Breast cancer detection using smart wearable devices with thermal sensors

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Keywords: Breast Cancer, Breast Thermography, Breast Cancer Detection, Wearable devices, Thermal Sensors, Smart Bra, Early Detection.

Abstract: Breast cancer is the most frequent cause of cancer-related mortalities among women worldwide. Early detection of breast cancer is one of the best approaches to prevent this disease. In some developed countries, the 5-year relative survival rate of breast cancer patients is above 90% due to early prevention. Many early detection tools have been developed and used such as mammography, ultrasounds, and magnetic resonance imaging (MRI). Still, these tools are not always the best in terms of cost, effectiveness, and risk-free. Developing a more effective, risk-free, and affordable technique for breast cancer detection has always been a necessity to increase survivability. Authors have found the potential of non-radiative and non-invasive thermography for anomaly breast detection. This systematic review aims to provide an introduction and guide for smart wearable devices for breast cancer detection using thermal sensors by discussing the advantages of these devices as well as the challenges of developing and implementing them. A total of 6 relevant works drawn from 286 papers on the subject were carefully analyzed, and the information was synthesized. The selected papers were synthesized according to the design of the wearable device, its data collection, and classification methodologies. Finally, this review tackles the challenges that come with developing such devices and the great promise and advantages they hold for early breast cancer detection.

1 INTRODUCTION

Breast cancer is a significant health concern worldwide as it is the most commonly diagnosed cancer worldwide (Sung et al., 2021). According to the World Health Organization, one in eight women will be diagnosed with breast cancer in their lifetime (Michaels et al., 2023). Late detection occurs when the cancerous cells have metastasized and caused devastating results, however, when breast cancer is detected at its early stages, the survival index may go up to 9O% in high-income countries (Arnold et al., 2022). Several methods and techniques are used by healthcare to detect breast cancer such as mammography, Ultrasound, and Magnetic Resonance Imaging (MRI).While breast cancer screening plays a vital role in early detection, there are certain limitations to currently used methods. Mammography requires compression of the breasts and may cause inconveniences to the patient, while exposure to ionizing radiation may even increase the health risk to the patient (Yaffe and Mainprize, 2011). Dense breast tissue appears white on mammograms, making it more challenging to detect abnormalities, as cancerous lesions can also appear white, women with dense breast tissue may require additional screening methods (Thigpen et al., 2018). Ultrasound has its limitations too, as it may miss smaller masses, resulting in the possibility of both false-positive and false-negative outcomes (Halim et al., 2021). Additionally, The quality of ultrasound images can vary depending on the operator's skill and experience (Xiao et al., 2015). MRI's rela-

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tively high cost and restricted accessibility can limit its utilization as a routine screening method. Also, its high sensitivity may detect noninvasive conditions that may not progress, potentially leading to a false diagnosis (Hylton, 2005).

The 5-year relative survival rate in 12 sub-Saharan African countries stood at 66% between 2008 and 2015 (Sung et al., 2021). Also, the mortality due to breast cancer is higher in women from poorer countries and also from lower socioeconomic status (Tao et al., 2014). Breast cancer detection in underdeveloped or poor countries faces unique challenges that can limit its effectiveness and accessibility. These challenges may manifest as restricted access to healthcare services, financial constraints, and a lack of awareness regarding breast cancer and its associated risk factors. These limitations accentuate the need for a more cost-effective and practical technique for early breast cancer detection. Many wearable devices in the form of bras designed for breast cancer diagnosis are currently in development and are at the prototype stage. These devices utilize various technologies to collect the signal, including thermal sensors, electrical impedance tomography (EIT), or ultrasound (Al Masry et al., 2021).

This work explores the emerging field of smart wearable devices designed for breast cancer detection using thermal sensors. We explore the underlying principles of thermal sensing and its relevance to breast cancer diagnosis. By highlighting the unique advantages and challenges of these wearable technologies, the study aims to provide a comprehensive overview of their potential impact on improving breast cancer screening methods. This review is exclusively dedicated to assessing and analyzing scientific devices aimed at research and diagnostic purposes. We do not cover commercially available products, but instead focus on the technical aspects, performance, and applications of these scientific instruments.

