

An AioT-Based Fistula Care System for Hemodialysis Patients

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An AioT-Based Fistula Care System for Hemodialysis Patients

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Abstract

Background: The fistula plays a crucial role in hemodialysis for patients, ensuring blood circulation between the patient's body and the dialysis machine, thereby enabling effective dialysis treatment. If the fistula loses its functionality without the knowledge of the hospital and medical staff, it poses significant risks to the patient, potentially even fatal.

Objective: This study designs a home care device based on AIoT technology that allows patients to easily operate it at home while facilitating the exchange of care information with medical institutions, addressing the aforementioned problem.

Methods: The designed detection device collects fistula blood flow sound signals using a microphone. These signals are then analyzed by a trained neural network model, which alerts the patient to the current status of their fistula through sound and light indicators. Additionally, the results are transmitted to the hospital's medical information system via low-power wireless modulation signals, enabling medical staff to record the patient's condition. The neural network model of the home care device was trained using 245 audio samples, each 30 seconds in length, of vascular sounds.

Results: The device achieved a 100% accuracy rate in identifying blockages (support=16, f1-score=1.00), a 100% accuracy rate in identifying slight blockages (support=19, f1-score=0.93), and a 91% accuracy rate in identifying no blockages (support=14, f1-score=1.00). The wireless signal transmission capability was effective over distances ranging from 8.68 km to 6.17 km, with RSSI (Received Signal Strength Indication) values between -107.2 dBm and -97.2 dBm, ensuring accurate and efficient data transmission. Additionally, a qualitative assessment using the Technology Acceptance Model was conducted to evaluate users' attitudes towards the system. Patients reported that the device is easy to use and expressed willingness to recommend it to others.

Conclusions: In conclusion, the proposed AIoT-based home care device demonstrates high detection accuracy, reliable wireless communication, and strong user acceptance. It not only enhances patient safety by enabling early detection of fistula issues at home but also facilitates proactive care coordination with medical institutions. This system shows great potential for widespread adoption in chronic dialysis care, improving both patient outcomes and healthcare efficiency.

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Original Manuscript

AN AIOT-BASED FISTULA CARE SYSTEM FOR HEMODIALYSIS PATIENTS

Abstract

The fistula plays a crucial role in hemodialysis for patients, ensuring blood circulation between the patient's body and the dialysis machine, thereby enabling effective dialysis treatment. If the fistula loses its functionality without the knowledge of the hospital and medical staff, it poses significant risks to the patient, potentially even fatal. This study designs a home care device based on AIoT technology that allows patients to easily operate it at home while facilitating the exchange of care information with medical institutions, addressing the aforementioned problem. The designed detection device collects fistula blood flow sound signals using a microphone. These signals are then analyzed by a trained neural network model, which alerts the patient to the current status of their fistula through sound and light indicators. Additionally, the results are transmitted to the hospital's medical information system via low-power wireless modulation signals, enabling medical staff to record the patient's condition.

The neural network model of the home care device was trained using 245 audio samples, each 30 seconds in length, of vascular sounds. The device achieved a 100% accuracy rate in identifying blockages (support=16, f1-score=1.00), a 100% accuracy rate in identifying slight blockages (support=19, f1-score=0.93), and a 91% accuracy rate in identifying no blockages (support=14, f1-score=1.00). The wireless signal transmission capability was effective over distances ranging from 8.68 km to 6.17 km, with RSSI (Received Signal Strength Indication) values between -107.2 dBm and -97.2 dBm, ensuring accurate and efficient data transmission. Additionally, a qualitative assessment using the Technology Acceptance Model was conducted to evaluate users' attitudes towards the system. Patients reported that the device is easy to use and expressed willingness to recommend it to others.

Keywords: Hemodialysis Fistula Monitoring, AIoT, Home Healthcare, LoRa.

1 Introduction

Hemodialysis is a common method for treating patients with chronic renal failure, helping to remove excess waste and fluids from the body. During hemodialysis, the patient's blood is filtered through an artificial kidney, or dialysis machine, and then returned to the body. For this process to occur, a reliable vascular access is required, which highlights the crucial role and importance of the venous fistula in hemodialysis.

A fistula is the passage that connects the patient's blood vessels to the dialysis machine. There are typically three types of vascular access: arteriovenous fistula, arteriovenous graft, and temporary catheter. The arteriovenous fistula is the most common and recommended type of vascular access. It involves surgically connecting an artery to a vein, causing the vein to expand due to the constant arterial blood flow, allowing 200ml-350ml of blood to be drawn per minute for dialysis. Its benefits include longer lifespan, lower infection risk, and good blood flow rates during dialysis. An arteriovenous graft uses an artificial blood vessel to connect an artery and a vein, often used for patients whose blood vessels are unsuitable for a fistula. The graft has a shorter lifespan and a slightly higher infection risk compared to the fistula. A temporary catheter is a soft plastic tube used in emergencies, inserted through a vein in the neck, chest, or groin, and connected to the dialysis machine. It has a very limited lifespan, usually only for short-term dialysis, and carries a higher risk of infection (Lok et al., 2020).

The fistula plays a vital role in hemodialysis by ensuring smooth blood circulation between the patient's body and the dialysis machine, enabling effective dialysis treatment. Selecting the appropriate type of vascular access is crucial for the patient's dialysis efficacy and long-term health. If the fistula loses functionality without the knowledge of the hospital and medical staff, it can pose significant risks to the patient, potentially leading to reduced blood flow, ineffective filtration, and accumulation of waste and fluids in the body,

worsening the patient's condition. Further dysfunction of the fistula may require emergency interventions to continue dialysis treatment.

