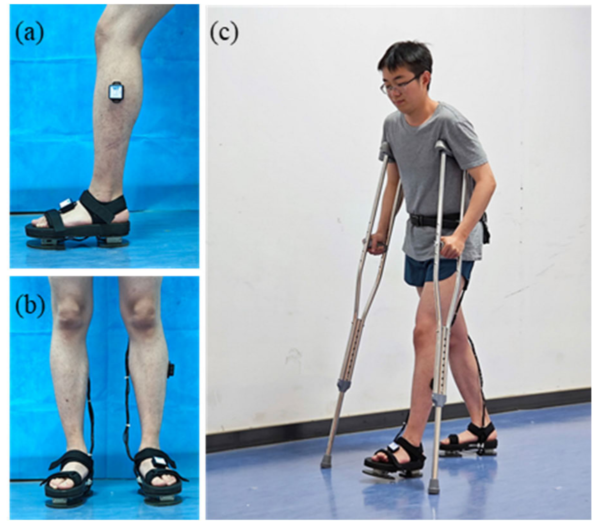

Fig. 2. (a) A lateral view of the subject wearing the biofeedback device; (b) An anterior view of the subjects wearing the biofeedback device; (c) A subject performing PWB. The subject has granted permission for the use of his identifiable image in this study.

E. Biomechanical Model

An overview of the lab-based data analysis and wearable-based data analysis is provided in Fig. 3. This study used the AnyBody Modeling System (AnyBody Technology A/S, Aalborg, Denmark) for data analysis. The data collected by OMC and FP were filtered with a 4th order low pass Butterworth filter with a 15 Hz cutoff frequency. All data within each gait cycle was normalized to 101 time steps. Rigid joints were added at the midpoint of the tibia in the AnyBody musculoskeletal model, and the model was adjusted to match the segment size and inertial properties of each subject using marker data. The joint kinematics and internal tibial loads of the lower limb were then computed. Although the analysis provided three-dimensional forces and moments in the tibia, we chose to only focus on longitudinal compression force due to the relatively small forces and moments in other directions of the tibia [25]. The tibial force generated by the biomechanical model (F_t) was regarded as the reference data.

F. Physics-Based Algorithm

The physics-based algorithm uses the data obtained by wearable sensors to calculate TCF according to traditional inverse

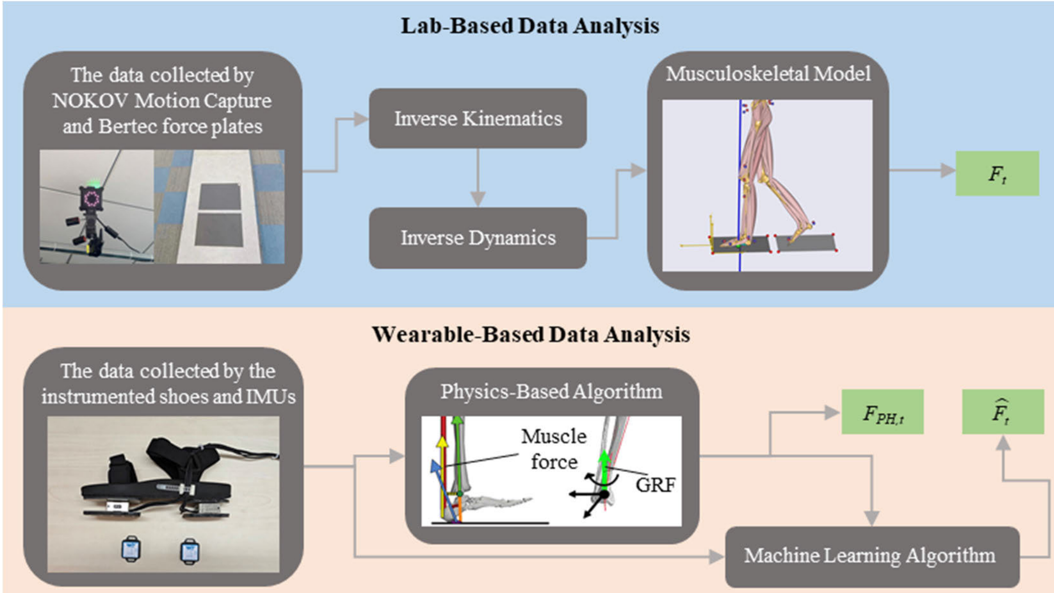

Fig. 3. Lab-based data analysis and wearable-based data analysis overview. The tibial force calculated from the musculoskeletal model using lab-based data (OMC and FP) was considered as the actual bone load. $F_{PH,t}$ represents the tibial force obtained from wearable sensors using the physics-based algorithm. $\widehat{F}_t$ represents the tibial force obtained from wearable sensors using the machine learning algorithm.

