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ORIGINAL RESEARCH

Synthetic Data Generation System for AI-Based Diabetic Foot Diagnosis

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Abstract
The paucity of readily available medical data poses a major challenge for the development of AI (artificial intelligence)-based healthcare applications and devices. To aid in overcoming this challenge, we propose a sensor-based medical time series data synthesis system especially designed for the training of diabetic foot diagnosis models. The proposed system utilizes statistical methods, augmentation techniques, and the *NeuralProphet* model to accomplish its purpose while still maintaining medical validity. Our results show that the generated synthetic time series data follow the trends and tendencies of real data. We also verify our work using machine learning-based clustering. By successfully clustering the synthetic data generated by our proposed system, we prove that our system is capable of meeting its objectives.

Keywords Data synthesis · Machine learning · Diabetic foot ulcer

Introduction

The number of people diagnosed with diabetes has shown a sharp rise from 108 million cases in 1980 to 422 million cases in 2014, according to the WHO (World Health Organization) [1]. It is also observable in relevant statistics that DFU (Diabetic Foot Ulcer) occurs in approximately 15% of diabetes cases, with 14–24% of DFU cases requiring lower extremity amputation [2]. Therefore, it could be said that the timely warning of DFU patients is a nontrivial task that may potentially prevent the necessity of measures that could greatly degrade the quality of life, for patients. Previous studies have attempted to reveal the relationship between DFU and other diagnostic indicators [e.g., foot temperature, transcutaneous oxygen pressure ($TcPO_2$), etc.] using traditional statistical techniques [3–8]. However, it is of our belief that AI may prove to be more effective in discovering the intricate relations between the dependent and independent variables of this case and uncovering the correlations between DFU and the above-mentioned diagnostic indicators. However, one limitation of AI techniques is that they demand an abundant supply of training data to

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produce results of appreciable quality. Unfortunately, medical datasets that were collected using wearable sensors are rarely available and often lack in size and diversity. The most practical solution to this issue is to synthesize the medical data required for the training and validation of AI models. Although the introduction of bias and inconsistency into the AI models in question is an inherent risk with this approach, as is typical with similar efforts, we believe that this may be remedied through the application of recommended medical criteria for each stage of the data synthesis process.

In our earlier research [9], we introduced a synthesis system for medical data that employed *Prophet*, a renowned time series prediction model by Facebook, Inc. In this system, data was synthesized and augmented under the supervision of medical professionals. However, the limitation of our previous work is that the generated data was not consistent with the characteristics of data collected by wearable sensors. To address this problem, we introduce an improved synthesis system that employs the *NeuralProphet*, an enhanced version of *Prophet* that leverages the strengths of neural networks thanks to a collaborative effort led by Stanford University, Facebook, Inc., and the open source community. The main contributions of this paper are as follows:

1. We propose a data synthesis system that implements various measures to ensure that the synthesized data adheres to the formal characteristics of actual medical data.
2. We suggest medical criteria, that may be used in future studies, that attempt to synthesize and validate data regarding the subject of DFU.
3. We demonstrate that our proposed system is capable of synthesizing diverse and realistic medical data for the development of AI-based DFU solutions.

We plan to apply the results of this study to a digital therapeutic device of our creation named *SmartInsole*, which specializes in the treatment of DFU, to assess and enhance its performance. Synthetic datasets are beneficial for the development of machine learning-based healthcare applications, as they fundamentally solve the scarcity of available wearable sensor collected medical data.

This paper will be presented in the following order. "Related Work" describes this work in relation to the subject areas. "Experimental Materials and Resources" provides a detailed explanation about the materials and open source dataset that were used in this study. "Synthesis System" provides details of the proposed data synthesis system and an illustration of the procedures involved. "Experiments" provides an overview of the experiment results obtained from this research. "Discussion" presents an analysis of the experiment results and a discussion of possible improvements to our system. Finally, in "Conclusion", we provide our concluding remarks on the study subject.

Related Work

DFU, which is a chronic disease [10], is classified into three distinguishable pathological types: neuropathy, ischemia, and infection [11]. These pathological types are each diagnosed using different indicators, according to their characteristics [12]. To accurately diagnose and predict the symptoms of DFU, it is advisable to consider the application of a long-term multiplicative time series.