To mitigate such risks, patients should work closely with healthcare providers, regularly check the fistula's functionality, and follow recommended care guidelines. Any abnormalities in fistula function should be promptly reported to a doctor for appropriate treatment. Various factors, including low vascular diameter, peripheral vascular disease, diabetes, and hypertension, can contribute to fistula dysfunction ((Lauvao et al., 2009; Lilly et al., 2012; Usta et al., 2012). Research indicates that loss of vascular access function is one of the causes of high complications and mortality rates in dialysis patients, leading to increased healthcare costs (Polkinghorne et al., 2004; Usta et al., 2012).

Therefore, this study aims to enhance patient safety and healthcare quality by designing an easy-to-operate home monitoring device with independent communication capabilities based on AIoT (Artificial Intelligence of Things) technology. This device aims to address the aforementioned issues by enabling continuous monitoring and timely communication with healthcare providers. The following sections will discuss current related research, the design and content of this study, and the validation results.

2 review of concepts and key research

2.1 Definition of Fistula Dysfunction

Based on the guidelines and clinical policies related to fistulas announced by the Society of Vascular Surgery, as well as vascular access educational research conducted by the American Association of Vascular Surgery and the North American Vascular Access Consortium, some relevant information on the definition of fistula dysfunction is provided. The definitions of fistula function loss are as follows:

- Primary Failure: Dysfunction occurring within 72 hours post-fistula surgery, which can be classified into early dialysis adaptation failure and delayed dialysis adaptation failure. This is determined if the fistula still cannot function by the third and sixth months post-vascular surgery.
- Primary Patency: The time from the establishment of the fistula to the first occurrence of fistula thrombosis or the need for vascular surgery to restore fistula patency.
- Secondary Patency: The interval from the establishment of the fistula to the first time the fistula must be abandoned.

The probability of primary failure for autogenous fistulas is 77%, and the subsequent usage rates for primary patency and secondary patency range from 50% to 70%. This indicates a high probability of fistula function loss, with fistula anastomosis obstruction being the most common type of obstruction (Al-Jaishi et al., 2014; Lee et al., 2011). Studies highlight the significant impact of frequent dialysis needle insertions and endothelial cell hyperplasia on the loss of fistula function in dialysis patients. These frequent needle punctures cause repeated endothelial injury, leading to endothelial cell proliferation and the formation of intimal hyperplasia, which are major contributors to fistula stenosis and thrombosis (Rothuizen et al., 2013).

2.2 Methods for Assessing Fistula Function

Duplex ultrasound and physical examination are recognized as the primary methods for detecting fistula occlusion. Compared to angiography, duplex ultrasound has been found to be more valuable in detecting significant fistula stenosis ($\geq 50\%$) and determining its location (Ćosović et al., 2020). However, the accuracy of physical examination in diagnosing fistula stenosis remains uncertain (Campos et al., 2007). Early clinical monitoring of fistulas, which combines clinical assessment with fistula monitoring techniques, has been shown to be more accurate than clinical assessment alone in detecting arteriovenous fistula stenosis (Gani et al., 1991). This combined approach is as effective as angiography in predicting clinical outcomes within six months (Berthezène et al., 1998).

Additionally, other less commonly used clinical methods have been proposed, such as indocyanine green dye injection followed by ultrasound echocardiography and gadolinium-enhanced magnetic resonance angiography for assessing fistula blood flow in various body regions (Pritchard et al., 1977). Due to the accessibility of medical methods and cost considerations, healthcare institutions most commonly rely on

clinical assessments to determine the presence of a thrill or use vascular ultrasound to assess the condition of the fistula. Less frequently are more accurate fistulography-type tests used. Even in clinical settings, ultrasound is generally employed, or data from the patient's hemodialysis, such as intrinsic maximum urea clearance rate or dialysis machine blood flow rate, is used to identify issues like reduced function or obstruction of the dialysis fistula (Koirala et al., 2016).

Color Doppler ultrasound can measure blood flow and identify the location of blockages within the fistula; however, this type of examination requires specialized medical personnel and time for testing. Some studies have explored non-invasive methods to detect vascular function (Koirala et al., 2016; Lopot et al., 2004), but these methods are not suitable for patients to perform at home to routinely monitor fistula function in advance.

Recent studies have adopted various approaches to provide more user-friendly yet accurate methods for detecting blockages in artificial blood vessels. Wang et al.'s research identified changes in blood flow sounds associated with stenosis, establishing a 2-D feature model that predicted a positive value with an accuracy of 87.84% (Wang et al., 2014). Another study by Wang et al. used a wavelet transform algorithm to extract features from vascular sounds, achieving an accuracy of 85.54% (Wang et al., 2011). Moreover, another study using the same wavelet transform reached almost perfect accuracy (Gram et al., 2011). Du and colleagues used photoplethysmography (PPG) to detect blockages in 11 patients, showing significant identification ability, though the study did not elaborate on how this could be applied clinically (Du & Stephanus, 2018). Research by Vesquez and Yeih applied machine learning techniques, specifically support vector machines, achieving an average accuracy of 90% (Vesquez et al., 2009; Yeih et al., 2014). These studies demonstrate promising advancements in non-invasive and accurate methods for detecting artificial blood vessel blockages, ranging from sound-based algorithms to machine learning techniques.

2.3 Home Devices and Hospital Communication Systems

Home devices and hospital communication systems mainly focus on remote monitoring, remote treatment, and electronic health records. The goal is to improve patients' quality of life, reduce healthcare costs, and provide timely data to healthcare professionals so they can better monitor patients' health conditions. As early as 2007, Varshney et al. began exploring the application of wireless technology in healthcare, including the interaction between home devices and hospital communication systems (Varshney, 2007). Demiris & Hensel conducted research on smart home applications for the elderly, including remote monitoring and communication with medical institutions (Demiris & Hensel, 2008). Pantelopoulos & Bourbakis reviewed wearable sensor health monitoring systems that can be integrated with hospital communication systems to achieve remote health monitoring (Pantelopoulos & Bourbakis, 2009).