dynamics method [32]. TCF is determined by adding the force exerted on the tibia by GRF (F_{ext}) and the force exerted on the tibia by plantarflexor calf muscles (F_m) [17], [32]. F_{ext} and F_m can be expressed as follows

$$F_{ext} = GRF_n \cdot \cos\beta + GRF_t \cdot \sin\beta \quad (2)$$

$$F_m = \frac{M_a}{r_t} = \frac{GRF_n \cdot COP_{ap}}{r_t} \quad (3)$$

where β represents the angle between GRF in the sagittal plane and the direction of the tibial segment. GRF_n is the normal force under the foot and GRF_t is the tangential force under the foot. M_a is the ankle moment in the sagittal plane. β, GRF_n and GRF_t were all obtained through the processing of data collected by wearable sensors [32], [39]. r_t is the Achilles tendon moment arm, which was assumed to be 5 cm for all subjects [40]. COP_{ap} is the anterior-posterior center of pressure distance relative to the ankle joint position. The anterior-posterior center of pressure is defined as the point of concentration of the GRF in the anterior-posterior direction. COP_{ap} can be expressed as follows

$$COP_{ap} = \sqrt{\left(\frac{F_{n1}x_{heel} + F_{n2}x_{toe}}{GRF_n}\right)^2 + \left(\frac{F_{n1}y_{heel} + F_{n2}y_{toe}}{GRF_n}\right)^2} \quad (4)$$

where F_{n1} and F_{n2} represent the forces experienced by two force sensors in the sagittal plane. We used $\vec{\mathbf{r}}_{heel}$ and $\vec{\mathbf{r}}_{toe}$ to respectively represent the relative displacement of the forefoot force sensor and the heel force sensor with respect to the center of the ankle joint, then x_{heel} and y_{heel} represent the projection lengths of $\vec{\mathbf{r}}_{heel}$ on the frontal and sagittal axis, respectively. Similarly, x_{toe} and y_{toe} represent the projection lengths of $\vec{\mathbf{r}}_{toe}$ on the frontal and sagittal axis, respectively.

G. Physics-Guided Neural Networks

The previous studies indicate that artificial neural network (ANN) is a promising method for evaluating human motion based on data from wearable sensors [29], [31]. However, they require a large amount of data, and data-driven models lack generalizability to out-of-sample scenarios [30]. Considering that collecting a large amount of data on PWB crutch walking is impractical, and the application of pure ML methods to small sample size training is usually not ideal [30], [33]. In order to fully leverage the advantages of both physical and data-driven methods, this study employed a Physics-guided neural networks (PGNN) approach that combined a physics-based model with ANN to solve TCF.

Firstly, an ANN model was established in MATLAB R2022a (MathWorks, United States). The results obtained through calculations based on the physical model and the data collected from wearable sensors were used as the input of the ML model. As shown in Fig. 4, ANN had 19 variables in the input layer. These variables consisted of 3-axis acceleration and angular velocity information from two IMUs, 3-dimensional force information from two force sensors on the instrumented shoe, and results from the physics-based algorithm ($F_{PH,t}$). The output layer of ANN had one variable (F_t). The ANN had two hidden layers, one with 100 and one with 50 neurons, connected to the input and output nodes. The network was trained for 1000 iterations, and training was stopped if the gradient did not decrease for six consecutive iterations.

To improve the consistency between ANN model and physical knowledge due to the limited dataset, a physics-based loss function was introduced to guide the learning of ANN model [41]. The custom loss function was defined as follows

$$Loss = Loss(\widehat{F}_t, F_t + \lambda R(\mathbf{W}) + Loss_{PHY}(\widehat{F}_t) \quad (5)$$