Unfortunately collecting medical time series data is costly, time consuming, and has uncertain availability. To solve these problems, Saloni et al. [13] endeavored to, and succeeded in synthesizing patients' records that are sporadic and longitudinal, in nature. In addition, Dahmen et al. [14] and Walonski et al. [15] proposed *SynSys* and *Synthea*, respectively, which both attempt to synthesize data for health care applications. The above-mentioned studies made use of medical records and IoT sensors, but not wearable sensors. Stephanie et al. [16] successfully demonstrated the synthesis of real valued multidimensional medical time series data from ICU (Intensive Care Unit) data. Andrew et al. [14] proposed *HealthGAN*, another framework for medical data synthesis. *HealthGAN* [17] intended to develop a framework that generates discrete medical data rather than continuous time series data.

In our previously proposed system [9], we employed the *Prophet* model for the synthesis of medical data. *Prophet* is an open source time series prediction model initially developed by Facebook Inc., that has been proven to display impressive accuracy in comparison with many other forecast methods and models. However, this approach also has its own limitations [18] when generating data for the training of AI models, in that the seasonality of the synthesized data cannot be accurately reflected [9]. Another problem with this approach is that the synthesized data fails to reflect the noisy nature of the data collected by wearable sensors, which we attempted to remedy with this research [9].

Data collected by wearable sensors is easily distorted by both external and internal factors [19]. This leads the data collected in this manner to display different characteristics compared to medical data procured using traditional methods using medical precision instruments [20]. In a different study [21], it was shown that AI models that were trained with clean medical data tended to yield unsatisfactory results when applied on noisy data. To deal with this problem, many augmentation methods have been employed for time series data augmentation. Early efforts on time series data augmentation manipulated data in the

Table 1 $TcPO_2$ Severity grades and range

$TcPO_2$ Severity grade	Value range (mmHg)	σ
1. Critical Ischemia	0–10	±15.6
2. Severe Ischemia	11–30	±15.5
3. At Risk	30–49	±8.92
4. Normal	40–59	±12.80
5. Healthy	From 60	±8.80

Table 2 Foot temperature severity grades and value range

Foot temperature category	Value range (C)/ Inferred value	μ	σ
1. Healthy	30.84–31.95	31.4	1.92
2. Neuropathic	32.1–33.16	32.73	1.48

time and frequency domains. Such examples include, but are not limited to, cropping, time warping, flipping, jittering, and magnitude warping [20, 22]. In our research, we apply the "Jittering" method so that our proposed system may synthesize medical data that is able to simulate the noisy nature of data collected by wearable sensors [20].

NeuralProphet is a novel approach to time series prediction. It is a neural network implementation of Facebook, Inc.'s well known *Prophet* forecast model. By utilizing *NeuralProphet*, we are able to leverage the power of AR-Net [23], a neural network proposed by Triebe et al., to enhance the accuracy and robustness of our data synthesis model. We believed that *NeuralProphet* would be a more suitable alternative for our proposal considering the scalability requirements of the increasingly large amounts of data that we must deal with in a production environment.

Experimental Materials and Resources

Medical Criteria

Even though medical criteria have been established empirically and scientifically over a long period of time, some of the variables, such as $TcPO_2$ and temperature, are not suitable for analysis concerning the diabetic foot, because they tend to represent only discrete momentary conditions, while continuous time series data are required for accurate results that account for developing conditions. Our efforts to remedy these issues can be seen in Tables 1 and 2.

$TcPO_2$ values were divided into five levels as shown in Table 1, as the fluctuation pattern of $TcPO_2$ values in a time series tend to display an irregular waveform within certain intervals [3–8, 24]. Foot temperature was divided into two categories, as derived from the medical research as shown in Table 2. In the case of HbA1c values, although not synthesized as part of this study, they have been found to be possible to calculate using certain mathematical formulas that make use of the relationship between HbA1c and MBG (Mean Blood Glucose) [25]. MBG, in this context, represents the average of blood glucose levels between two to three months from the same instance. The equations to be used for the aforementioned calculations depend on the type of diabetes in question. Eq. 1 (for type 1 diabetes) and Eq. 2 (for type 2 diabetes) may be employed to generate the relevant HbA1c levels based on the provided synthetic glucose data [25].

$$\mathrm{MBG} = 28.7 \times \mathrm{HbA1c} - 46.7 \tag{1}$$

$$\mathrm{MBG} = 36.6 \times \mathrm{HbA1c} - 77.3 \tag{2}$$

Without following medical criteria derived from medical research results, the synthesis system may generate distorted data. Consequently, a biased dataset resulting from data distortion may in turn lead to the training of a biased AI model. To ensure medical validity and prevent any distortion, we employ two of the most popular distributions in medical statistics, the normal distribution and the F distribution [26].