There are numerous systematic reviews on home devices. Silva et al. conducted a review on mobile healthcare technologies, covering many methods and applications for connecting home devices with hospital communication systems (Silva et al., 2015). More recent studies have begun applying IoT technology, such as Bublitiz et al., who highlighted various applications of IoT in remote patient monitoring and the interaction between home devices and hospital communication systems (M. Bublitiz et al., 2019). Kondylakis and Tsanas discussed how AI-based machine learning and digital health applications or tools impact healthcare in real-life situations, which also involves the interaction between home devices and hospital communication systems (Kondylakis et al., 2020; Tsanas et al., 2021; Woodward et al., 2020). Mahajan and Wardhani focused on the application of IoT-based health monitoring systems for chronic patients, including the interaction between home devices and hospital communication systems (Mahajan & Birajdar, 2019; Wardhani et al., 2021).

From the above literature, it can be observed that most studies on artificial blood vessel blockage detection focus on experimenting with new methods and verifying their accuracy. However, these methods are limited by their sample labeling and approach, being able to only identify the presence or absence of blockages, without detecting intermediate deterioration. Recent AI algorithm studies have shown that alternative methods can achieve an approximately 90% success rate in detecting blockages, but they do not further explore how to apply these methods in clinical settings and hospital workflows. Therefore, applying communication, IoT, and AI technologies in home healthcare has significant potential and room for development. These technologies can improve patients' quality of life, enhance healthcare efficiency, reduce costs, and enable healthcare professionals to closely monitor patients' health. In remote monitoring, connecting home devices to hospital communication systems allows healthcare professionals to monitor patients' physiological indicators, such as

heart rate, blood pressure, and blood glucose, in real-time. This helps detect changes in patients' conditions early and provides appropriate treatment when necessary. Electronic health records can integrate patients' health information into the electronic health record system, facilitating information sharing and improving the accuracy and efficiency of diagnosis and treatment. IoT-based home care systems can intelligently provide important reminders, while AI technology can analyze patient data, predict disease progression trends, and formulate corresponding treatment plans in advance. We can see that communication, IoT, and AI technologies have broad application prospects in home care. As these technologies continue to develop and improve, home care will become increasingly intelligent, bringing better healthcare quality to patients and medical professionals.

3 Methods

The primary objective of this study is to develop a low-cost, non-invasive home monitoring device for patients who regularly undergo hemodialysis at the hospital. The device should be easy to use, provide intuitive feedback, and allow patients to monitor their fistula function at home. Additionally, the device should transmit data in real-time to the hospital's clinical system, effectively preventing situations where patients arrive at the hospital only to discover that their fistula function has deteriorated or is completely blocked. Such issues, if not addressed promptly, could result in the inability to perform hemodialysis and lead to life-threatening conditions for the patient.

The system is designed to automatically notify the corresponding case manager at the hospital, enabling the hospital to arrange for early interventional treatment. This proactive approach avoids discovering fistula dysfunction only when hemodialysis is necessary, thereby reducing patient risk and lowering healthcare costs. The design utilizes low-power, long-range independent wireless signal transmission, avoiding the need to rely on paid mobile network infrastructure and signals.

As shown in Figure 1, the system's data transmission and processing flow begins when the patient places the monitoring device on the fistula site. The device's sound collector gathers fistula blood flow sound signals, which are then analyzed by a trained AI (Artificial Intelligence) model. The device provides feedback on the current fistula status using sound and LED (Light-Emitting Diode) indicators. The results are transmitted via a LoRa (Long Range) module to a LoRa antenna and receiving gateway installed at the hospital. The data is then integrated into the hospital's medical information system and forwarded as real-time messages to the case manager, nurses, and attending physicians for timely follow-up with patients who require intervention.

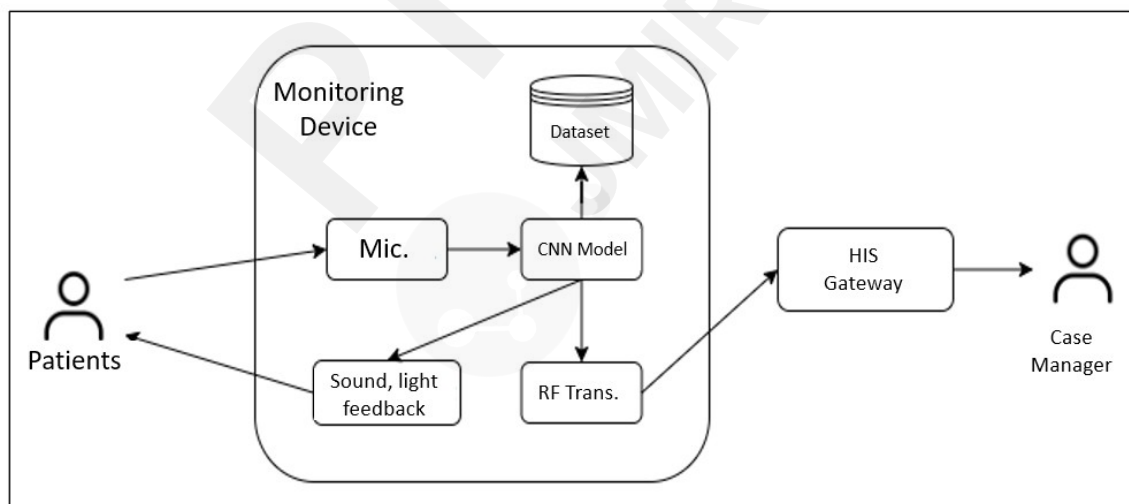


Figure 1. Data transmission and processing flow of the system in this study.