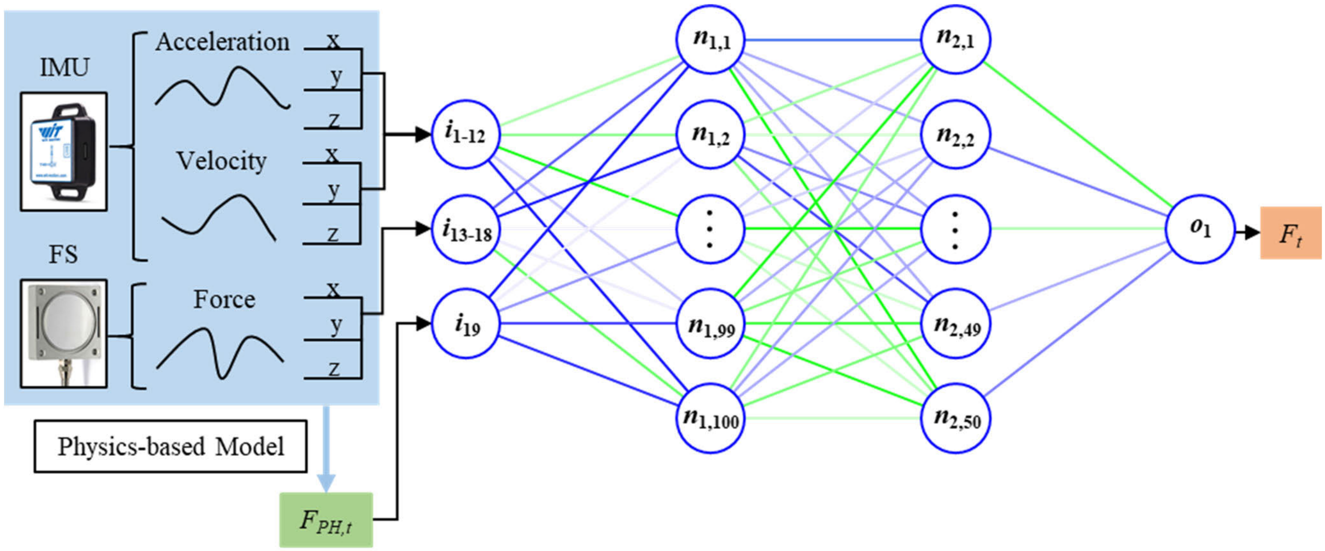

Fig. 4. A schematic diagram of the hybrid-physics-data (HPD) model.

where $Loss(\widehat{F_t}, F_t)$ is the mean squared error of the predicted value ($\widehat{F_t}$) and reference value (F_t), $\lambda R(\mathrm{W})$ as regularization terms, and $Loss_{PHY}(\widehat{F_t})$ is a physical-based loss function. It can be seen from (2) and (3) that the sum of the normal and tangential forces of the two force sensors, FGRF, should not be greater than TCF at each moment during walking. Therefore, the physics-based loss function can be expressed as follows

$$Loss_{PHY}(\widehat{F_t}) = \mathrm{ReLU}(F_{GRF} - \widehat{F_t}) \tag{6}$$

where ReLU denotes the rectified linear unit function. The addition of the physics-based loss function ensured the physical consistency of the predictions. Finally, for each type of weight-bearing walking, a cross-validation strategy was employed by sequentially partitioning the data of 15 subjects into 15 folds. Fourteen of these folds were used for training the model, while one fold was used for testing. The process was repeated until the whole set was exhausted.

H. Statistical Analysis

For each type of weight-bearing walking, the results obtained from all methods were normalized to the subject's body weight (BW). The Pearson's correlation coefficient (r) was used to evaluate the similarity between the results predicted by the physics-based algorithm and PGNN, respectively, and those calculated by the musculoskeletal model. The accuracy of the two methods was evaluated by calculating the root mean squared error (RMSE) and relative root mean squared error (rRMSE) in units of BW [42]. The rRMSE facilitates the comparison between the different weight-bearing walking with different force amplitudes. The averages and standard deviations were calculated for r, RMSE and rRMSE from the 15 cross-validation subsets. The Fisher's z-transformation was applied to r, and the mean of the transformed values was calculated. The average value of r was obtained by reversing the transformation. In addition, we also calculated the percent differences (%Diff) between the peak tibial compression force predicted by the physics-based algorithm and the PGNN, respectively, and the peak value of tibial compression force calculated by the musculoskeletal model.