This paper is organized as follows: Section 2 describes the methodology used in the review. In section 3 we go through the fundamental principles underlying thermal sensing and its relevance to breast cancer detection. Section 4 presents and discusses the devices developed in the selected papers. Section 5 underlies the advantages and challenges of the studied wearable devices. Finally, section 6 concludes the works with future research direction.

2 LITERATURE SEARCH METHOD

The methodology employed in this study aims to comprehensively review and synthesize the existing literature on smart wearable devices for breast cancer detection using thermal sensors. Through a systematic approach, we collected, evaluated, and organized relevant research articles, conference papers, and technical reports that contribute to the advancement of this field. To identify pertinent sources, we conducted a rigorous literature search across various academic databases. A combination of keywords was employed to ensure the search's specificity to our interest: Breast cancer, Breast abnormalities, thermal sensors, and wearable devices. These keywords are combined with a search query to get relevant articles only: ("Breast cancer" **OR** "breast anomalies" **OR** "breast cancer detection") **AND** ("Thermal sensors" **OR** ("wearable device" **AND** "thermography")). The review was conducted on the Google Scholar database as it includes articles from other specific databases such as PUBMED, IEEE, and SCOPUS. The first query returned **286** articles. Excluding the thermal imaging and thermotherapy keywords with a new query narrowed it down to **231** articles.

To ensure the selection of high-quality and relevant sources, we established clear inclusion and exclusion criteria:

- Inclusion criteria: Research papers, conference papers, and technical reports focusing on wearable devices for breast cancer detection using thermal sensors; studies involving thermal sensing principles, device design, experimental evaluations, and clinical applications were included.
- Exclusion criteria: Papers published before 2000, review papers, wearable devices combining other techniques than thermal sensing, works using thermal imaging instead of thermal sensing, papers that do not specifically address breast cancer detection (such as thermotherapy), or non-wearable systems.

Papers resulting from the query are screened based on their title, abstract, and keywords, irrelevant papers are excluded based on the exclusion criteria cited above. Those screened papers are then read in full text by the reviewers to assess their contribution to the topic of interest. A total of 6 papers from 2007 to 2023 were selected to be the most relevant to this study.

3 THERMAL SENSING FOR BREAST CANCER DETECTION

Breast thermography is a non-invasive technique that uses infrared cameras or sensors to measure and map the heat patterns emitted by the breasts (Singh and Singh, 2020). The underlying principle of breast thermography is based on the fact that abnormal cells, such as cancer cells, generate more metabolic heat and alter blood flow patterns in the breast tissue.

Breast thermography is a passive, fast, painless, moderate, and risk-free imaging technique. It has been documented that thermography when used with well-defined protocols, can detect early signs of cancer 8 to 10 years earlier than mammography (Singh and Singh, 2020). Thermography was approved as an adjunct imaging modality to mammography by the FDA (Food and Drug Administration) in 1982.

Most of the works found in the literature use thermography with infrared cameras to acquire breast thermal images. Despite being mostly used, thermal data acquired by infrared cameras can have many limitations. Some limitations are due to external factors such as ambient temperature, clothing, or contact with external heat sources that can impact the surface temperature of the breast and introduce noise or artifacts in the thermal images. These factors need to be carefully controlled or accounted for during data acquisition to ensure accurate and reliable results. Also, the quality of thermal data acquired using infrared cameras can be influenced by the operator's skill and technique. Factors such as camera positioning, calibration, and image capture settings can affect the consistency and reliability of the acquired data.

To take advantage of thermography's potential to detect breast cancer without these limitations, some works propose to acquire the breast thermal matrix with highly sensitive thermal sensors put in contact with the skin. Digital thermal sensors may be considered advantageous for medical applications due to their ability to provide reliable temperature measurements across a broad range from -55°C to 150°C (Meijer et al., 2018). Their exceptional accuracy, which can achieve a precision of 0.01°C within the human body temperature range, makes them particularly suitable for medical devices. Furthermore, their compact size, as small as 1mm x 1mm, facilitates integration into a wide array of medical equipment and wearable health devices. Additionally, these sensors are budget-friendly, typically priced at around 4 to 5 US dollars per sensor, enhancing their accessibility for various healthcare applications. Sensors can be placed in direct contact with the breast tissue, allowing for more accurate temperature measurements. This direct contact ensures better thermal coupling and reduces the potential interference with external factors.

