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Evaluation of a piezoelectric pulse wave analysis system for noninvasive carotid plaque screening in a field study against Doppler ultrasonography

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Abstract

Carotid artery atherosclerosis is a major contributor to ischemic stroke, but access to flagging arteries for confirmatory imaging remains limited in primary care and rural hospitals. Doppler ultrasonography, the clinical standard for plaque assessment, requires costly equipment and trained operators, underscoring the need for a portable and affordable screening alternative. We evaluated the SKAI-TOUCH system, a piezoelectric transducer-based platform that acquires carotid pulse wave signals and applies a deep-learning algorithm to detect plaque-related flow disturbances. In a prospective field study of 100 participants (200 carotid arteries), SKAI-TOUCH measurements were compared with Doppler ultrasonography, with arteries classified as plaque-positive (score ≥ 1) or plaque-negative (score 0). Data was divided 80/20 for model training and testing. The algorithm achieved a sensitivity of 92.3%, specificity of 92.6%, positive predictive value of 85.7%, negative predictive value of 96.2%, and overall accuracy of 92.5%. These findings support SKAI-TOUCH device as a promising noninvasive tool for decentralized carotid plaque screening.

Introduction

Early detection of carotid artery disease remains a major unmet need in global stroke prevention. Although carotid atherosclerosis is a well-established precursor of ischemic stroke, most individuals at risk are never screened because definitive assessment relies on Doppler ultrasonography, an operator dependent and resource intensive modality largely confined to hospitals and vascular laboratories[1–5]. This limited accessibility creates a critical gap in early identification, particularly in community and primary care settings where most stroke risk accumulates. Addressing this screening bottleneck is essential for reducing preventable cerebrovascular events.

Cerebrovascular disease remains the second leading cause of death and the third leading cause of combined mortality and disability worldwide. In 2021, ischemic stroke accounted for more than 65% of new stroke cases and contributed substantially to the global burden of lost healthy life years[6]. In Thailand, cardiovascular and cerebrovascular diseases have become central public health priorities, mirroring an overarching epidemiological transition across Asia marked by rising death and disability rates from major non-communicable conditions[7]. Projections using Bayesian Age-Period-Cohort modelling indicate that ischemic stroke mortality will continue to rise through 2030, underscoring the need for more effective and accessible screening approaches[8].

The presence and severity of carotid atherosclerosis are strong predictors of long-term cardiovascular outcomes[9]. Non-invasive risk assessment is therefore central to stroke prevention, particularly for detecting subclinical plaque before symptoms emerge[10]. Carotid plaque is also closely associated with silent brain infarction, which often remains undiagnosed until substantial neurological injury has occurred[11]. Biomechanical studies further show that plaque vulnerability is influenced by local mechanical strain, with 3D stress analyses identifying structural instability as a key determinant of rupture[12]. These mechanistic insights have motivated interest in hemodynamic markers that reflect underlying vascular pathology. Recent studies using pulse wave imaging have demonstrated that the stiffness and composition of plaque constituents significantly alter the propagation of arterial pressure waves, providing a physical basis for advanced acoustic screening methods[13].

Advanced neurovascular imaging techniques such as high-frame-rate vector flow imaging and 3D plaque characterization provide detailed assessments of morphology and hemodynamic stress but remain restricted to specialized centers[1]. This technological concentration limits early detection, particularly in prehospital and community settings where rapid triage is most impactful. Evidence from Mobile Stroke Units demonstrates that earlier vascular assessment substantially improves functional outcomes by accelerating thrombolytic therapy[14–16]. These findings highlight the need for point-of-care screening tools capable of supporting early decision-making outside tertiary hospitals.

Arterial pulse waves encode biomechanical information related to stiffness, compliance, and local structural changes[17]. Fluid structure interaction models show that pressure-wave propagation is altered by focal arterial abnormalities[18], providing a physiological basis for non-invasive hemodynamic screening. Consequently, carotid pulse-wave analysis has emerged as an active area of investigation for assessing vascular risk and may offer a pathway toward more accessible screening strategies[19]. Recent developments in high-sensitivity sensing have demonstrated feasibility for rapid detection of cerebrovascular abnormalities in emergency settings[20], supporting the broader potential of hemodynamic approaches for decentralized screening.

In this study, we investigated the preclinical feasibility of the SKAI-TOUCH system (SKAI MED Co., Ltd.), a portable vascular flow sensing platform designed to address limited access to carotid plaque screening in resource constrained settings. The system integrates a piezoelectric transducer with a deep-learning spectral analysis model to characterize frequency domain patterns associated with carotid artery plaque. By enabling automated, low-complexity evaluation, the SKAI-TOUCH system is intended to augment front-line clinical workflows, acting as an accessible pre-diagnostic screening tool to identify high-risk individuals before referral for formal, operator-dependent Doppler ultrasonography. We conducted a preclinical evaluation of 100 participants (200 carotid arteries) to assess the system's screening feasibility for carotid artery plaque detection, using Doppler ultrasound as the reference standard.

Ethical approval and availability of data and materials. This feasibility study was conducted to evaluate the performance of the SKAI-TOUCH system for carotid artery plaque screening in comparison with Doppler ultrasound imaging. Participants (n = 100) were recruited from Phaem Suk Subdistrict Health Promotion Hospital, Loei Province, Thailand. All study procedures were performed in accordance with relevant institutional requirements and guidelines. Ethical approval was granted by the Human Research Ethics Committee, Suranaree University of Technology (Project Code: EC-68-122), and written informed consent was obtained from all participants prior to enrollment.

Methods

The procedures of the proposed method, the criteria for subject selection, and the methodology followed in this study are described in the subsequent sections.

SKAI-TOUCH device architecture. The SKAI-TOUCH system is a platform developed by SKAI MED Co., Ltd. The SKAI-TOUCH architecture (Fig. 1) comprises four principal components: (1) a piezoelectric sensor for pulse wave acquisition (Fig. 2), (2) a pulse wave signal measurement and processing module responsible for signal amplification, ADC conversion (PicoScope 2204A; Pico Technology), definition of measurement conditions, signal verification, and data recording, (3) an analysis and evaluation module for signal and data processing, metadata integration, and feature extraction workflows, and (4) a deep-learning based predictive classification algorithm for carotid artery plaque screening, compared with Doppler Ultrasound data.

Reference gold standard: Doppler ultrasound sonography and Rotterdam plaque score. Doppler ultrasound imaging (GE LOGIQ S7 Expert; Loei Ram Hospital, Thailand) was used as the reference standard for identifying carotid artery plaque. Plaques were defined according to the Rotterdam criteria, which classify a plaque as any focal thickening that protrudes into the carotid artery lumen with a height of at least 1.5 mm[9,21]. Each carotid artery was examined in three anatomical segments (internal carotid artery/external carotid artery bifurcation, carotid bulb, and common carotid artery) on both the left and right sides. For each segment, the presence or absence of plaque was recorded, yielding a plaque score ranging from 0 to 3 for each side, with a total possible score of 0 to 6 across both arteries. Participants were then categorized as plaque positive or plaque negative for each side based on the corresponding score.