III. Results

Table I shows an overview of the accuracy of the two methods for estimating four types of weight-bearing tasks. The TCF predicted by the physics-based algorithm showed a moderate to strong correlation with the reference values. The PGNN-predicted TCF yielded r values that ranged from 0.65 to 0.86 for the different weight-bearing tasks. The results predicted by the physics based algorithm and PGNN had the highest correlation with F_t during slow walking without crutches, with values of 0.86 ± 0.46 and 0.98 ± 0.25, respectively. For all weight-bearing tasks, the RMSE for the physics-based algorithm was between 0.09 ± 0.03 and 0.40 ± 0.19 BWs, whereas for the PGNN, that was between 0.04 ± 0.02 and 0.27 ± 0.14 BWs. The rRMSE for the different weight-bearing tasks ranged between 20.7 ± 9.7% and 31.8 ± 28.7% for the physics-based algorithm and between 9.3 ± 6.0% and 14.2 ± 7.4% for the PGNN.

Table II presents the %Diff results for four types of weight-bearing walking. The mean %Diff between the predicted peak tibial compression force by the physics-based algorithm and the reference values across all weight-bearing walking was 16.85 ± 16.5%. In contrast, the mean %Diff between the peak tibial forces predicted by PGNN and the reference values was 7.4 ± 6.1%. For all types of weight-bearing tasks, the mean difference for the peak tibial compression force predicted by PGNN were smaller than those predicted by the physics-based algorithm. The FWB showed the smallest %Diff (5.3 ± 3.7%) for the PGNN-estimated peak tibial compression force in comparison to the reference values.

Fig. 5 shows the differences between the predicted results by the physics-based algorithm and PGNN and the reference values for the four types of weight-bearing tasks. Additionally, the vertical GRF data collected by force plates were also presented for comparison.

IV. Discussion

In this paper, we have developed a new wearable biofeedback system and proposed a method to predict TCF during walking by combining a physics-based model and ANN.

TABLE I
ACCURACY (r, PEARSON'S CORRELATION COEFFICIENT; RMSE, ROOT-MEAN-SQUARED ERROR; rRMSE, RELATIVE ROOT-MEAN-SQUARED ERROR) OF TWO METHODS FOR ESTIMATING CONTINUOUS RESULTS

	Physics-based Model			Physics-guided Neural Networks		
	r	RMSE(BW)	rRMSE(%)	r	RMSE(BW)	rRMSE(%)
25% PWB	0.71±0.32	0.09±0.03	26.5±11.9	0.96±0.43	0.04±0.02	12.1±3.7
50% PWB	0.65±0.31	0.20±0.11	31.8±28.7	0.97±0.24	0.07±0.05	9.3±6.0
75% PWB	0.79±0.42	0.34±0.21	28.5±15.1	0.95±0.42	0.27±0.14	14.2±7.4
FWB	0.86±0.46	0.40±0.19	20.7±9.7	0.98±0.25	0.12±0.08	10.3±5.3
Mean	0.75±0.39	0.26±0.19	26.9±18.4	0.97±0.35	0.12±0.12	11.5±6.1

TABLE II
PERCENT DIFFERENCES(%DIFF) BETWEEN TIBIAL FORCE PEAKS PREDICTED BY TWO METHODS AND REFERENCE VALUES

	Physics-based Model	Physics-guided Neural Networks
	%Diff	%Diff
25% PWB	19.5±20.6	8.5±5.8
50% PWB	17.9±20.1	7.4±7.1
75% PWB	15.5±13.0	8.3±6.8
FWB	14.5±8.8	5.3±3.7
Mean	16.85±16.5	7.4±6.1

We compared the performance of PGNN with the traditional physics-based algorithms. For the physics-based algorithm, foot mass and inertia were ignored, the Achilles tendon moment arm was considered a constant, and there was a lack of real estimation of the ankle joint center. Therefore, the equations used were simplified, leading to overestimation or underestimation of TCF [17], [26]. In comparison, as shown in Table I, for all weight-bearing tasks, the prediction results of PGNN were more accurate than those of the physics-based algorithm, and the TCF predicted by the PGNN showed a strong correlation with the reference values. For each PWB task, the average rRMSE of PGNN was below 15%. For the prediction of peak tibial forces during walking, PGNN also showed higher accuracy than the physics-based algorithm.