Sensor-based breast thermography systems may be more cost-effective compared to infrared cameras as sensors are generally smaller, more portable, and less expensive than infrared cameras, making them more accessible for healthcare facilities or clinics with limited resources. Combining sensors' potential to detect temperature variation very sensitively with a wearable device such as a brassiere, bra, or wearable textiles can create a very promising, non-invasive, cost-effective, and portable detection tool for breast cancer.

The next section reviews the papers found in the literature about wearable devices using thermal sensors for breast cancer detection.

4 A COMPARATIVE STUDY

The papers found in the literature are different in terms of device maturity, some of them are just a proposition for a wearable bra for breast cancer detection supported by numerical simulation with COMSOL or simulated breast phantoms and others are in the clinical trial phase for validation.

This comparative study employs a two-step approach. First, it comprehensively evaluates each wearable device featured in the selected papers by a classification based on wearable device type, the number and type of thermal sensors employed, and the duration of data collection during experiments. Second, the devices are systematically classified and compared with a focus on their respective detection methodologies. This analysis includes data types, the size of the testing population, data preprocessing steps, data analysis methodologies, and the performance of the used methodology.

4.1 Wearable device design

The selected papers from 2007 to 2023 used very different wearable devices. These devices exhibited distinct designs, including lightweight wearable patches integrated with miniature sensors and conventional textile brassieres with fixed thermal sensors. The number of sensors employed in these devices varied significantly, ranging from 8 to 28 sensors per breast. Additionally, the papers employed different types of temperature sensors with varying accuracies (from 0,75°C to 0.01°C). The collection time also varies from 30 seconds to 24 hours. Table 1 provides a summary of the reviewed breast cancer detection devices,

offering insights into their diverse design features, the number and type of sensors used, as well as the testing duration. Additionally, pictures of the devices are included alongside the table for more clarity and reference.

The first known paper to use thermal sensors to detect breast cancer in women was (Ng et al., 2007). They used 8 contact thermal sensors per breast. The design had more sensors in the upper outer quadrant of the breast as a high proportion of malignant and benign diseases arises in this quadrant (Lee, 2005). Cyrcadia breast monitor (S et al., 2020) is an improved version of the first device proposed by (Ng et al., 2007), more enhancements are added to the initial version to improve the data capture and analysis processes. The new device is a smart breast patch equipped with 8 thermal sensors per breast. The thermal sensors used in this device are ADT7420 digital temperature sensors with a ± 0.25 °C accuracy, which are compliant with medical device uses as mentioned in the manufacturer datasheet. The Cyrcadia breast monitor collects thermal data for 24 hours at every five-minute intervals.

In (Laila Fadhillah et al., 2018), the authors also used a brassiere equipped with the same number of sensors as (Ng et al., 2007) and (S et al., 2020) (8 sensors per breast). However, it is not known if the used sensors (LM35 with a ±0,75 °C accuracy) are adequate for medical or clinical use as it is mentioned in their data sheet that they are for power supplies and battery applications. The authors measured the temperature simultaneously for a duration of only 30 seconds, which represents the shortest test duration among all the devices. In (Antony et al., 2020), the authors introduced a bra design equipped with a higher number of sensors per breast compared to previous devices, ranging from 12 to 20 sensors per breast, depending on the bra size. These sensors were Nickel Manganate-based NTC chip thermal probes, which were developed in-house and detailed in (Arathy et al.,), with an accuracy of ±0.01°C. The authors in (Elouerghi et al., 2022) employed a flexible card design shaped as a star that incorporated a significantly higher number of sensors compared to previous studies, their device featured a total of 28 contact thermal mini biosensors per breast. The authors mentioned that the sensors are compliant with the ASTM E1112 standard (Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature) and come with an accuracy of 0.1°C. Finally, (Ashreetha et al., 2023) proposed an IOT-based system to collect breast temperature data with a wearable device (a jacket). In this work, neither the number of sensors nor their type or the acquisition protocol were specified.

It is worth mentioning that (S et al., 2020) and (Antony et al., 2020) are the only papers among the reviewed studies that introduced variable sizes for their wearable systems. However, these papers did not provide extensive details regarding the exact sizes or the specific number of sensors allocated to each size variation of the wearable device.