3.1 Research Subject

In terms of selecting the research subjects, this study targets two general hospitals with approximately 1,100 beds, focusing on its hemodialysis center. The hemodialysis centers at these two hospitals have a combined

total of 130 beds. This study aims to collect 250 soundwave recordings of arteriovenous fistulas under varying conditions. Cases involving non-hemodialysis or non-fistula patients were excluded from the study.

This research has been approved by the Institutional Review Board (IRB number: 220406). Regarding the recruitment of participants, the researchers consulted with the patients in the dialysis center about their willingness to participate, and an informed consent form was provided to ensure that the participants understood the relevant details of the study. To protect the rights of the research subjects, the researchers will only have contact with the patients during the actual collection of the soundwave files and will not have any physical or non-physical contact with the patients at any other time. Consent will be obtained from the patients prior to recording, and no personal information will be marked.

Moreover, to protect the personal data of the research subjects, all patient-related information will be deleted and destroyed one year after the conclusion of the study. The informed consent form will also provide contact information for consultation, allowing participants to contact the researchers at any time.

3.2 System Design

This study focuses on collecting soundwave samples from the arteriovenous fistulas of the research subjects undergoing dialysis. The collected soundwave files are then processed by first labeling and classifying the samples into three major categories: normal, slightly occluded, and occluded requiring intervention. The classification of samples is primarily based on the physical examination guidelines specified in the Hemodialysis Clinical Guidelines (KDOQI, 2005). When vibrations are felt at the arterial end, mid-section, and venous end of the arteriovenous graft, it indicates a blood flow rate of greater than 450 ml/min. If the vibration turns into a pulse or turbulence is heard, it indicates a low blood flow rate, classified as slight stenosis or occlusion. Complete occlusion is characterized by the absence of sound and vibration. Excessive venous pressure and significant blood flow recirculation during dialysis are also classified as occlusion (KDOQI, 2006). Since all patients in this study are from the dialysis center, blood flow rates on dialysis machines are additionally used to confirm occlusions. A blood flow rate of less than 600 ml/min in the arteriovenous graft indicates a high probability of thrombosis. The labeled data is subsequently converted from analog to digital format, followed by model training using a neural network AI model.

Once a suitable model is tested, it is transferred to a single-chip processor in a home monitoring sensor and integrated into a home device design. This includes the integration of soundwave collection, recognition, lighting, sound, and transmission modules, along with the assembly of the prototype device casing. The device is then tested for usability, adjusted, and finally evaluated for system performance. The following sections detail the data collection, processing, neural network model training, and firmware and hardware design.

3.2.1 Data collection methods

Data collection took place between February and May 2023. A custom-built electronic stethoscope was used to collect the soundwaves of blood flow in the patients' arteriovenous fistulas. The sound was recorded and stored in WAV format as stereo audio files using recording software. The custom-built electronic stethoscope utilizes a standard stethoscope head equipped with a diaphragm to capture the sound of blood flow, with the other end connected to an electronic microphone via a soft tube. The microphone is connected to a laptop or other recording device via a 3.5 mm audio jack, effectively capturing the sound of blood flow through the patient's fistula.

The collected audio files were labeled according to the sample classification method. Of the samples, 45 were classified as unobstructed, each lasting 30 seconds in WAV format. Slight occlusion samples totaled 10, each also lasting 30 seconds, and there were 6 occlusion samples of 30 seconds. The remaining samples were classified as normal blood flow.

3.2.2 Data processing

The collected WAV audio files of fistula blood flow were imported and decoded using TensorFlow tools, such as 'tf.io.read_file' and 'tf.audio.decode_wav'. The 'tf.squeeze' function was applied to squeeze and remove dimensions with a size of 1. The audio files were converted into 'int64' format and then resampled to 16,000 Hz using the 'tf.io.audio.resample' function to reduce the sample size.

A 30-second audio file was divided into segments using a 1000ms window size and 350ms, 500ms, and 700ms window increments to generate subsequent training datasets for the AI model. Of the 45 audio samples, 36 were used for training, while the remaining 9 were used as test data to evaluate model accuracy. A label array was generated with the same number of entries as the training dataset. The labels and actual data were connected using the 'tf.data.dataset.zip' function to create labeled training sets.

Compared to the commonly used Fourier Transform (FT), the Short-Time Fourier Transform (STFT) retains both frequency and time information, making it more suitable for dynamic audio analysis (Bracewell, 2000). The processed audio data was converted using STFT with a frame length of 320 and a step size of 32, producing spectrograms containing both time and frequency information. To ensure consistency, all generated data were converted into spectrograms with a length of 1491 and a width of 257. Long audio files were trimmed, while shorter ones were zero-padded. The data was shuffled to prevent clustering of positive and negative samples, which could impact accuracy.