In this study, PGNN employed the results obtained from a physics-based algorithm as input for ANN, which could be regarded as predicting and compensating for errors in the physics-based approach. Due to the limited data collection and processing capabilities of wearable sensors for all subjects, the physics-based algorithm employed a generic and simplified biomechanical model to compute TCF, which could not provide personalized adjustments for each individual based on their collected data, unlike musculoskeletal modeling software. In contrast, PGNN compensated for the errors caused by the lack of personalized scaling in the simplified biomechanical model of the human body to a significant extent through data training, as it automatically learned the simplifications and unconsidered factors in the physical algorithm, such as variations in the lengths of lower limb bones and muscles, as well as differences in Achilles tendon moment arm among individuals. Another key to accurately obtaining TCF is to accurately estimate the ankle joint torque to obtain the muscle force F_m acting on the tibia. However, the data from wearable sensors is often scattered and incomplete, making it impossible to achieve the very accurate estimation of the changes in the center of foot pressure and ankle joint angle during walking, as achieved by OMC and FP [29], [33]. Therefore, the calculated ankle joint torque often contains errors, which may accumulate during the computation process and lead to deviations in the final predicted results. Incorporating the outcomes obtained from the physics-based algorithm and wearable sensor data as inputs to machine learning can also enable the ML model to learn the patterns of measurement and computation errors of the sensors, adjust the neural network weights, and thus reduce the impact of errors on the predicted results. Furthermore, in PGNN, we introduced a physics-based loss function to guide the learning of the ANN model. The use of physics-guided constraints provided effective regularization for training deep generative models, reducing the possible search space of parameters, especially in cases where the cost of acquiring data is high and the available data sets are small [43]. As an ML model that follows the required physical characteristics, PGNN is more likely to be generalizable to out-of-sample scenarios. Additionally, although the ANN used in this study was not compared with other types of ML algorithms, such as convolutional neural networks and long short-term memory networks, previous research has demonstrated that the dataset, neural architecture search, and hyperparameter optimization are more influential in determining the predictive performance than the type of neural network used [44], [45], [46]. We believe that embedding biomechanical knowledge into a simple neural network architecture can serve as a starting point for developing other wearable sensor methods for continuous monitoring of lower limb loading during walking.

Currently, various commercial wearable biofeedback systems on the market only guide lower limb fracture patients in weight-bearing walking by monitoring GRF [14]. However, as shown in Fig. 5, for all types of weight-bearing walking, the peak tibial forces were significantly greater than $F_{GRF,max}$. Especially during slow walking without crutches, the load of muscles on bones was much greater than the forces exerted on the tibia by GRF, which is consistent with the results of other scholars [15], [16], [17], [33]. Moreover, the $F_{GRF,max}$ and