Study design and subjects. The SKAI-TOUCH system was evaluated through a prospective, cross-sectional field validation study designed to ensure a representative clinical population. To minimize selection bias, a broad recruitment strategy was employed at a primary care center in Loei Province, Thailand, enrolling 100 participants (200 carotid artery assessments) aged 20–70 years. The cohort reflected a heterogeneous spectrum of clinical risk, including healthy volunteers and individuals with established non-communicable disease (NCD) risk factors specifically hypercholesterolemia, diabetes mellitus, hypertension, and hyperlipidemia as well as elderly patients undergoing routine health checkups. To maintain data integrity and signal quality, objective exclusion criteria were strictly applied by the study physician. Candidates were excluded if they presented with unstable vital signs (e.g., tachycardia or hypertensive crisis) or respiratory conditions that could introduce mechanical artifacts into the piezoelectric readings. Additionally, those with physical or cognitive barriers that precluded informed consent or stable positioning were excluded to ensure consistent measurement protocols. To uphold the gold-standard comparison, all participants underwent bilateral common carotid artery examinations performed by certified sonographers at Loei-Ram Hospital, with results blinded to the SKAI-TOUCH operators, thereby ensuring an independent and objective validation of the transducer-based platform.

SKAI-TOUCH piezoelectric sensor device measurements (Fig. 3) were performed by trained operators who positioned the piezoelectric sensor on the skin overlying each common carotid artery while the participant was seated during the measurement (Fig. 3a). The sensor unit incorporates a piezoelectric ceramic element that generates an electrical charge in response to mechanical deformation. Housed in a compact enclosure, the sensor is applied directly to the skin surface above the common carotid artery. Unlike conventional ultrasound probes, which measure blood flow velocity using the Doppler effect, the SKAI-TOUCH piezoelectric transducer detects mechanical vibrations (surface displacement) produced by pulsatile arterial blood flow (Fig. 3b). This approach offers several practical advantages: it does not require coupling gel, is relatively insensitive to probe angles, and enables rapid measurements with minimal operator training. Each signal acquisition was recorded with 8-bit resolution at a sampling rate of 200 Hz for a duration of 30 seconds per carotid side. The complete bilateral measurement procedure required less than 10 minutes per participant. Subsequently, Doppler ultrasonography was performed using clinical grade ultrasound systems equipped with high frequency linear array probes. B-mode and Doppler imaging were utilized to assess plaque morphology; findings were then quantified according to the established Rotterdam scoring criteria[9,21].

Finally, carotid pulse wave signals were digitized, and the resulting waveform data were transmitted to a computing unit for processing via an AI-driven analysis pipeline. Using carotid plaque scores from Doppler ultrasonography as the ground-truth evidence, a deep-learning model was employed for classification. The system architecture supports both local (laptop-based) and cloud-based analysis via an Application Programming Interface (API), with results displayed on a clinical dashboard (Fig. 1). For each participant, the left and right carotid arteries were evaluated independently, yielding a total of 200 arterial assessments. All study procedures were conducted in accordance with relevant ethical guidelines, and written informed consent was obtained from all participants prior to enrollment.

Standard methodological controls. To ensure methodological accuracy and minimize sources of bias, several standard controls were implemented throughout the study. First, the use of a prospective field-study design reduced selection bias by recruiting participants in real time rather than relying on retrospective records that may over-represent clinically obvious cases. Second, overfitting was mitigated through strict data partitioning: the 20% test set was fully isolated from the training and validation processes, providing an unbiased assessment of model performance. Finally, bilateral carotid assessments from each participant contributed to a balanced dataset that captured intra-individual physiological variation, supporting a more representative evaluation of the algorithm across diverse vascular presentations.

Signal processing and feature extraction. Pulse waves were detected using a piezoelectric transducer (SKAI-TOUCH) from the bilateral common carotid arteries of each subject, with multiple cardiac cycles recorded over a standardized acquisition window. The detected analog carotid pulse wave signals were amplified and digitized at high sampling rates using a dedicated acquisition module. These digitized waveform data were then transmitted to a computing unit for processing via an AI-driven analysis pipeline. To prepare the data, individual cycles were identified, segmented, and ensemble averaged to generate representative waveforms, which were subsequently normalized by their maximum amplitude to facilitate inter subject comparison. The SKAI-TOUCH predictive model (Fig. 4) begins by standardizing raw signals using min-max normalization to minimize amplitude variability arising from environmental factors and differences in transducer skin coupling.

Classification algorithm and predictive model optimization. Normalized pulse wave signals were transformed into the frequency domain via Fast Fourier Transform (FFT)[22] to identify periodic and harmonic structures associated with plaque induced flow disturbances. Spectral feature extraction included identifying the main frequency peak and calculating the harmonic ratio, defined as the amplitude of the first repeating frequency component relative to the main (fundamental) frequency. The hybrid feature set consisting of extracted spectral features together with the full FFT spectrum was used as input to a

one-dimensional convolutional neural network (1D-CNN) implemented in PyTorch[23]. The network's convolutional layers learned localized spectral patterns and progressively formed hierarchical representations relevant to plaque detection. Using this supervised framework, the SKAI-TOUCH system classified each carotid artery as plaque-positive or plaque-negative based on bilateral PZT pulse waveforms[22,23]. The model produced a probability score reflecting the likelihood of plaque-related flow disturbance, with values ≥ 0.6 designated as plaque-positive to prioritize high specificity (Fig. 4). Ground truth labels were derived from Doppler ultrasonography, where plaque scores ≥ 1 were defined as positive and scores of 0 as negative, according to the Rotterdam criteria[9,21]. To ensure an unbiased evaluation, the 200 carotid artery assessments were partitioned into an 80/20 split, with the 80% training subset further utilized for cross-validation and hyperparameter optimization to prevent data leakage. The final model was selected based on its performance during the validation phase and was only then evaluated against the strictly independent, held-out test set to provide an objective measure of screening accuracy. SKAI MED Co., Ltd. provides detailed architectural model design services and training procedures.

Screening performance. The classification proficiency of the SKAI-TOUCH algorithm and its predictive model was evaluated using a 2×2 confusion matrix[24], which compared deep-learning predictions with the ground-truth labels derived from confirmatory imaging obtained via Doppler ultrasonography. From this matrix, the screening performance metrics including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated according to Equations (1), (2), (3), (4), (5), respectively[24,25].

$$\frac{TP}{TP+FN} \quad (1)$$

$$\frac{TN}{TN+FP} \quad (2)$$

$$\frac{TP}{TP+FP} \quad (3)$$

$$\frac{TN}{TN+FN} \quad (4)$$

$$\frac{TP+TN}{TP+TN+FP+FN} \quad (5)$$

where TP is true positive, FP is false positive, FN is false negative, TN is true negative.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to institutional restrictions regarding patient privacy and ethical constraints but are available from the corresponding author on reasonable request.

Code availability

Code used for signal preprocessing, Fast Fourier Transform based feature extraction, and model evaluation is available from the corresponding author upon reasonable request. Trained models are not publicly released. The model architecture and training procedures described in the Methods section provide sufficient detail to enable replication of the analytical workflow.