UCI Diabetes Data Set

The time series glucose level data utilized in our implementation is the *Diabetes Data Set* obtained from *UC Irvine Machine Learning Repository*. In an attached note, the contributor of this dataset explains that the data was recorded by both automatic electric recording devices and paper records of patients. Each record in the dataset has four fields: date (in MM:DD:YYYY format), time (in HH:MM format), code, and glucose level values. The values in the code field indicate a specific action or influencing factor that affected the glucose levels. However, one of the problems with this dataset is that the timestamps of paper recordings seem to be unreliable [27]. This is illustrated by the existence of glucose measurements for a nonexistent date.

To prevent the inaccuracies in the source dataset from negatively affecting our system, we resorted to preprocessing. The inaccurate or unreliable portions of the dataset were completely removed during preprocessing.

Synthesis System

The proposed synthesis system consists of four stages, as shown in Fig. 1. We modularize the whole system into multiple stages to enhance the flexibility and reproducibility of our system. For instance, II. Preprocessor is designed to work with both data that follow medical criteria, which

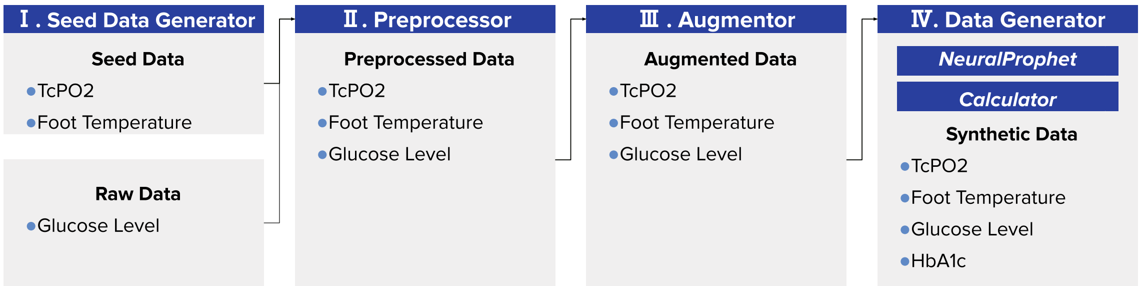


Fig. 1 Schema of synthesis system

we define as seed data (i.e., $TcPO_2$ and foot temperature), and data that display seasonality or is influenced by a number of external factors, which we define as raw data (i.e., glucose levels). In the case of $TcPO_2$ and foot temperature, the I. Seed Data Generator produces relevant data based on the proposed medical criteria, which is then passed on to the II. Preprocessor. In the case of the glucose levels, actual medical data (i.e., *UCI Diabetes Data Set*) is given to the II. Preprocessor. The job of the II. Preprocessor is to filter inappropriate or unnecessary data from the raw glucose level data, and to synthesize data from the provided seed data using statistical methods.

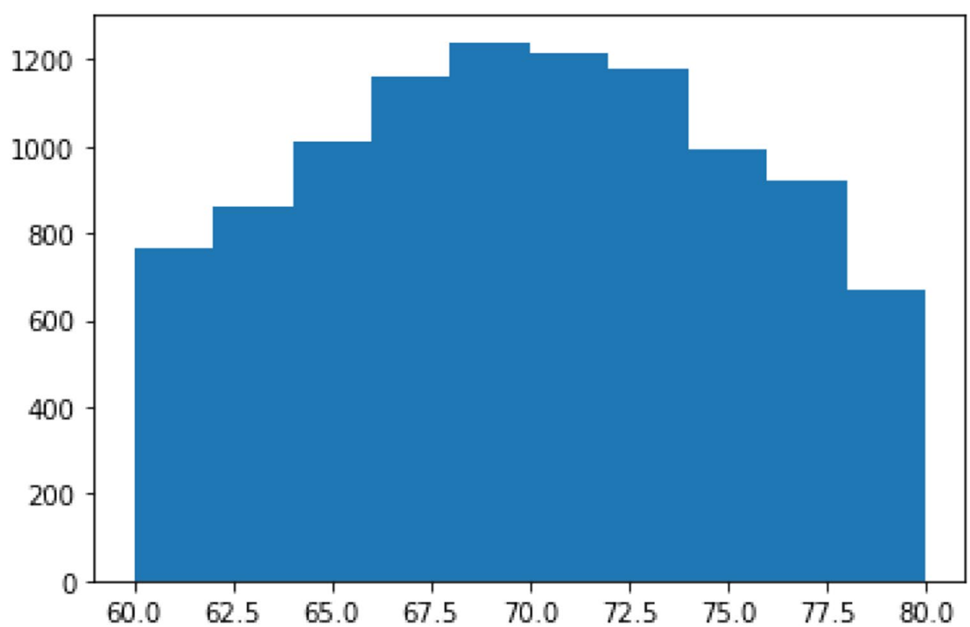
The processed data of each kind is augmented by the III. Augmentor. Finally, the IV. Data generator employs the *NeuralProphet* forecast model to synthesize $TcPO_2$, foot temperature, and glucose level data. Since the HbA1c data may be derived from glucose levels, a simple *Calculator* module may be implemented to calculate the HbA1c data based on synthetic glucose level data. Each stage is described in detail in the following sections.