3.2.3 Neural network classifier for model training

This study employed a Convolutional Neural Network (CNN) model to recognize soundwave data. CNN is a type of deep learning model widely used in image recognition, object detection, and speech recognition applications. CNN models are composed of multiple convolutional and pooling layers that automatically learn useful features from input sound data, enabling classification and recognition tasks. The key feature of the designed model is its ability to capture local features and spatial relationships in sound data, allowing it to extract and classify relevant features from both time and frequency dimensions. Since audio signals are high-dimensional data, they must be compressed and abstracted for classification. CNN achieves this by using convolution and pooling operations to extract critical features at different times and frequencies, reducing dimensionality and improving accuracy. The model development and training process are described below.

a. Model architecture

As shown in Table 1, the original training data consists of spectrograms sized 1491x257. The first convolution layer (Convolution Layer) uses a 3x3 filter with 16 different feature detectors to extract features from the input data. After feature extraction, the feature map has a size of 1489x255. Max pooling is applied using a 3x3 pool size to select the maximum values from the matrix, reducing overfitting and noise. After pooling, the matrix size is reduced to 494x83. The subsequent convolution and pooling layers serve the same purpose and are not described in detail. The fully connected layer (Fully Connected Layer) serves as the classifier, outputting a value for the final judgment.

Neural Network Layer	Output Shape	Parameters
CONV2D (CONV2D)	(None, 1489, 255, 16)	160
MAX_POOLING2D (MAXPOOLING2D)	(None, 496, 85, 16)	0
CONV2D_1(CONV2D)	(None, 1487, 253, 16)	2320
X_POOLING2D_1 (MAXPOOLING2D)	(None, 164, 27, 16)	0
FLATTEN(FLATTEN)	(None, 6019376)	0
DENSE(DENSE)	(None, 128)	9068672
DENSE_1(DENSE)	(None, 1)	129

Table 1. Model architecture dimensions and parameters used in the research designment.

b. Model Performance Evaluation

To evaluate the performance of the CNN-based neural network model, various metrics can be used, as described below:

- Accuracy: Accuracy is one of the most fundamental evaluation metrics, representing the proportion of correctly predicted samples out of the total number of samples.
- Precision: Precision refers to the proportion of correctly predicted positive samples among all samples that the model classified as positive. A high precision score indicates fewer false positives (incorrectly classified positive samples).
- Recall: Recall measures the proportion of actual positive samples that are correctly identified as positive by the model. A high recall score suggests fewer false negatives (missed positive samples).
- F1-Score: The F1-Score is the harmonic mean of precision and recall, helping to balance the trade-off between these two metrics.

Additionally, the (confusion matrix) incorporates the above-mentioned metrics into a single matrix, allowing for a comprehensive quantification of the model's performance. In a confusion matrix: TP (True Positive): The number of positive samples correctly predicted as positive. TN (True Negative): The number of negative samples correctly predicted as negative. FP (False Positive): The number of negative samples incorrectly classified as positive. FN (False Negative): The number of positive samples incorrectly classified as negative. Based on the confusion matrix, multiple performance metrics can be derived. For a three-class classification problem, the corresponding confusion matrix can be designed as shown in Table 2.

Actual Blockage (B)	Actual Slight Blockage (S)	Actual No Blockage (N)
Predicted Blockage (B)	PBB	PSB
Predicted Slight Blockage (S)	PBS	PSS
Predicted No Blockage (N)	PBN	PSN

Table 2. The corresponding confusion matrix for three-class classification.

Among them, PBB, PSS, and PNN represent the correctly predicted blocked, slightly blocked, and unblocked values, respectively, which correspond to the True Positive (TP) values for each category. The other fields represent the incorrectly predicted values. We can calculate the True Negative (TN), False Positive (FP), and False Negative (FN) for each category as follows:

For Blocked Category: TN (True Negative) = PSS + PNS + PSN + PNN; FP (False Positive) = PSB + PNB; FN (False Negative) = PBS + PBN

For Slightly Blocked Category: TN (True Negative) = PBB + PNB + PBN + PNN; FP (False Positive) = PSS + PNS; FN (False Negative) = PSB + PSN

For Unblocked Category: TN (True Negative) = PBB + PSB + PBS + PSS; FP (False Positive) = PSN + PNN; FN (False Negative) = PNB + PNS

Based on the above definitions, we can further compute the following metrics:

- Accuracy: $(TP + TN) / (TP + TN + FP + FN)$
- Precision: $(TP) / (TP + FP)$
- Recall: $(TP) / (TP + FN)$
- F1-Score: $2 * ((Precision * Recall) / (Precision + Recall))$
- False Positive Rate (FPR): $FP / (FP + TN)$
- False Negative Rate (FNR): $FN / (TP + FN)$

c. Model Conversion

Considering that microprocessors require lightweight models, TensorFlow Lite employs various techniques to reduce model size compared to standard TensorFlow models. This enables the model to be used for real-time recognition on devices with relatively limited computing power—such as endpoint devices and mobile apps.

The conversion is performed using the `tf.lite.TFLiteConverter` function to transform a TensorFlow model into a TensorFlow Lite model, which is then exported. After exporting, the Linux `xxd` command is used to convert the model into hexadecimal data formatted as a C language array that can be utilized by microprocessors.

3.2.4 Firmware and Hardware Design

This study utilizes Visual Studio Code combined with Platform.io as the development platform. The development board used is TTGO-T-Beam ESP32 LoRa, chosen for its compact size, low power consumption, and widely adopted ESP32 core. Additionally, this development board integrates a LoRa module, enabling long-distance data transmission without requiring an internet connection. The TensorFlow Lite Micro package is utilized to enable interaction between the microprocessor and TensorFlow Lite models.