Results and discussion

Study population and clinical protocol. A total of 100 adult participants (N = 100) were enrolled to undergo carotid artery screening via the SKAI-TOUCH device at the Phaem Suk Subdistrict Health Promotion Hospital (primary care setting). To establish screening accuracy, confirmatory Doppler ultrasonography was performed at Loei-Ram Hospital, serving as the gold standard reference[2,26]. All participants (75% female, 25% male) successfully completed both assessment modalities without attrition. The cohort represented the target screening demographic, with ages ranging from 20 to 70 years and a balanced distribution of baseline clinical characteristics. A side level analysis was conducted, yielding 200 independent carotid observations (100 left and 100 right), which facilitated a comprehensive bilateral evaluation of structural and hemodynamic features. The comparative performance of the SKAI-TOUCH device against the Doppler ultrasound benchmark was utilized to evaluate its clinical feasibility for non-invasive carotid plaque screening.

Waveform observations. A piezoelectric (PZT) transducer was employed to capture arterial pulse wave morphologies, converting mechanical vascular pulsations into analog electrical signals. These signals were subsequently processed via a conversion module to extract frequency domain characteristics, including the fundamental frequency and associated harmonic components[27–29]. To mitigate amplitude variability stemming from environmental noise and sensor-coupling inconsistencies, all raw pulse wave signals underwent min-max normalization, ensuring standardized comparison across the study cohort[30,31]. Qualitative assessment of the pulse wave morphologies revealed distinct differences between plaque-negative and plaque-positive carotid arteries. Figures 5 and 6 illustrate representative waveforms captured by the SKAI-TOUCH system for the left and right common carotid arteries (CCA). When benchmarked against Doppler ultrasound imaging (Figs. 5a and 6a), the PZT derived pulse waves demonstrated clear morphological divergence associated with the presence of atherosclerotic plaque.

In plaque-negative subjects, bilateral pulse waveforms exhibited low variability, characterized by a distinct positive peak during arterial expansion (point a), a corresponding negative peak during arterial recoil (point b), and an overall smooth signal profile (point c). The waveform demonstrates symmetric cycle to cycle flow patterns (Fig. 5b), consistent with normal laminar flow and indicative of undisturbed arterial wall motion[3,20]. In the frequency domain, the spectrum showed a gradual decline in energy from the main frequency component to the subsequent harmonic components, with higher frequency elements

becoming progressively smaller (Fig. 5c). In contrast, subjects with carotid plaque confirmed by ultrasonography exhibited distinct waveform alterations on the ipsilateral side (Fig. 6b). These alterations included morphological shifts in the positive (point a) and negative (point b) peaks, increased oscillatory components indicative of disturbed flow, and retrograde wave reflections originating from the plaque site. Such disturbances resulted in asymmetric flow patterns and higher cycle to cycle cardiac variability signals at points a to c. These findings are consistent with established hemodynamic mechanisms, where plaque induced turbulence, vortex formation, and spectral broadening disrupt the normal vibration profile of the arterial wall[4,20,32]. Correspondingly, the frequency domain representation showed an irregular distribution of harmonic energy, with some higher frequency components appearing (Fig. 6c).

However, pulse wave morphology and frequency patterns alone are not sufficient for reliably distinguishing plaque-positive from plaque-negative arteries, as these features can be difficult to interpret visually. For this reason, the SKAI-TOUCH system incorporates additional deep learning analysis, using Doppler ultrasound findings as the reference, to improve its screening performance. The results of this classification model are presented in the following section.

Screening performance. The arterial pulse wave was transformed into the frequency domain using Fast Fourier Transform (FFT) to capture harmonic structures and spectral disturbances associated with plaque-related flow abnormalities[22]. The resulting FFT spectra from normalized PZT signals were used as input to a one-dimensional convolutional neural network (1D-CNN) implemented in PyTorch[23], which learned discriminative spectral patterns relevant to plaque classification. The trained model was subsequently evaluated against Doppler ultrasonography, which served as the clinical reference standard, and its screening performance was quantified using confusion matrix (Fig. 7a) and ROC curve (Fig. 7b)[24,25].

The confusion matrix for the SKAI-TOUCH classification algorithm, benchmarked against the Doppler ultrasonography reference standard, is presented in Table 1, and the corresponding screening performance metrics are summarized in Table 2. The algorithm demonstrated high sensitivity value of 92.3%, correctly identifying 12 of 13 plaque-positive arteries in the test set, and a specificity of 92.6%, with only two false-positive classifications among 27 plaque-negative arteries. The high negative predictive value (NPV) of 96.2% is of clinical significance for a screening application. In population level screening, the primary objective is to reliably identify individuals who do not require further evaluation (rule out) while flagging those who warrant confirmatory imaging.

Table 1
Confusion matrix: SKAI-TOUCH algorithm vs. Doppler ultrasonography (test set).

Predicted YES	**Plaque Detected (US+)**	**No Plaque (US–)**
	12 (TP)	**2 (FP)**
Predicted NO	1 (FN)	25 (TN)

US = ultrasonography; TP = true positive; FP = false positive; FN = false negative; TN = true negative.

Table 2
Screening performance metrics of the SKAI-TOUCH system.

Metrix	**Value**
Sensitivity	92.3%
Specificity	92.6%
Positive Predictive Value (PPV)	85.7%
Negative Predictive Value (NPV)	96.2%
Overall Accuracy	92.5%

The 96.2% NPV indicates that fewer than 4% of individuals screened negative by the SKAI-TOUCH system would have undetected plaque. This aligns with epidemiological findings from Matangi et al.[9] which demonstrated that low plaque scores are associated with extremely low long-term cardiovascular event rates, reinforcing the value of reliable negative screening. Meanwhile, the positive predictive value (PPV) of 85.7% indicates that the majority of positive screening results will be confirmed by subsequent ultrasonography. In a screening context where positive results trigger referral for confirmatory imaging, a PPV at this level is clinically acceptable, as it ensures efficient utilization of specialist imaging resources while maintaining a low miss rate. Furthermore, the algorithm achieved an overall accuracy of 92.5%, and the Receiver Operating Characteristic (ROC) curve yielded an Area Under the Curve (AUC) value of 0.969. These metrics demonstrate a strong capacity to differentiate between plaque-positive and plaque-negative cohorts within our field study sample[33–35].

The comparative performance analysis presented in Table 3 demonstrates a clear difference between traditional Doppler Ultrasound indices and the deep-learning enhanced SKAI-TOUCH system in this field study (100 subjects). Intima Media Thickness (IMT) was identified as a statistically significant predictor of carotid plaque, with a p value of 0.0009 and an odds ratio of 17.9. However, its clinical usefulness was limited by an overall accuracy of 58.4%. This limitation reflects the subjective nature of manual boundary tracing, which introduces measurement error and substantial variation between operators[36]. Hemodynamic parameters, including Peak Systolic Velocity (PSV) and the Resistive Index (RI), showed even lower screening reliability, with specificities of 0.2072 and 0.1802 and overall accuracy below 50%. These findings are consistent with the known sensitivity of Doppler measurements to probe placement and angle of insonation, as well as the fact that these indices typically become clearly abnormal only when stenosis exceeds 50% area, which restricts their value for early screening[37].