Seed Data Generator

As highlighted in "Medical Criteria", the $TcPO_2$ and foot temperature data each have their own specific grade and category ranges. Based on these ranges, which are presented as in Table 1 and 2, we synthesize random data that follows a normal distribution of a specified range and standard deviation. Figure 2 shows the distributions of the generated seed data of $TcPO_2$. A truncated normal distribution was used for each of the ranges of the specified severity grades.

As earlier stated, the glucose level data was not synthesized by the I. Seed Data Generator, but was directly obtained from the *UCI Diabetes Data Set* and given to the II. Preprocessor. Unlike other parameters, blood glucose levels display a clear pattern in daily fluctuations. This strong seasonality is the reason why they cannot be produced using typical statistical generative techniques.

Fig. 2 Distribution histogram of generated $TcPO_2$ seed data



Preprocessor

We apply two different methods for preprocessing the seed and raw data inside the stage II. Preprocessor. For the seed data of $TcPO_2$ and foot temperature, the preprocessing procedure is mainly consists of statistical processing. To synthesize data for the two categories (i.e., non-diabetic and diabetic) in amounts that closely reflect the ratio between the two, as may be observed in real data, we elected to have our synthesized data follow an F distribution by grade. This is because the F distribution tends to closely represent the distribution of the diseased and non-diseased populations in a given random community [28, 29]. As shown in Fig. 3, we synthesize data in amounts that fit an F distribution, whose sum of *y*-axis values equal the size of the preprocessed seed data that was generated earlier. While there may be difficulties in visually identifying parts of Fig. 3, the five columns of the data shown in the histogram represent the proportion of data that each of the severity grades must adhere to, if we were to follow the F distribution. Albeit being a rough estimate, by having the ratio of the amount of data for each severity grade follow the F distribution, we are able to train our clustering model in an environment that is closer to that of reality, where most people are healthy and much fewer people are ill.

We filter the raw data (i.e., glucose level data from the *UCI Diabetes Data Set*) so that only portions of raw data that contain glucose measurements before and after breakfast, lunch, and dinner are used. This is done to increase the reliability and generalization capability of models trained from the raw data [9]. These conditions were formulated to exclude erratic and case specific glucose measurement data, such as measurements taken after insulin doses (Codes 33, 34, 35, etc.), unspecified special events (Code 72), etc. In addition, since most people are likely to regularly consume three meals per day, basing our model on such consistent and regular activities should prove to be beneficial for the generalization capability of our model. The preprocessing, as explained above, helps us to properly augment the data and, later, train the *NeuralProphet*.