The project structure includes:

- `lib` folder: Stores function libraries.
- `src` folder: Contains the main `main.cpp` file, the model data exported via `xxd`, and functions for interacting with TensorFlow Lite Micro.
- `platformio.ini`: Stores development board configuration information.

a. Acoustic Signal Acquisition

The device is self-contained with only a single operation button and is powered by a battery. It remains in sleep mode for power saving. When the button is pressed, the device emits a prompt sound and begins detecting vascular acoustic signals for approximately 10-30 seconds. The audio signal is captured using an ADC (Analog-to-Digital Converter) combined with a stethoscope-like unidirectional microphone. The I2S (Inter-IC Sound) protocol is used to transfer the audio data to the ESP32 for further processing.

b. Sound Processing and AI Prediction

When the ESP32 receives the fistula sound data, it follows the same processing flow as the previously handled training audio data. First, the audio signal is **decoded and converted into int64 format. Then, Short-Time Fourier Transform (STFT) is applied to extract frequency and time-domain information, which is used to generate a spectrogram.

For model inference, in addition to embedding the pre-converted C array format model into the microprocessor, it is necessary to utilize TensorFlow Lite Micro components for interaction. Two key files are primarily used:

i. `tensorflow/lite/micro/all_ops_resolver.h`

This file loads all available TensorFlow Lite operations that can be executed on the microprocessor.

To optimize memory usage, only the required functions for the model are loaded selectively.

ii. `tensorflow/lite/micro/micro_interpreter.h`

This is the core tool for running the model inference.

Input data is sequentially sent to the interpreter input buffer, ensuring that it matches the expected input shape of the model. Once the input data is fully loaded, the function `interpreter.Invoke()` is executed to perform the prediction.

c. LED and Speaker Alerts

The AI model classifies the results into three categories: `status_1` (No Blockage), `status_2` (Partial Blockage) and `status_3` (Severe Blockage). Once the classification is complete, the device uses LED indicators and a speaker to inform the user of the current fistula condition: `Status_1` the LED displays a green light, and the speaker announces that the fistula is functioning normally. `Status_2` the LED displays a yellow light, and the speaker warns that the fistula may have minor abnormalities, advising the user to pay close attention. `Status_3` the LED displays a red light, and the speaker alerts the user that the fistula is severely blocked,

urging them to immediately contact their healthcare provider. Figure 2 shows the circuit architecture of this study. This hardware and firmware integration ensures efficient, real-time vascular anomaly detection, making it suitable for home-based health monitoring applications.

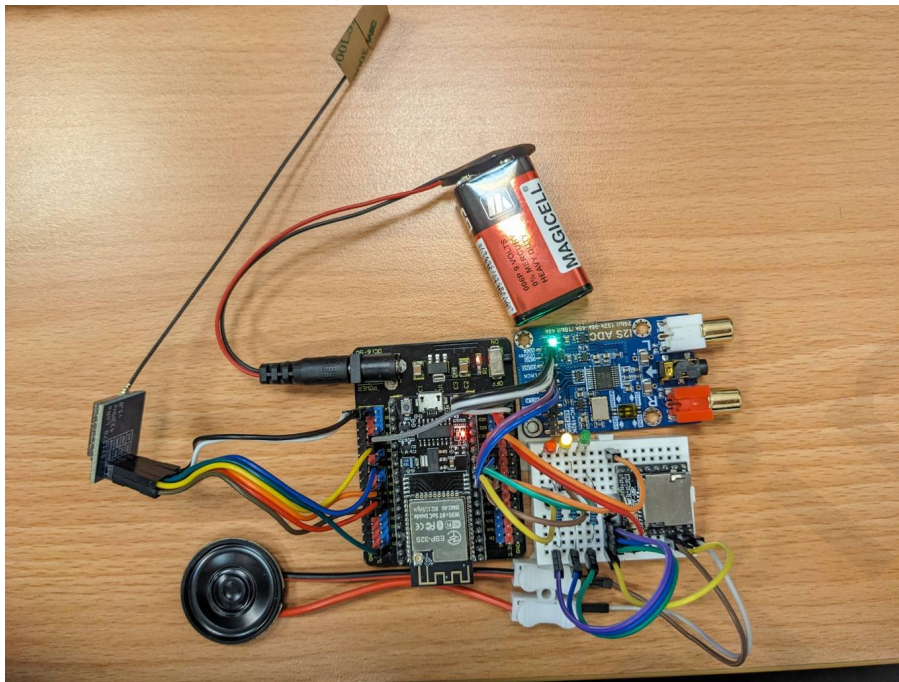


Figure 3. Circuit components of the home detection device. Left side: Wireless signal transmission module and antenna. Top section: 9V battery power supply. Upper right: Audio input processing unit.

d. Remote communication mechanism with the hospital

The device is equipped with a built-in LoRa transmission module and utilizes the LoRa.h library to send independent long-range wireless signals to the receiving station. When the patient powers on the device, it immediately transmits a startup signal. If the model predicts that the patient's fistula is currently blocked, the receiving station will proactively send the detected blockage information, detection time, and other relevant data to the hospital's case management system. Once the case manager receives the data, they can use the transmitted information to notify the patient for further examination and determine any additional tests or treatments required. The system is designed to send an alert to the hospital's case management system if the receiving station does not receive a startup signal or vascular status update for a predefined period, such as five days. This notification prompts the case manager to follow up on the patient's condition.

4 results

This system is characterized by its ability to use fistula blood flow acoustic features and artificial intelligence to assess the health status of artificial blood vessels. It can autonomously and independently transmit data back to the hospital without relying on other network infrastructures. The device is an all-in-one, fully independent unit with low power consumption, making it convenient for patients to store and use. This study evaluates the AI model's recognition accuracy, signal transmission, and users experience by TAM (Technology Acceptance Model) (Davis, 1989).

4.1 AI model performance evaluation

The AI performance evaluation adopts the confusion matrix method to quantify model performance. In this study, a total of 245 samples were used to test the model: 158 samples of non-blocked fistulas (each

containing 30 seconds of audio); 54 samples of mildly blocked fistulas; 33 samples of fully blocked fistulas. The trained AI model's confusion matrix is shown in Table 3.