Table 3
Comparison of predictive model performance between Doppler Ultrasound (DUS) features and the SKAI-TOUCH system for carotid plaque detectic

Predictive Model	Data	Feature	AUC	Threshold	Beta	OR	p_value	Sensitivity	Specificity	PPV	NPV	Over
Logistic regression	DUS	PSV	0.5193	0.3196	-0.0084	0.9916	0.3039	0.9516	0.2072	0.4014	0.8846	0.47
		EDV	0.5304	0.3886	-0.0294	0.9710	0.3032	0.2903	0.8288	0.4865	0.6765	0.63
		RI	0.3854	0.3597	-0.0586	0.9431	0.6945	0.871	0.1802	0.3724	0.7143	0.42
		IMT	0.6695	0.2876	2.8852	17.9074	0.0009	0.7742	0.4775	0.4528	0.7910	0.58
Deep-learning (1D CNN)	SKAI-TOUCH	FFT	0.969	0.6000	-	-	-	0.9231	0.9259	0.8571	0.9615	0.92

In contrast, the SKAI-TOUCH system applies a 1D-CNN to frequency-domain features obtained from piezoelectric sensors. This approach achieved an area under the curve of 0.969 and an overall accuracy of 92.5%. By leveraging an automated, localized analysis of peripheral pulse-wave variations, the SKAI-TOUCH system provides an alternative approach to manual imaging workflows. While Doppler ultrasonography remains the definitive clinical standard for arterial mapping, these field findings suggest that surface-applied hemodynamic sensing can serve as a reliable, scalable framework for initial early-stage risk classification. According to the screening performance, the SKAI-TOUCH system offers several practical advantages over existing screening modalities. Unlike Doppler ultrasonography, the device is compact, affordable, and operable by primary-care personnel with minimal training. The measurement procedure requires less than one minute per subject and does not require coupling gel, a dedicated examination room, or patient preparation, apart from ensuring the patient is seated in a relaxed position.

Data comparison in Table 4 indicates that the SKAI-TOUCH piezoelectric sensor complements existing screening standards by providing a scalable solution for early-stage triage and long-term monitoring of carotid health. These characteristics make the system suitable for deployment in primary care clinics, community health screening programs, mobile health units, and potentially prehospital emergency medical services, where rapid identification of patients with significant carotid disease could inform triage and transport decisions[38,39]. Because the carotid arteries carry approximately three times the blood flow volume of the brachial artery, and their superficial anatomical location makes them accessible to surface applied sensors. Maintaining carotid artery health is particularly important in aging populations, as arterial stiffness and plaque burden increase with age, influencing both cardiovascular risk and cognitive function[40,41]. The availability of an affordable, point of care screening tool could facilitate broader population level surveillance and earlier intervention[42]. Therefore, integration with broader cardiovascular risk assessment platforms represents an important future direction. Machine-learning models trained on electronic health record data such as gradient boosting algorithms incorporating clinical laboratory features have demonstrated strong predictive performance for cardiovascular events in Asian populations[43,44]. Combining real time SKAI-TOUCH plaque screening data with such predictive models could enable comprehensive risk stratification that incorporates both structural vascular assessment and longitudinal clinical information.

Table 4
Comparison of SKAI-TOUCH and gold-standard methods for carotid plaque screening and monitoring.

Feature	Carotid Ultrasound (DUS)[1–5]	CT Angiography (CTA)[2,45]	MRI/MRA[5,12,46]	SKAI-TOUCH device This work
Mechanism	High-frequency sound waves reflection (Doppler effect)	X-ray with iodinated contrast	Magnetic resonance sequences	Piezoelectric transduction, pulse wave analysis, ML/DL integration, classification
Primary Focus	2D image, flow velocity, IMT thickness, stenosis%	Calcification, 3D volume	Plaque tissue composition/Biology	Pulse waveform, functional hemodynamics, predictive model
Clinical Strength	Non-invasive, widely available, excellent for flow velocity, gold standard for initial screening	High anatomical precision, 3D plaque visualization	Best for “vulnerable plaque” (soft tissue) analysis	Non-invasive, fast, continuous monitoring, operator independent, wearable
Limitations	Highly operator-dependent, poor continuous monitoring	Radiation exposure, risk of contrast-induced nephropathy, snapshot-only data	Expensive, slow scan times, inaccessible for routine screening, low accessibility	Indirect measurement
Clinical Role	First-line diagnosis	Surgical planning	Research/complex cases	Population screening and monitoring
Cost	Moderate	High	Very High	Low

However, several limitations of this exploration field validation must be noted. First, while our sample of 100 subjects (200 arteries) provides a baseline feasibility assessment, the cohort is geographically constrained to a single region in Thailand, necessitating broader multi-center trials to confirm demographic generalizability. Second, our predictive algorithm currently utilizes a binary classification model (plaque presence vs. absence). It does not grade the percentage of luminal stenosis severity or characterizes morphological plaque stability features, which are vital components handled by professional Doppler imaging. Third, anatomical confounders such as variations in neck tissue thickness, body mass index, and carotid bifurcation geometry were not systematically isolated and may induce signal morphology artifacts in surface-applied piezoelectric arrays. Finally, this validation compared

performance exclusively against a single bedside reference standard (Doppler ultrasound); future validation protocols would benefit from structural validation against computed tomography angiography (CTA) or magnetic resonance imaging (MRI) cohorts.

Overall, these findings show that the SKAI-TOUCH piezoelectric sensor system achieves clinically meaningful screening accuracy for detecting carotid artery plaques when compared with Doppler ultrasonography. Ongoing and planned development includes expanding the training dataset through multi-site clinical trials, refining the algorithm with additional waveform features, exploring deep-learning architectures for end-to-end waveform analysis, and developing a fully integrated point of care device with real time cloud-based analysis and clinical decision support.

Conclusion

The SKAI-TOUCH piezoelectric sensor-based pulse wave analysis system demonstrated high feasibility of detection efficiency, with balanced sensitivity and specificity (> 92%), indicating its ability to effectively distinguish between cases with and without carotid plaque. The system demonstrated high screening accuracy for the non-invasive detection of carotid artery plaque. Given its portable architecture, low operational complexity, and user independent functionality, the SKAI-TOUCH system offers a viable solution for primary care and community-based health settings where access to conventional ultrasonography remains limited. In conclusion, the deep-learning enhanced SKAI-TOUCH platform demonstrated strong technical screening efficiency within a localized primary care setting, yielding a high negative predictive value (96.2%) suitable for clinical triaging. While it serves as an adjunctive monitoring tool rather than a diagnostic replacement for high-resolution ultrasound imaging, its portable design and low operational complexity provide a scalable pathway for decentralized community cardiovascular risk mapping.

Declarations

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Author contributions

P. T., S. S., and P. N. contributed to the study concept, data analyses and interpretation. N. B., T. B., C.M., and V. T. contributed to product design and data acquisition. All authors read and approved the manuscript.

Competing interests

Competing interests: Authors N.B., T.B., C.M., and V.T. are employees of SKAI MED Co., Ltd., the manufacturer of the SKAI-TOUCH device described in this study and may benefit financially from its commercialization. Authors P.T., S.S., and P.N. declare no competing interests. The funder participated in study design and manuscript preparation; final analytical decisions and the decision to submit for publication were made by the academic authors.