4.2 Detection methodologies

As previously mentioned, the reviewed devices display varying levels of maturity and can be categorized into two distinct groups. Some devices are primarily focused on demonstrating the feasibility of breast anomaly detection using contact thermal sensors just with numerical simulation and physical phantoms such as (Laila Fadhillah et al., 2018) and (Elouerghi et al., 2022), while others have progressed beyond this stage to clinically validate their proposed devices.

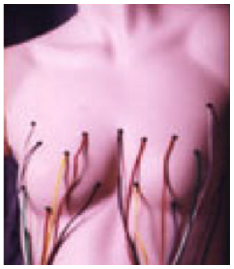
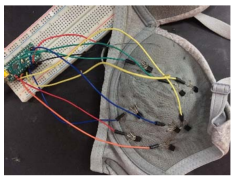
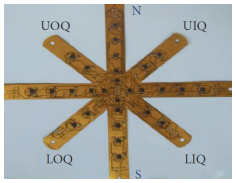
These key steps applied for breast cancer detection for all the reviewed devices are summarized in table 2.

4.2.1 Devices based on physical simulation

In the first category, the papers consisted of a proof of concept for the proposed device. Two of the six works (Laila Fadhillah et al., 2018) and (Elouerghi et al., 2022) used a physical phantom and heaters to mimic the human breast and the tumor in order to collect data. The developed phantoms were very simple. In (Laila Fadhillah et al., 2018), they used a phantom made of just one layer of agar, while (Elouerghi et al., 2022) used the same layer and added a 1mm skin layer made of silicone. Both papers did not mention the thermal properties of the phantom materials nor highlighted their limitations as they offer a simplified representation of real breast tissue, lacking the full complexity and dynamic properties of living tissue. Additionally, the two devices were tested for a very short period of time (30 seconds for (Laila Fadhillah et al., 2018) and one minute according to the graphs of (Elouerghi et al., 2022)).

In (Laila Fadhillah et al., 2018), authors measured the temperatures simultaneously for 30 seconds and changed the position of the heater in different quadrants of the phantom. The temperatures were in the range of 27.34°C to 29.79°C for a normal phantom while in a heated phantom, the range was from 30.27°C to 34.18° and higher measurements were captured in the heated quadrants compared to the other quadrants which proved that these thermal sensors are able to detect changes of heat in the phantom. These results are supported by the infrared cam-

Table 1: A summary of the reviewed smart wearable devices for breast cancer detection using thermal sensors.

Study	**Device type**	**Number of sensors per breast**	**Type of sensors**	**Time of data collection**
(Ng et al., 2007)	Sensors connected to a data recording device with wires. 	8 sensors	Not mentioned	Not mentioned
(Laila Fadhillah et al., 2018)	Wearable Brassiere 	8 sensors	LM35 sensors with ±0,75 °C accuracy	30 seconds
(S et al., 2020)	Wearable breast patch in 6 different sizes 	8 sensors	ADT7420 sensors with ±0.25°C accuracy	24 hours
(Antony et al., 2020)	Stretchable bra with different sizes 	From 12 to 20 sensors depending on the size of the wearable device	Nickel Manganate based thermal sensor with ±0.01 °C accuracy	30 minutes
(Elouerghi et al., 2022)	Flexible star shaped card 	28 miniature biosensors	Micro biosensors with 0.1°C accuracy	Not mentioned
(Ashreetha et al., 2023)	Wearable jacket	Not mentioned	Not mentioned	Not mentioned

era reading, where the difference between the sensor's measurement and the camera's measurement was in the range of 0.82°C to 1.27°C.

Similarly, the authors of (Elouerghi et al., 2022) conducted a comparative analysis against a reference phantom without heat sources, displaying minimal temperature fluctuations ($\Delta T < 0.1$°C). Another experiment scenario of a tumor located at a depth of 15mm is done, eliciting a temperature disparity of +0.6°C. (Elouerghi et al., 2022) also compared the phantom collected data with the numerical simulated data to find a 0.11°C maximal difference. They highlighted that their study's ultimate objective is to explore alternative sensor options, integrate the gathered data with artificial intelligence models, and undergo clinical validation for their proposed devices.