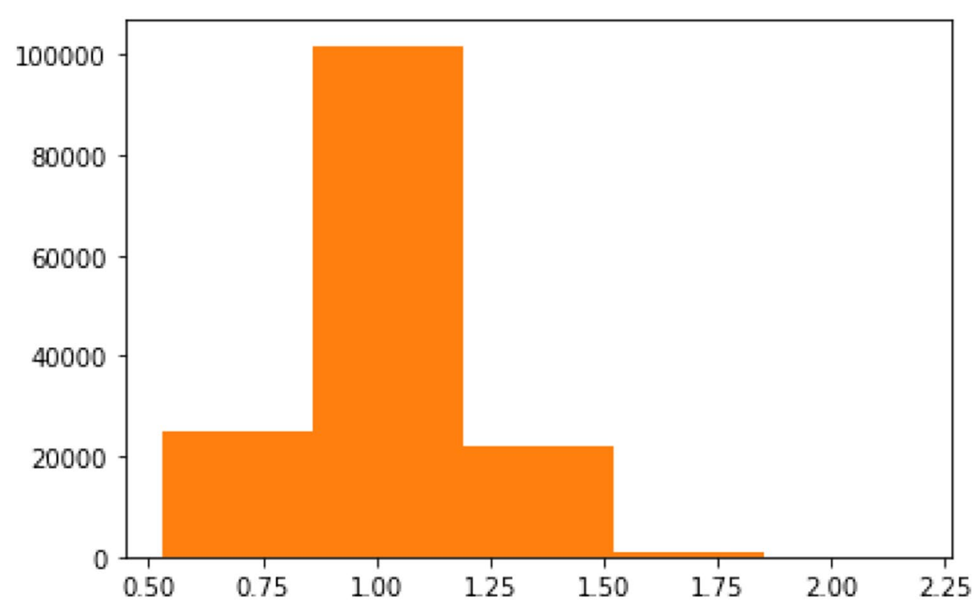
Augmentor

This study employs a data augmentation method called "Jittering" on the preprocessed data to mimic the "noisiness" of data generated by wearable sensors. Jittering was successfully implemented by Um et al. [20] as a time series data augmentation method to copy the effects of additive noise in accelerometer sensor data from Parkinson's disease patients. Jittering introduces a reasonable level of noise to the subject data by extracting random data from a normal distribution, and then adding this random data to input data. By using jittering, we are able to transform the clean seed data (i.e., $TcPO_2$ and foot temperature data) and raw data (i.e., glucose level data taken from the *UCI Diabetes Data Set*) into data similar to the kind collected by wearable sensors. The augmentation method we employ greatly enriches our dataset and enhances the robustness of AI models that try to classify or cluster the time series dataset synthesized by our system.

Data Generator

We employ *NeuralProphet* as a synthesis model for the IV. Data Generator. *NeuralProphet* is a novel forecast model for time series prediction that is a fork of Facebook's well renowned *Prophet*. One of the most distinguishable aspects

Fig. 3 Preprocessed $TcPO_2$ Data distribution between severity grades



of *NeuralProphet* in comparison to *Prophet* is that it harnesses the power of neural networks.

By utilizing *NeuralProphet*, we can leverage the powers of *AR-Net* [23], to enhance the accuracy and robustness of our data synthesis model.

To properly train *NeuralProphet*'s, we divide augmented data into two groups. First, we designate and extract 20% of the data as the test dataset. The remaining 80% of the entire dataset is again divided following a ratio of 2:8, each being the validation dataset and training dataset, respectively.

We conducted this experiment with various differing amounts of epochs and have reached the conclusion that the optimal number of epochs, where the training and validation error rates converged to the minimum, is 100 epochs. As such, the training of *NeuralProphet* is conducted for 100 epochs in this research.

To synthesize realistic and diverse data using *NeuralProphet*, setting up appropriate future regressors is essential. Future regressors are important components of how external factors, seasonality, and errors are reflected in the overall data pattern in a time series prediction model. Future regressors should be resistant to errors even in error-prone environments [30]. The multiplicative future regressors employed in this study precisely predict the future under a highly variable environment [31, 32]. After training, *NeuralProphet* will predict and generate $TcPO_2$, foot temperature, and glucose level data.

Lastly, HbA1c data may be calculated using the above-mentioned (Eqs. 1 and 2) in conjunction with the synthesized glucose level data.

Experiments

To evaluate our system, we take two steps. First, we generate synthetic medical data using our system, following the proposed medical criteria. Second, we apply K-means clustering on the data, synthesized in the first step, to verify how closely it resembles the features of each of the respective categories or severity grades. The following describes the experiment methods, procedures, and the results in detail.