Additional information

The SKAI-TOUCH system evaluated in this study is a product of SKAI MED Co., Ltd., intended for feasibility studies in screening applications and is not registered as a medical device (“Investigation use only”). This system does not diagnose, treat, or predict any medical condition. Individuals requiring medical advice for clinical evaluation should consult a qualified healthcare professional.

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Figures

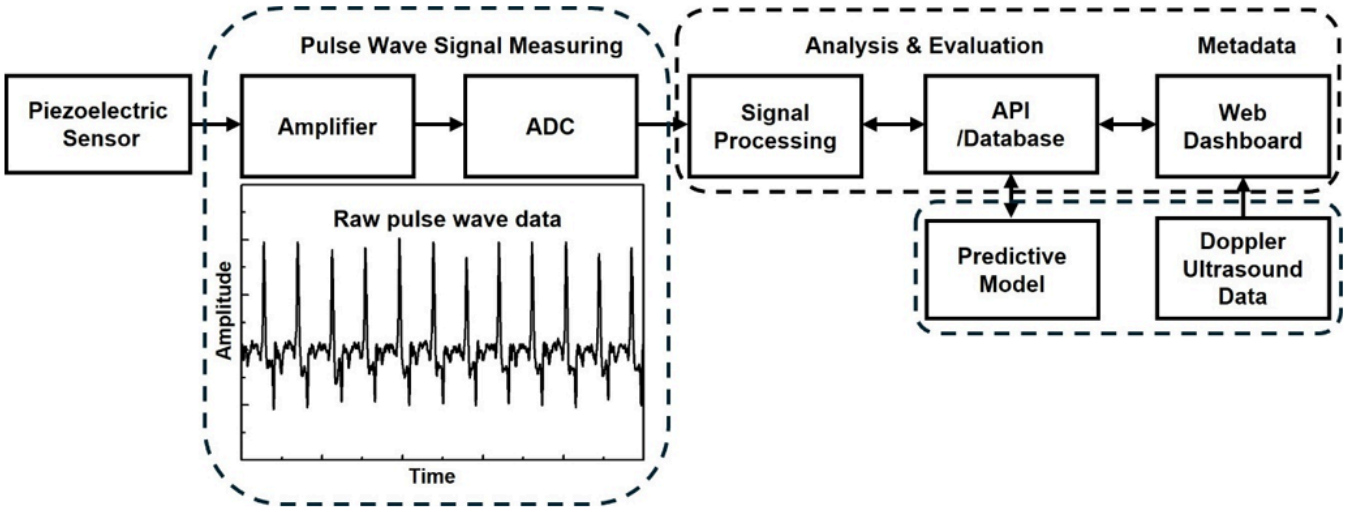


Figure 1

SKAI-TOUCH Architecture.

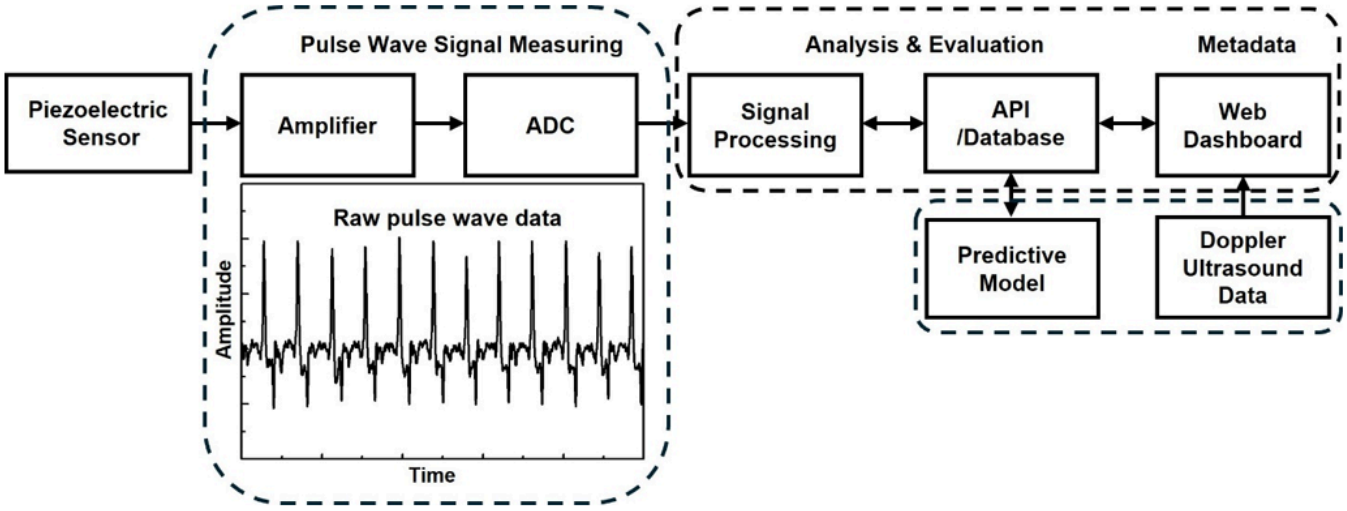


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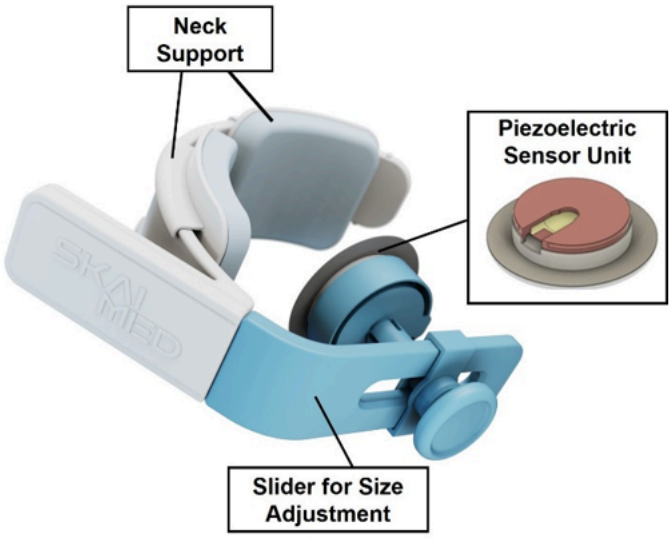


Figure 2

SKAI-TOUCH design: a hemodynamic sensor holder.