4.3 Devices based on clinical trials

Within the second category of devices, those undergoing clinical validation, a notable consistency emerges in the testing procedures. The authors initiated the process by defining a target population and establishing inclusion and exclusion criteria. After that, they performed a preprocessing phase to clean and prepare the collected thermal data for further analysis. This analysis step involved either the application of traditional statistical techniques or the training of machine learning models. The results were evaluated using metrics such as accuracy, specificity, and sensitivity.

Data collection: First, in the data collection step, authors designated a testing population with specific inclusion and exclusion criteria. Inclusion criteria were similar in all clinical tests, consisting mainly of age (at least 21 years old), recent breast mammogram availability for healthy subjects, and a biopsy for patient subjects. Common exclusion criteria were: pregnant or lactating, previous breast mastectomy or breast surgery or biopsy within the last 90 days for healthy subjects. In the study conducted by (Ng et al., 2007), data was collected from a cohort of 54 individuals, while (Antony et al., 2020) performed clinical tests involving 60 individuals. Notably, (S et al., 2020) stood out as the sole study that conducted data collection at two distinct centers spanning two countries (Clem Plam Breast Clinic in La Plata, Argentina, and Ohio State University (OSU) in Ohio, USA). This multi-center approach to clinical trials holds the potential to enhance population diversity, ultimately supporting the validity and generalizability of the proposed device. On the other hand, (Ashreetha et al., 2023) did not mention any details about the clinical data collection step, such as the number of participants or the inclusion and exclusion criteria.

Data processing: Wearable devices continuously capture a stream of data, and this data may contain errors or anomalies due to various reasons, including sensor inaccuracies, signal noise, or device malfunctions. For these reasons, the authors performed data preprocessing before analyzing or driving conclusions from the collected data. In (Ng et al., 2007) and (S et al., 2020), the authors removed missing data and outliers while (Ashreetha et al., 2023) replaced irrelevant and missing data with the mean temperature which may appear as a better way in order to not lose valuable information from the collected data. Acknowledging the diversity in individual temperature profiles, authors in (Ng et al., 2007) proceeded to normalize the dataset to a standardized ratio ranging from 0 to 1. Additionally, the authors of (S et al., 2020) and (Ashreetha et al., 2023) did not use raw temperature data to detect breast anomalies. (S et al., 2020) used a wrapper feature selection technique to rank features, which resulted in using the best 13 features. On the other hand, (Ashreetha et al., 2023) calculated statistical features such as Mean, mode, median, range, variance, and standard deviation in order to use them in a detection algorithm.

Data analysis: For analyzing the preprocessed data in order to detect breast anomalies, the authors used various detection methodologies. First, (Ng et al., 2007) used a backpropagation (BPA) neural network with an input layer, output layer, and 2 hidden layers and compared it to an RBF-based (Radial Basis Function) neural network. The RBF model had more specific, accurate, and sensitive results compared to BPA yielding 100% classification efficiency for normal and cancer cases, 92% for benign cases, and 90% for cancer patients. Second, (S et al., 2020) used the best-extracted features to train several classifiers (Decision Trees, Support Vector Machines, Random Forest, and Back Propagation Neural Networks...). The classifier and Best Features combination that presented the best prediction accuracy are chosen as the final predictive models. It is pertinent to note that the detailed composition of the extracted features and the classifier remained undisclosed due to ongoing patent proceedings. This methodology yielded a predictive model of considerable performances. This model demonstrated an accuracy of 78%, sensitivity of 83.6%, and specificity of 71.5% under a 10-fold cross-validation. On the other hand, (Antony et al., 2020) used a different methodology. (Antony et al., 2020) author's work consisted of estimating the tumor's size and depth and reconstructing a 3D thermal image of the breast based on the discrete measured temperature of the surface of the breast. The parameter estimation methodology consisted of 3 parts:

Table 2: Breast cancer detection methodologies.