	Actual Blockage	Actual Slight Blockage	Actual No Blockage
Predicted Blockage	97.50%	0%	2.5%
Predicted Slight Blockage	0%	100%	0%
Predicted No Blockage	1.3%	0	98.7%
F1-Score	0.96	1.00	0.99
Precision	0.99	1.00	0.99
Recall	0.99	1.00	0.99

Table 3. Confusion Matrix of the AI Model

Using the results from the confusion matrix, the model's performance was evaluated for each fistula condition. In detecting fistula blockages, the model demonstrated a higher accuracy in identifying mild blockages, while the other two categories achieved an accuracy rate of approximately 97% or higher.

Additionally, for the same dataset, this study conducted cross-validation using an SVM (Support Vector Machine) machine learning model. The True Positive (TP) rates for the blocked, mildly blocked, and non-blocked categories were 85.71%, 100%, and 83.33%, respectively, with F1-Scores of 0.75, 1.00, and 0.88. While the SVM model performed slightly worse than the CNN model, it still achieved an accuracy rate of over 85% with the same dataset.

4.2 Signal transmission

This study employs radio packets as the data transmission mechanism. Using LoRa modulation, the home transmission device sends a short message packet to the hospital's receiving gateway, which contains the device ID, timestamp, and status code. Since this system relies on wireless communication, antenna placement and proper height significantly affect signal reception.

Home signal transmission is influenced by building obstructions, so a small indoor relay device is placed inside the house to retransmit the signal to an external antenna. The home device uses a 127 cm flexible antenna to improve transmission distance, while the hospital's gateway is equipped with a 200 cm vertical coaxial antenna mounted on the hospital rooftop.

The study measures the relative position of home devices, their distance from the hospital, and signal strength, using RSSI (Received Signal Strength Indication) as the measurement unit. The prototype system experiment results are as follows:

- Hospital Gateway Location: 120.44164E, 23.78082N
- Home Device 1: 120.49921E, 23.75716N, 8.68 km away, RSSI: -107.2 dBm
- Home Device 2: 120.42840E, 23.71519N, 10.96 km away, RSSI: -112.7 dBm
- Home Device 3: 120.49097E, 23.76556N, 617 m away, RSSI: -97.2 dBm

The LoRa communication protocol supports SF (Spreading Factor) settings, where a higher SF value increases communication distance but lowers transmission speed and increases power consumption. The SF value can be set between SF7 and SF12. Since this study requires only a small data transmission volume, high speed is unnecessary. Instead, distance and power consumption are the primary considerations. Therefore, SF was set to 12 (Bouras et al., 2021).

4.3 Technology acceptance of system-related users

The final part of the study adopts a qualitative analysis approach, using the Technology Acceptance Model (TAM) as the framework to evaluate system-related users' perceptions of the system in terms of perceived usefulness, perceived ease of use, attitude toward using, and intention to use (Davis, 1989). The evaluation consists of the following four dimensions:

- Perceived Usefulness: Whether patients, nurses, and doctors believe the system helps improve the management of artificial blood vessel health.

- ii. Perceived Ease of Use: Whether patients find the system easy to use.
- iii. Attitude Toward Using: The positive attitude of patients and nurses toward the system.
- iv. Intention to Use: Patients' willingness to use the system.

For the evaluation method, a case-based qualitative interview approach was adopted to collect feedback from system-related users on these four dimensions. The evaluation framework, interviewees, and question design are shown in Table 4.

Dimension	Respondents	Questions
1. Perceived usefulness	Patients (3 individuals) Nurses and Case Managers (1 individual each) Kidney Specialist (1 individual)	a. Do you think this system can assist in improving the management of vascular health? b. Do you think this system can help reduce the safety risks associated with artificial blood vessels?
2. Perceived Ease of Use	Patients (3 individuals)	a. I think the device is easy to learn. b. I think the device is easy to operate.
3. Attitude Toward Using	Patients (3 individuals) Nurses and Case Managers (1 individual each)	a. I feel excited about this system. b. I think using this system is a good choice.
4. Intention to Use	Patients (3 individuals)	a. I would like to use this device. b. I would recommend this device to others.

Table 4. Interview dimensions, respondents, and question design.

The interview content was structured based on the TAM (Technology Acceptance Model) framework, forming questions corresponding to its four dimensions. The interview responses were text-coded and analyzed according to these four dimensions, yielding the following results. 1st Perceived Usefulness: Specialist nurses and doctors indicated that they believe the system, utilizing fistula blood flow acoustic features and AI recognition, helps patients monitor their vascular health independently. They also expressed satisfaction with the system's ability to automatically transmit data to the hospital and proactively notify relevant parties. However, the kidney specialist noted that, from a physician's perspective, the system would be more useful if it could provide more precise clinical data. Currently, the device can only detect a few basic conditions, and patients still require further evaluation upon arriving at the hospital. Therefore, it has not yet reached the level of personal health management. 2nd Perceived Ease of Use: Patients mentioned that the standalone device is simple to use: they only need to press the power button and place it on the vascular site, and within approximately 30 seconds, the system can determine the vascular condition. If an issue is detected, the device automatically notifies the hospital without requiring any additional action from the patient. The device is compact, easy to use, and convenient to store. 3rd Intention to Use: According to the interviews, patients stated that the device is easy to use and convenient to maintain. When asked if they would recommend it, they expressed enthusiasm about recommending it to other patients. Patients also showed a sense of reliance on healthcare professionals, indicating a desire for frequent attention, not only in device usage but also in its maintenance and monitoring. 4th Attitude Toward Using: All feedback on attitudes toward using the system was positive. Nurses, in particular, highlighted that if the system could proactively and timely inform them of a patient's condition, it would allow them to assist in arranging vascular treatments more effectively and provide them with more time to respond to patients' needs.