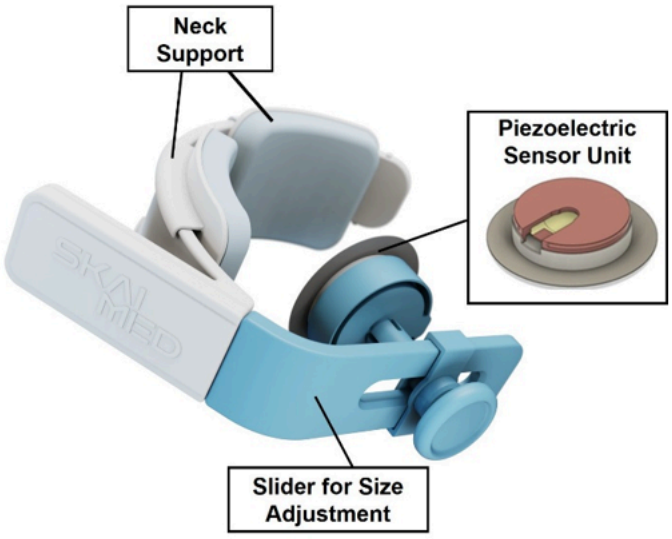


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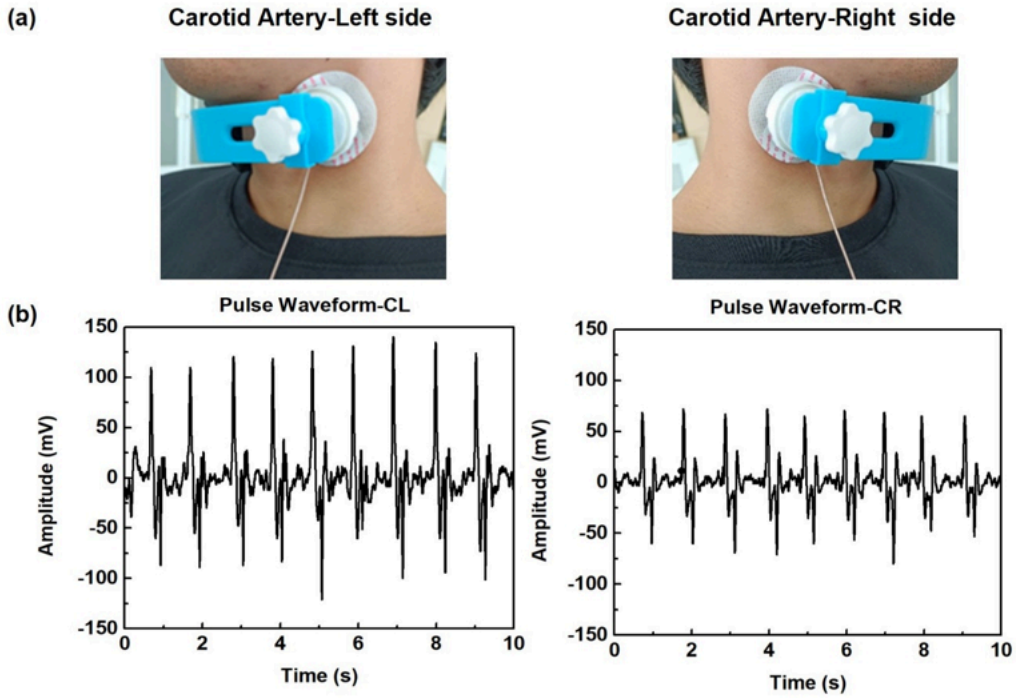


Figure 3

Measurement of the left and right carotid arteries using the SKAI-TOUCH device (a), along with the raw carotid pulse waveform recorded from each side over a 10-second interval. (24 years old, male, healthy)

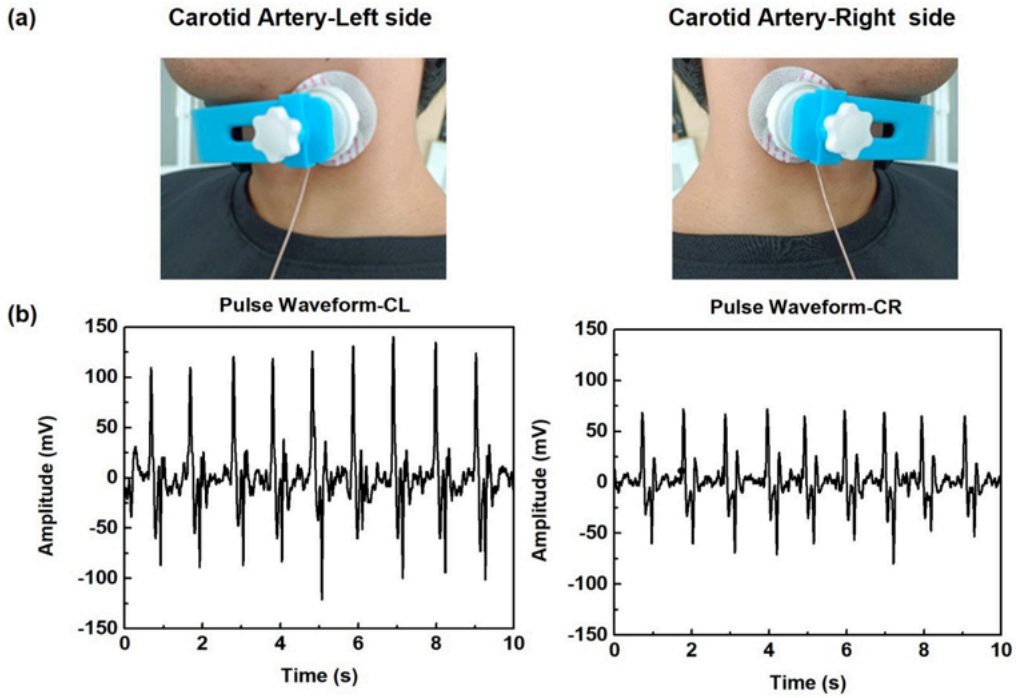


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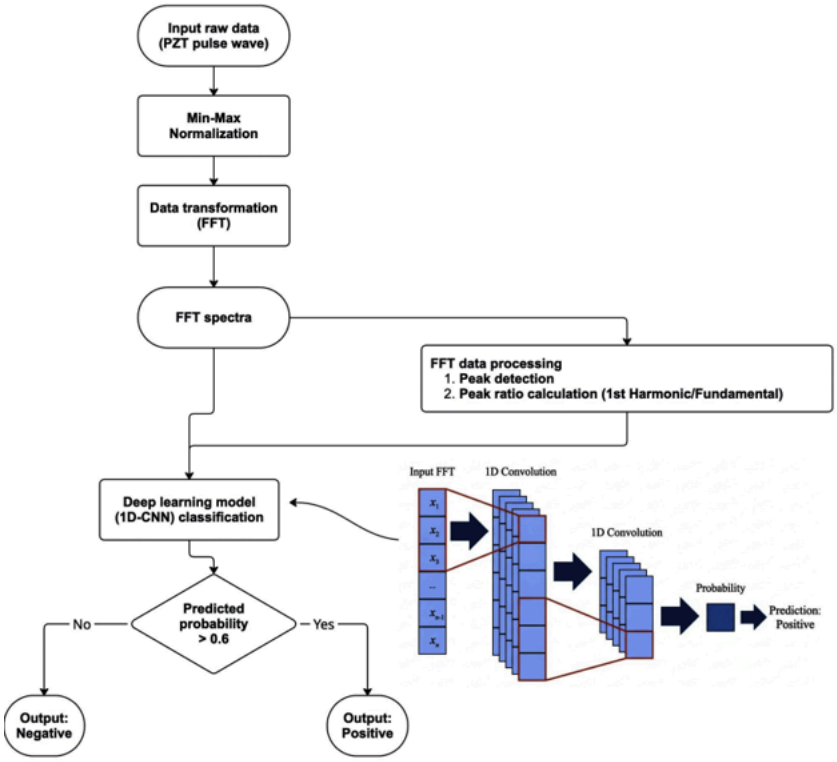


Figure 4

Procedures for the predictive model analysis of the SKAI-TOUCH system.