Study	Data Collection	Population size	Data preprocessing	Data Analysis	Results
(Ng et al., 2007)	Clinical trial	54 individuals	-Removing temperature from defectuous sensors and outside the normal range. - Data normalization.	Backpropagation neural network and Radial basis function (RBF) classifier	Sensitivity =91.67%, Specificity =100%, Accuracy =92%
(Laila Fadhillah et al., 2018)	physical simulation	None	None	Studied the difference between a phantom with a heater and no heater ΔT	$2.93°C < \Delta T < 4.39°C$
(S et al., 2020)	Clinical trial	93 benign cases and 108 malignant	-Removing missing values and outliers. -Best Feature ranking and selection.	Decision Tree, Support Vector Machines, Random Forest, and Back Propagation Neural Network including bagging and boosting ensemble techniques.	Sensitivity =83.6%, Specificity =71.5%, Accuracy =78%
(Antony et al., 2020)	Numerical and physical simulation, Clinical trial.	60 females (29 patients and 31 healthy)	None	Tumor parameter estimation (location, blood perfusion, diameter, and metabolic heat generation) with FEM and genetic algorithm. 3D thermal image construction.	Sensitivity= 82.78%, Specificity= 87.09%, Accuracy=85%
(Elouerghi et al., 2022)	Numerical and physical simulation	None	None	Compared between phantoms temperatures with and without heaters	T= 0.1°C with no heater and T= 0.6°C with a heater
(Ashreetha et al., 2023)	Clinical trials	150 observations	-Null or irrelevant data is replaced by the mean temperature. -Mean, mode, median, range, variance, and standard deviation of the breast temperature are calculated.	Statistical features comparison	Not mentioned

forward heat transfer problem, inverse heat transfer problem, and 3D thermal imaging. The forward heat transform problem is the breast surface temperature estimation by a breast numerical model using Penne's bioheat equation on the software COMSOL. The inverse heat transfer problem aimed to minimize the difference between experimental and simulation results using an evolutionary optimization algorithm. The obtained parameter for these experiments is within an error of 10% (0.005 W.cm^{-3}) for heat generation and 15% (0.3 cm) for tumor size. Also, the proposed estimation methodology yielded a sensitivity of 82.78% and a specificity of 87.09% on the clinical data. In order to differentiate between normal and abnormal breasts, (Ashreetha et al., 2023) used a conventional rule-based algorithm to compare the calculated statistical features to show that the asymmetry analysis of the left and right breasts could differentiate between abnormal and normal breasts.

4.4 Evaluation based on device development process

The reviewed devices yielded very good performances in clinical tests, although neither of the studies tackled an acceptance study before the clinical tests. An acceptance study is a phase before the clinical trials where the device is evaluated for its ac-

ceptability, feasibility, and practicality among potential participants and healthcare providers in order to improve its efficiency and integration in the current healthcare process.

Also, the authors of the reviewed papers presented the performances of their detection methodologies without interpretation. The papers mentioned that the advantage of these wearable devices embedded with thermal sensors is being able to detect breast abnormalities better in mammography, especially in dense breasts and younger women, but no interpretation of the used detection models was presented based on the proportion of dense breasts or age in the studied population. Analyzing the detection efficiency based on different categories of breast, age, and ethnicity... can widely support the validation and the utility of the device.

The papers did not mention a follow-up clinical investigation to assess the long-term performance, safety, and clinical utility of the device. A follow-up study is crucial before validation of this type of clinical device, it helps to explore patient-reported outcomes, including quality of test, comfort, and satisfaction with the wearable technology.

Cost-effectiveness is one of the major advantages that these wearable devices can offer, that's why assessing the cost of the proposed wearable devices for breast cancer detection is vital for the effective integration of this technology into healthcare systems. Unfortunately, this cost analysis was not tackled in any of the reviewed devices, despite its importance. Understanding the cost structure aids in setting fair pricing strategies and ensuring that patients have access to these potentially life-saving technologies. Transparent cost assessments promote accountability and help optimize the utilization of healthcare resources, ultimately facilitating the successful integration of such innovative devices into clinical practice while ensuring economic feasibility and patient accessibility.

In order to compare and evaluate the devices presented in this section, table 3 summarizes this evaluation by checking what has been tackled by the reviewed papers and their limitations.

5 DISCUSSION

The studies presented about wearable devices embedded with thermal sensors show the potential of this new technique for detecting breast cancer in an early stage. Thermal sensors are proven to be capable of detecting specific temperature variations that are able to indicate the presence of breast abnormalities. These devices hold great promise in the field of non-invasive and cost-effective breast cancer detection. In this section, we will present the advantages and challenges of the mentioned studies. Table 4 summarizes the advantages, challenges, and areas of improvement for developing wearable devices embedded with thermal sensors for breast cancer detection.