Data Synthesis

In the first experiment, we synthesize three types of data, that is, $TcPO_2$, foot temperature, and glucose level data. The experiment is conducted as follows:

1. We generate seed data for both the diseased and non-diseased categories based on the medical criteria used for the synthesis of $TcPO_2$ and foot temperature data. In the case of glucose level data, the *UCI Diabetes Data Set* was used in order to generate data that reflects the seasonality of glucose levels in diabetic patients.
2. The II. Preprocessor processes the synthesized data following the procedures mentioned earlier, and randomly selects a certain amount of data, whose amounts conform to the F distribution, from a pool of synthesized data. The F distribution is used to reflect the volume distribution of data collected in a real-world environment.
3. The III. Augmentor applies jittering on preprocessed data with the σ parameter (which decides the size of the normal distribution to extract random data from) set to 0.5.
4. The IV. Data Generator trains *NeuralProphet* on augmented data with the test to remaining dataset ratio being 2:8. The remaining dataset is again split by a 2:8 ratio for the validation and training datasets, respectively. The model is trained for 100 epochs, thereafter. Finally, the IV. Data Generator synthesizes data for both the diseased and non-diseased categories, based on trends and patterns learned from the seed data.

Clustering

In our second experiment, we perform unsupervised machine learning (i.e., K-means clustering) on the synthesized data from the previous stage. By performing clustering, we can verify whether our proposed synthesis system is able to correctly and accurately synthesize medical data that is consistent with the general characteristics of each category or severity grade. When choosing the metric to use for cluster assignment, we elected to proceed with dynamic time warping (DTW) as it is less sensitive to the subtle changes of the sequence on the time axis, compared to the widely used Euclidean method, as described by Wang et al. [33]. The *tslearn* library [34] of Python was used to implement the clustering model.

Results

Table 3 presents the results of our clustering experiment on the $TcPO_2$ and foot temperature data generated by our system. The "Ground truth" column displays the actual amount of data that was chosen for each of the two categories (i.e., diseased and non-diseased). The "Clustered" column displays the amount of data that the K-means clustering algorithm considered to belong to each category. The "Classification accuracy" column shows the ratio between the amount of data that was clustered together and the amount of data that actually belongs to the given category. With this measure, we may evaluate whether the data synthesized by

Table 3 Clustering results of $TcPO_2$ and foot temperature (two clusters)

	Clustered	Ground truth	Classification accuracy
$TcPO_2$			
Non-diseased	441,428	441,428	1.00
Diseased	58,572	58,572	1.00
Foot temperature			
Non-diseased	192,119	192,119	1.00
Diseased	7881	7881	1.00

Table 4 Clustering results of $TcPO_2$ (five clusters)

	Clustered	Ground truth	Classification accuracy
$TcPO_2$			
Healthy	360,041	81,387	4.42
Normal	81,387	360,041	0.23
At risk	56,844	56,844	1.00
Severe	1701	1699	1.00
Critical	27	29	0.93

our system successfully imitates the aspects of actual data belonging to each of the respective categories. The fact that the "Classification accuracy" is 1.00 for all categories and types of data indicates that our system is appropriate for synthesizing training data for models tasked with the binary classification of diseased and non-diseased people.

To ensure the accuracy, robustness, and scalability of our system, we repeat the same clustering experiment again; this time with a larger number of data and with the implementation of a five-tiered severity grade (i.e., healthy, normal, at risk, severe, and critical). Table 4 presents the clustering results for the above-mentioned expanded clustering experiment. This time, we can observe that the "Classification accuracy" exhibits a certain level of deviation from the optimal ratio of 1.00. However, if we sum the values of the "Healthy" and "Normal" severity grades, which are showing the above-mentioned deviation, we can observe that the numbers add up to 441,428; which is the total amount of "Ground truth" data that was labelled "Non-Diseased". As shown in the experiment results, all grossly incorrect clustering happened within the "Non-Diseased" category, and the worst level of classification for the "Diseased" category was achieved for the "Critical" severity grade, which scored a classification accuracy of 0.93 out of 1.00. Although exhibiting some room for improvement, it could be said that our system is generally robust, accurate, and fulfills our purpose of synthesizing medical data to train AI models, aimed at the enhanced diagnosis of diabetic patients.

Since the *UCI Diabetes Data Set* only contains data taken from diabetic patients, we found it unnecessary to perform clustering for the glucose levels. However, we were able to calculate the seasonality trend of diabetic patients' glucose levels by having *NeuralProphet* learn from the data, as shown in Fig. 4. We received confirmation from a medical specialist that the seasonality learned by *NeuralProphet* displays a trend that reflects that of actual diabetes patients, and is within a medically valid range. Thus, we may reasonably claim that our proposed model holds up to its description even for glucose level data.