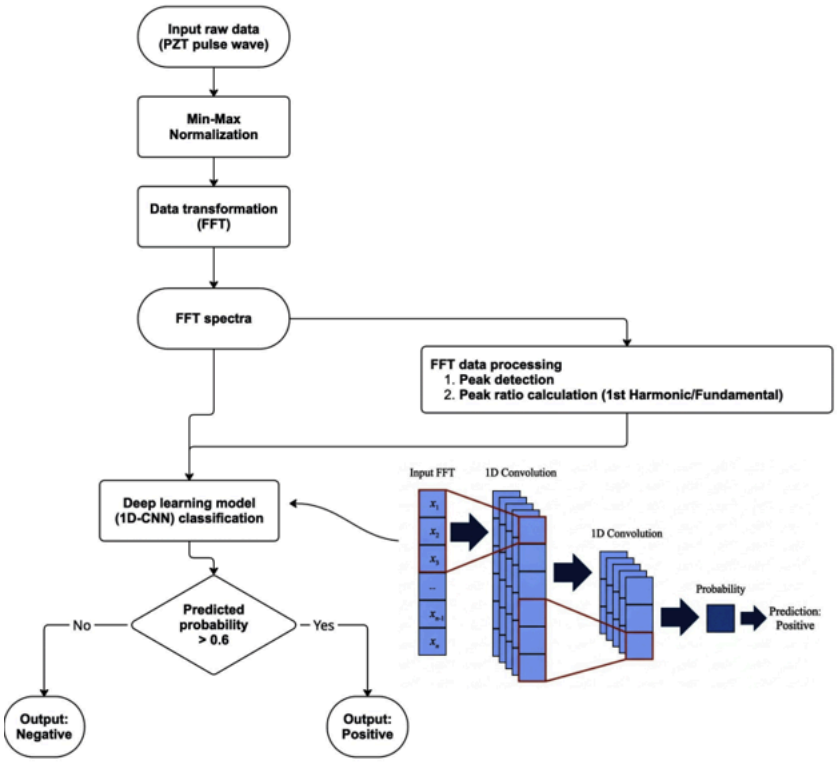


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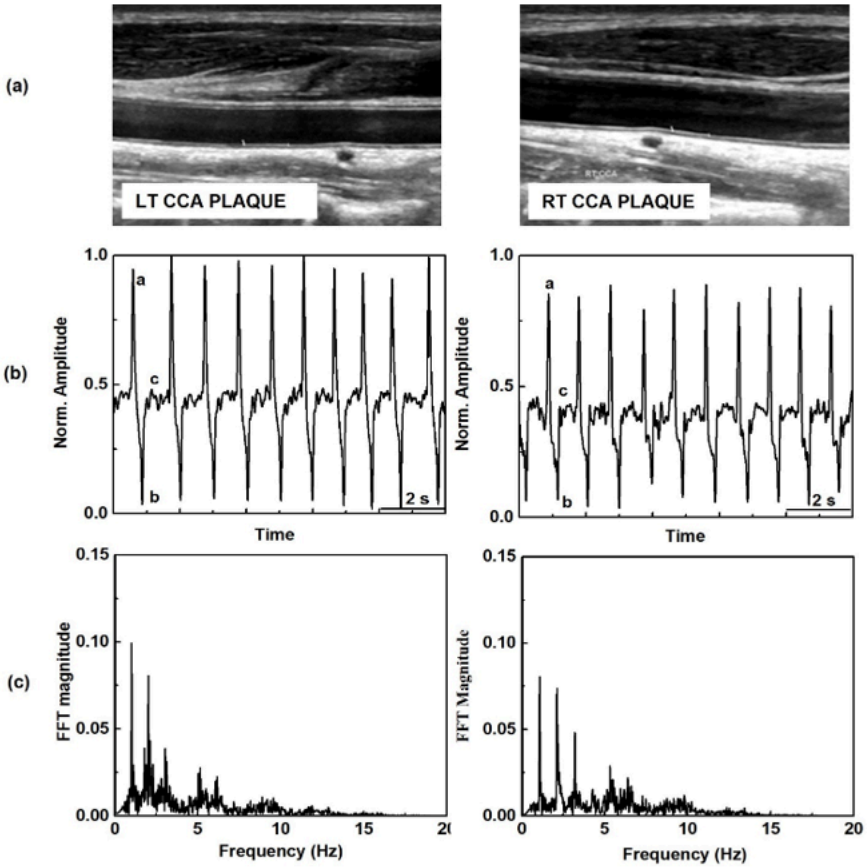


Figure 5

Doppler ultrasound images of the left and right carotid arteries (a), together with the normalized pulse wave amplitude recorded over a 10-second interval (b), and FFT magnitude of the pulse wave versus frequency (c) in a **plaque-negative** subject. (49 years old, female, NCD)