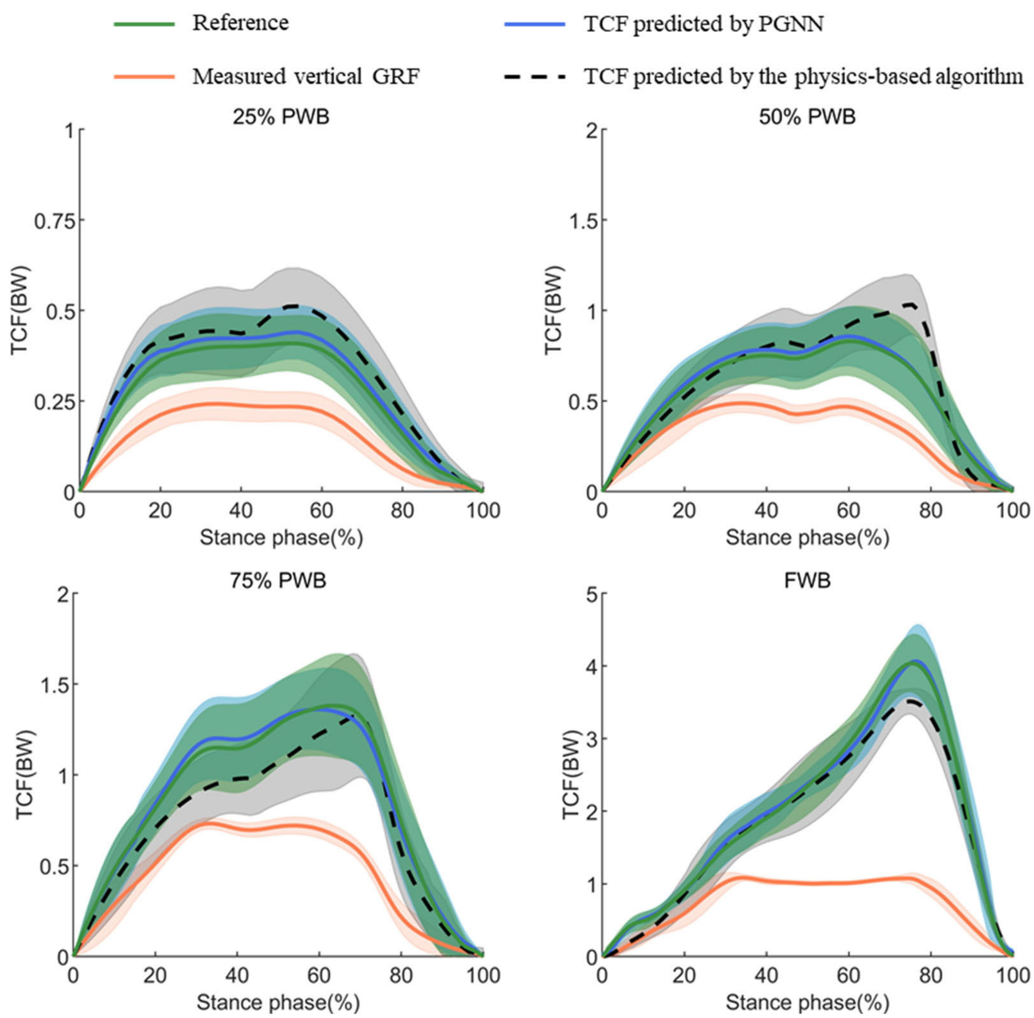

Fig. 5. The TCF and vertical GRF curves during four different weight-bearing walking conditions for fifteen participants. Green lines and shaded areas represent the mean and standard deviation of TCF, which was calculated by importing the data obtained from FP and OMC into the biomechanical model. Blue lines and shaded areas represent the mean and standard deviation of TCF obtained by PGNN. Black dashed lines and shaded areas represent the mean and standard deviation of TCF obtained by the physics-based algorithm. Coral lines and shaded areas represent the mean and standard deviation of the vertical GRF collected by FP.

the peak values of TCF may not have occurred simultaneously during walking. The peak vertical GRF typically occurred when the foot contacted the ground at the beginning of the stance phase, while the peak TCF usually appeared at the terminal stance. Table III presents the Pearson's correlation coefficient ($r_{G,T}$) between the vertical GRF measured by FP and the reference value (F_t) of tibial force for 15 subjects across four types of walking. The mean and standard deviation of the correlation coefficients for each weight-bearing task were obtained through Fisher's z-transformation. Table III shows that the average correlation coefficient between vertical GRF and TCF ranged from 0.61 ± 0.11 to 0.64 ± 0.25 across all types of weight-bearing walking. Among them, 5 participants demonstrated weak positive correlation ($0.3 \leq r_{G,T} < 0.5$) between their vertical GRF and TCF in each type of PWB walking. Consistent with the views of Walker et al., there was no strong correlation ($r_{G,T} \geq 0.8$) observed between vertical GRF and TCF across all types of weight-bearing walking. Particularly, with the increase of the load on the affected limb, the $r_{G,T}$ tended to decrease, which may have been attributed to the possibility that the increase in load caused the influence of muscle force on the tibia to increase faster compared to the influence of GRF on the tibia. Furthermore, in all types of weight-bearing walking, no negligible correlation ($r_{G,T} < 0.3$) was observed between vertical GRF and TCF, further indicating that the impact of GRF on tibial force could not be ignored [17]. However, the standard deviation of the correlation coefficients among the subjects in each PWB walking type was large, indicating that there may be significant differences in the relationship between the GRF curve and the TCF curve across individuals due to physiological characteristics, movement habits, and other factors. This suggests that GRF and TCF cannot be regarded as having a simple linear relationship, and that more biomechanical data should be collected to estimate the actual TCF for each individual during walking. Therefore, even if traditional wearable biofeedback systems achieve the same level of measurement accuracy as FP in measuring GRF, these devices are severely limited in reflecting the tibial loading of different individuals during PWB walking, and may even mislead lower limb fracture patients in understanding the load on the fracture site.