5 discussion

Based on the system evaluation results, the application of the AI model, the independent remote communication system, and the technology acceptance behavior of related users all received positive feedback. Additionally, the system designed in this study is the first known low-cost, user-friendly device specifically developed for monitoring artificial vascular functionality at home, as reported in relevant international research publications. Feedback from different system user roles provided insights into the Technology Acceptance Model (TAM) of this AI-powered monitoring system, which can serve as a basis for future improvements. The Remote Patient Management (RPM) technology not only enables patients to

monitor their fistula functionality at home in real-time but also prevents situations where fistula blockages are only discovered during infrequent hospital visits, which might lead to delayed repairs. Through AI recognition technology, the system can accurately monitor whether the fistula is currently unobstructed or shows signs of mild blockage. Using LoRa, a non-network-based communication technology, the system can immediately report the patient's fistula status to the case manager. This allows case managers to respond promptly and effectively to the patient's current condition.

References

- Al-Jaishi, A. A., Oliver, M. J., Thomas, S. M., Lok, C. E., Zhang, J. C., Garg, A. X., Kosa, S. D., Quinn, R. R., & Moist, L. M. (2014). Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis. *American Journal of Kidney Diseases*, 63(3), 464-478.
- Berthezène, Y., Howarth, N., & Revel, D. (1998). Pulmonary arteriovenous fistula: detection with magnetic resonance angiography. *European radiology*, 8, 1403-1404.
- Bouras, C., Gkamas, A., Katsampiris Salgado, S. A., & Papachristos, N. (2021). Spreading Factor Analysis for LoRa networks: A supervised learning approach. *Trends and Applications in Information Systems and Technologies: Volume 1* 9,
- Bracewell, R. N. (2000). *The Fourier Transform and Its Applications*. McGraw Hill. <https://books.google.com.tw/books?id=ZNQQAQAAIAAJ>
- Campos, R. P., Chula, D. C., Riella, M. C., & Nascimento, M. M. (2007). O exame físico como método de detecção de estenose da fístula arteriovenosa. *J. bras. nefrol*, 64-70.
- Ćosović, A., van der Kleij, F. G., Callenbach, P. M., Hoekstra, M. C., Hissink, R. J., & van den Berg, M. (2020). The diagnostic value of duplex ultrasound in detecting the presence and location of a stenosis in an autologous arteriovenous fistula. *The Journal of Vascular Access*, 21(2), 217-222.
- Davis, F. D. (1989). Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS quarterly*, 319-340.
- Demiris, G., & Hensel, B. K. (2008). Technologies for an aging society: a systematic review of “smart home” applications. *Yearbook of medical informatics*, 17(01), 33-40.
- Du, Y.-C., & Stephanus, A. (2018). The feasibility study of photoplethysmography features for arteriovenous fistula stenosis detection in hemodialysis patients with statistical approach. 2018 IEEE International Conference on Applied System Invention (ICASI),
- Gani, J. S., Fowler, P. R., Steinberg, A. W., Wlodarczyk, J. H., Nanra, R. S., & Hibberd, A. D. (1991). Use of the fistula assessment monitor to detect stenoses in access fistulae. *American Journal of Kidney Diseases*, 17(3), 303-306.
- Gram, M., Olesen, J. T., Riis, H. C., Selvaratnam, M., Meyer-Hofmann, H., Pedersen, B. B., Christensen, J. H., Struijk, J., & Schmidt, S. E. (2011). Stenosis detection algorithm for screening of arteriovenous fistulae. 15th Nordic-Baltic Conference on Biomedical Engineering and Medical Physics (NBC 2011) 14-17 June 2011, Aalborg, Denmark,
- Koirala, N., Anvari, E., & McLennan, G. (2016). Monitoring and surveillance of hemodialysis access. *Seminars in interventional radiology*,
- Kondylakis, H., Katehakis, D. G., Kouroubali, A., Logothetidis, F., Triantafyllidis, A., Kalamaras, I., Votis, K., & Tzovaras, D. (2020). COVID-19 mobile apps: a systematic review of the literature. *Journal of medical Internet research*, 22(12), e23170.
- Lauvao, L. S., Ihnat, D. M., Goshima, K. R., Chavez, L., Gruessner, A. C., & Mills Sr, J. L. (2009). Vein diameter is the major predictor of fistula maturation. *Journal of vascular surgery*, 49(6), 1499-1504.
- Lee, T., Mokrzycki, M., Moist, L., Maya, I., Vazquez, M., Lok, C. E., & Consortium, F. t. N. A. V. A. (2011). Standardized definitions for hemodialysis vascular access. *Seminars in dialysis*,
- Lilly, M. P., Lynch, J. R., Wish, J. B., Huff, E. D., Chen, S.-C., Armistead, N. C., & McClellan, W. M. (2012). Prevalence of arteriovenous fistulas in incident hemodialysis patients: correlation with patient factors that may be associated with maturation failure. *American Journal of Kidney Diseases*, 59(4), 541-549.
- Lok, C. E., Huber, T. S., Lee, T., Shenoy, S., Yevzlin, A. S., Abreo, K., Allon, M., Asif, A., Astor, B. C., & Glickman, M. H. (2020). KDOQI clinical practice guideline for vascular access: 2019 update. *American Journal of Kidney Diseases*, 75(4), S1-S164.
- Lopot, F., Nejedlý, B., & Válek, M. (2004). Vascular access monitoring: methods and procedures—something to standardize? *Blood purification*, 23(1), 36-44.

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