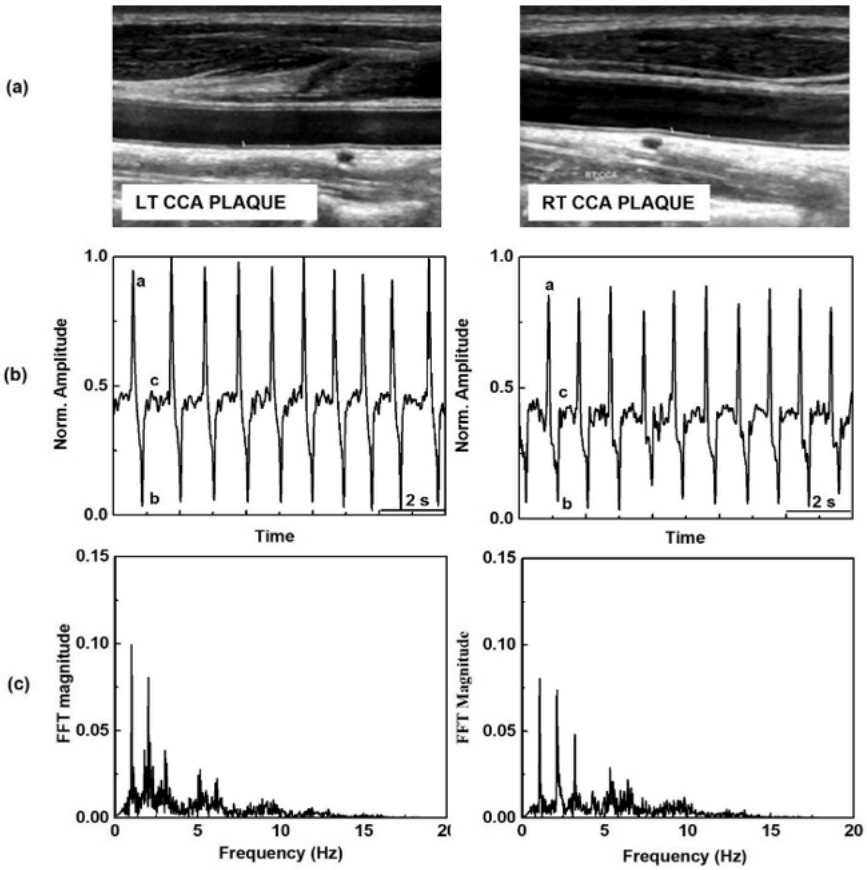


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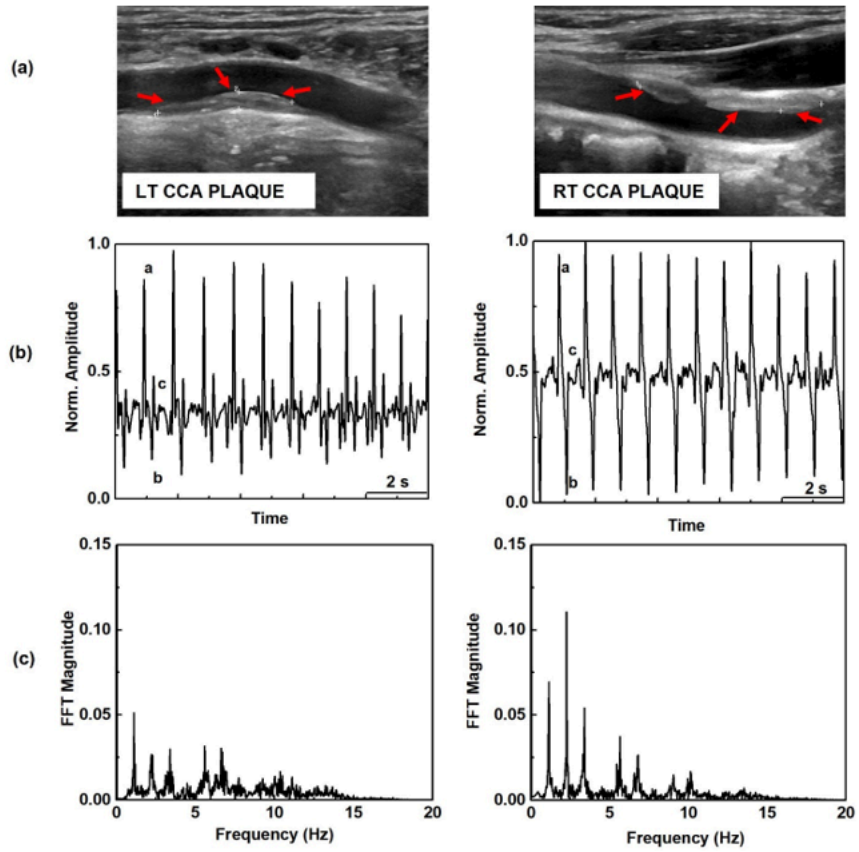


Figure 6

Doppler ultrasound images of the left and right carotid arteries (a), together with the normalized pulse wave amplitude recorded over a 10-second interval (b), and FFT magnitude of the pulse wave versus frequency (c) in a **plaque-positive** subject. (66 years old, female, NCD)

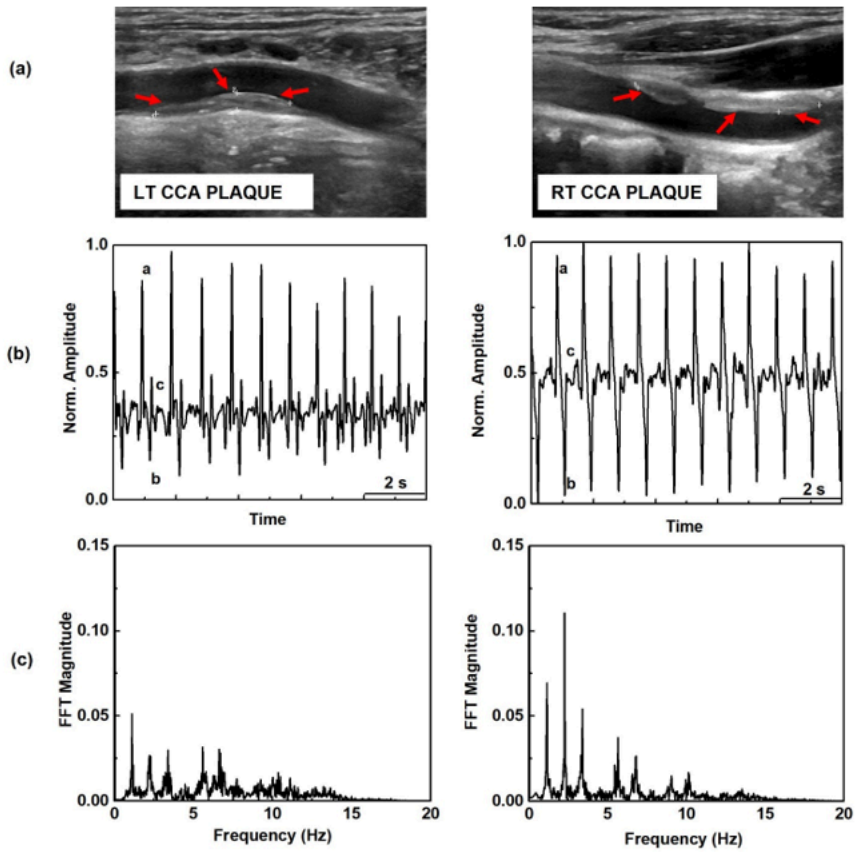


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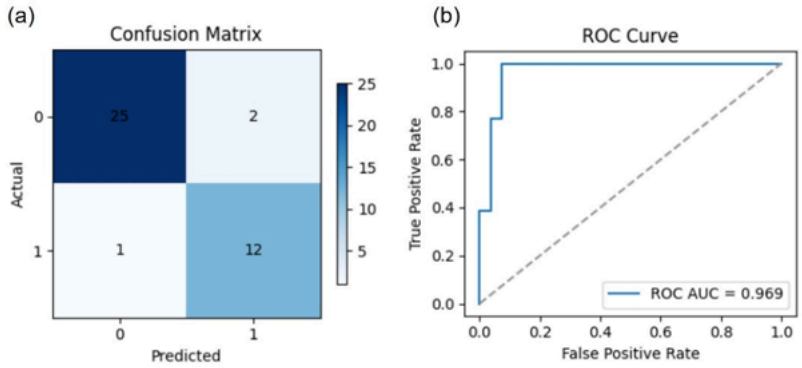


Figure 7

Confusion Matrix (a) and Receiver Operating Characteristic (ROC) curve (b) analysis on a test dataset (n = 40).

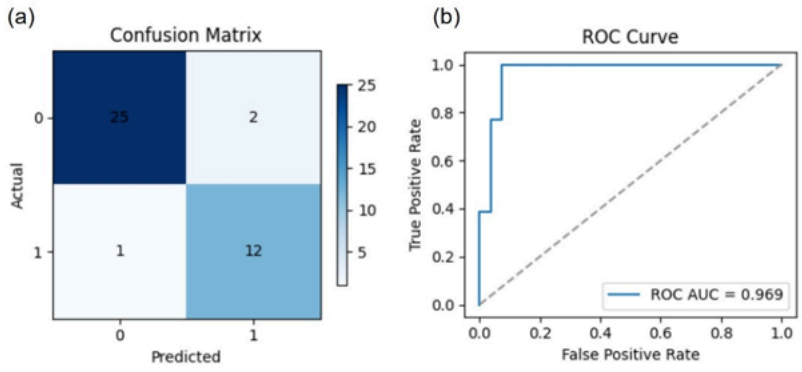


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