TABLE III
THE PEARSON'S CORRELATION COEFFICIENT BETWEEN THE VERTICAL GRF AND TCF

	25% PWB	50% PWB	75% PWB	FWB
Subject1	0.42	0.40	0.43	0.53
Subject2	0.76	0.69	0.77	0.74
Subject3	0.78	0.77	0.75	0.67
Subject4	0.49	0.59	0.58	0.61
Subject5	0.74	0.72	0.69	0.62
Subject6	0.41	0.43	0.42	0.53
Subject7	0.33	0.32	0.31	0.48
Subject8	0.75	0.72	0.67	0.61
Subject9	0.72	0.69	0.72	0.64
Subject10	0.73	0.72	0.68	0.63
Subject11	0.48	0.49	0.41	0.50
Subject12	0.69	0.68	0.67	0.60
Subject13	0.74	0.73	0.71	0.65
Subject14	0.45	0.47	0.49	0.60
Subject15	0.76	0.70	0.68	0.62
Mean	0.64±0.25	0.63±0.22	0.62±0.22	0.61±0.11

In the field of orthopedics, while surgical treatment techniques are rapidly advancing, the level of attention to postoperative rehabilitation treatment, which promotes bone healing and functional recovery, is still low [21], [36]. Although PWB is a common recommendation for the rehabilitation of orthopedic patients, the effectiveness of PWB walking is still controversial due to the inability to accurately understand and control the load on the fracture site during gait rehabilitation training [22]. Moreover, there is no international consensus on postoperative weight-bearing strategies [14], [22]. Rehabilitation training for most fracture patients is often blind and based on experience. Currently, the advantage of using GRF as an indicator of tibial load in many human movements is simply due to its ease of monitoring. Reference [17]. However, in situations where there is a lack of effective estimation of the load on the fracture site during rehabilitation training, PWB walking may not be particularly effective [47], [48]. This can further lead to a lack of emphasis on gait rehabilitation training, resulting in a non-benign cycle in orthopedic rehabilitation. Our study shows that for all types of PWB walking, GRF is not the sole dominant factor in the increase of tibial force. The increase in tibial force can occur without an increase in GRF. Physicians should guide patients to control the actual force on the fracture site during rehabilitation training according to the recovery status of the affected limb to achieve the target load. Therefore, it is crucial to use wearable devices to monitor the TCF of the affected limb in real-time and establish personalized rehabilitation plans, instead of letting tibial fracture patients follow common rehabilitation plans based on GRF.

It should be noted that this study also has some limitations. Firstly, the PGNN method did not consider intra-subject training because collecting a large amount of walking data from a single subject that achieves the target load is not practical. Previous studies have shown that the prediction performance of intra-subject training is better than that of inter-subject training [29], [31]. In the future, we can expect the application of biofeedback systems in the rehabilitation training of tibial fracture patients, and collect more gait data for neural network training to achieve better prediction performance. Another limitation of the study is that we could not directly measure tibial load. However, compelling evidence from cadavers [15] and implanted sensors [16] suggests that using musculoskeletal modeling software to process data collected from OMC and FP can provide a reasonable approximation of tibial bone loading. In addition, this study was limited to analyzing weight-bearing training on flat ground and did not consider other types of activities, such as stair climbing, walking on slopes, and sit-to-stand. It is expected that our future research will expand to other types of activities and investigate the potential impact of long-term use of this system on weight-bearing activities in individuals. Additional device development would also be needed to determine if and how to embed 3D force sensors into shoes in a manner that would be acceptable to patients for daily at-home use, as well as to create the remote data monitoring capabilities. Finally, we did not discuss the compliance of subjects after using the device in this study. Nevertheless, previous research has shown that audio feedback can significantly improve patient compliance [10], [14]. In fact, the future of orthopedic rehabilitation lies in combining robotics technology and developing intelligent devices that do not rely on patient compliance to accurately control the load on the fracture site during walking. Our study also provides an important theoretical and hardware foundation for the design and control of future intelligent orthopedic rehabilitation devices.

V. CONCLUSION

This study developed a wearable biofeedback system composed of instrumented shoes and IMUs to estimate tibial load in patients with tibial fractures during PWB walking. We compared the effectiveness of the PGNN and the physics-based algorithm method in predicting tibial force and demonstrated the advantages of combining a physics-based model and ANN. The research showed that PGNN can achieve better prediction of tibial force during different weight-bearing walking than traditional methods when training data is limited. The study results also showed that current commercial devices that only monitor GRF cannot effectively reflect the load on the tibia during PWB walking in individuals. This study combined wearable sensors, musculoskeletal biomechanics, and ML to estimate tibial load in real-time during walking, which is of great significance for improving rehabilitation treatment plans for lower limb fracture patients and developing intelligent orthopedic rehabilitation devices.

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