Discussion

Currently, it is proving to be difficult to apply more sophisticated evaluation methods to the synthetic data generated by our system, since we lack any other data of a similar nature for comparison. Nevertheless, the result from *NeuralProphet* shows promising results. We have confirmed that our model correctly identifies sharp increases in blood glucose level

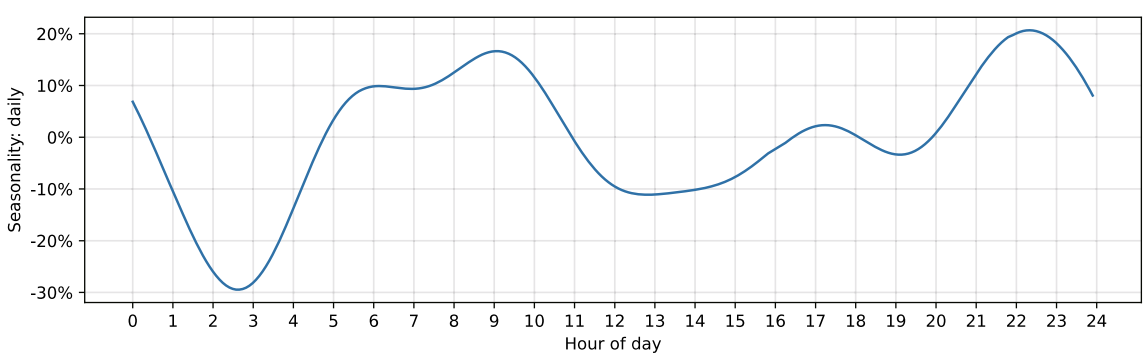


Fig. 4 An example of *NeuralProphet* daily seasonality of glucose level data

Table 5 Proposed list of custom specified seasonality for each parameter

Type of seasonality	Affected data	Name of custom seasonality
Hourly	Glucose level	Insulin from body
Sub-daily	Glucose level	Insulin intake, eating habit
	Foot temperature	Regular exercises, external temperature changes
Monthly	Glucose level	Insulin intake dosage change
	$TcPO_2$	Blood pressure changes
Quarterly	HbA1c	Mean glucose level changes

during time periods that are traditionally associated with regular meal consumption, and downward fluctuations during the rest of the day. It is also noteworthy that our system successfully imitates the characteristics of wearable sensor collected data, thanks to the data augmentation method (i.e., jittering) we implemented.

To test the validity of our work in the absence of a real dataset to compare with, we conducted a clustering experiment using the K-means algorithm on data synthesized by our system. The results of this experiment demonstrate the integrity and usability of our data. As such, this is expected to help accelerate the development of *SmartInsole*'s DFU diagnosis model. Based on the two experiments presented in this paper, we can expect to be able to synthesize medical data in a more sophisticated manner in the future. To improve the quality of data synthesized by our system, we may fine-tune our model further by customizing the *Seasonality* and *Holiday* of the *NeuralProphet*. This would contribute to the production of data that reflects more diverse and possibly personalized trends, with better reflection of external influencing factors. Table 5 shows the tentative custom *Seasonality* types of each parameter. This customizable *Seasonality* can be used in *NeuralProphet* model as well as *Prophet*.

As clinical trials based on *SmartInsole*, shown in Fig. 5, are scheduled to be conducted this year, we expect that we will soon be able to further this research with empirical data. We look forward to being able to shed light on the correlations between the parameters of *NeuralProphet* and the pattern of characteristics displayed by the synthesized data with the help of empirical data collected by *SmartInsole*.

Conclusion

Through this research, we proposed an advanced and flexible medical data synthesis system for DFU. Our system synthesizes time series data that factors in the characteristics of data collected by wearable sensors. The greatest merit of our system is that it takes a great leap forward in combatting the scarcity of readily available medical data through use of cutting-edge scientific methods; all the while maintaining medical validity. We also presented a systematic approach on how to synthesize medical data while following predefined medical criteria, which will undoubtedly be an asset for future researchers in this discipline. However, a limitation of our effort is that our system is currently incapable of synthesizing multivariate data simultaneously. This results in possible under-representation of correlations between external factors. We look forward to remedying this limitation through upcoming research, after the acquisition of empirical data collected by *SmartInsole*. In the future, we hope to enhance our proposed system, so that it may simultaneously synthesize multivariate medical time series data using a single deep learning model; hopefully in a versatile manner that is easily adaptable for other purposes.

Fig. 5 3D model and prototype of *SmartInsole*

(a) 3D model of *SmartInsole*

(b) Prototype of *SmartInsole*

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval In this study, the original research has been carried out by following the ethical principles.

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