One of the most significant advantages of these devices is their ability to detect breast abnormalities at an early stage. According to (Ng, 2001), it has been recorded that, with the implementation of carefully established protocols, thermography has the potential to identify early signs of cancer approximately 8 to 10 years prior to the detection capabilities of mammography. These devices provide a significant benefit of being non-irradiative as they don't expose patients to any radiations of X-rays and are non-invasive by measuring the temperature only on the breast surface. Devices embedded with thermal sensors can be exclusively beneficial for breast abnormalities detection in dense breasts since conventional methods have problems of false diagnosis in dense breasts, especially mammography.

These devices can provide a cost-effective breast cancer detection method. They eliminate the need for expensive imaging equipment and reduce the financial burden on both healthcare systems and patients. This affordability can make breast cancer screening more accessible to a broader population, including those with limited financial resources. In many third-world countries, healthcare resources are concentrated in urban areas, leaving rural regions underserved. Portable wearable devices can be taken to remote and rural locations, ensuring that women in these areas have access to breast cancer screening without the need for long and costly journeys to urban centers.

In some communities, discussing breast health or undergoing breast screening may carry stigma or taboos. Portable wearable devices can help destigmatize these topics by offering a discreet and less invasive way to monitor breast health, potentially encouraging more women to participate in screening programs. While the field of wearable devices employing thermal sensors for breast cancer detection holds immense promise, it is not devoid of challenges. The pursuit of accurate and reliable detection through this innovative approach demands a critical examination of the obstacles that lie ahead. In this discussion, we unravel the intricacies of these challenges and their potential impact on the implementation of this transformative technology.

The integration of these devices, with other technologies holds the potential for advancing breast can-

Table 3: Evaluation of the reviewed studies based on a wearable device development process.

Study	**Phases**								
	Acceptance Study	Numerical Simulation	Physical Simulation	Clinical Tests	Multi-centric Clinical tests	Data Cleaning	follow-up Study	Cost Analysis	Commercialization
(Ng et al., 2007)	-	-	-	✓	-	✓	-	-	-
(Laila Fadhillah et al., 2018)	-	-	✓	-	-	-	-	-	-
(S et al., 2020)	-	-	-	✓	✓	✓	-	-	-
(Antony et al., 2020)	-	✓	✓	✓	-	✓	-	-	-
(Elouerghi et al., 2022)	-	✓	✓	-	-	-	-	-	-
(Ashreetha et al., 2023)	-	-	-	✓	-	✓	-	-	-

Table 4: Advantages, challenges, and areas of improvement for developing wearable devices for breast cancer detection.

Advantages	Challenges	Areas of improvements
• Early detection of breast Abnormalities • Non-irradiative • Non-invasive • Effective in dense breasts • Affordable and cost-effective • Accessible for women from low-income countries • Wearable, painless, and easy to use	• Physical and numerical simulations complexity • The size of the testing population • Patient data privacy • Clinical trials patients recruitment • User acceptance and usability of the device • Integration in current healthcare workflows	• Enhancing patients recruitment strategies • Promoting inclusivity in the testing population • Thermal data quality assessment and improvement • Integrating machine learning into for analyzing complex thermal patterns to improve the detectio • Data privacy and security measures • Interoapbility with the healthcare system

cer detection in the future. By combining sensors with artificial intelligence, machine learning, and cloud computing techniques, we can improve the accuracy and effectiveness of diagnosing breast cancer. These advanced technologies have the capability to analyze data, identify patterns, and offer valuable insights to healthcare professionals. Moreover, integrating wearable devices with telemedicine platforms can enable monitoring and consultation, thus increasing access to breast cancer detection, in underserved regions.

Clinical validation is a critical aspect of the development and implementation of wearable medical devices in healthcare. Conducting rigorous studies to compare the device's performance against established breast cancer diagnostic methods to determine its sensitivity, specificity, and overall diagnostic accuracy is not very evident. Clinical trials come with several challenges that need to be carefully addressed to ensure the reliability of trial results and the safety of participants.

First, Finding and enrolling a sufficient number of eligible participants can be challenging. The recruitment step can be very long and challenging for clinical trials. Second, achieving a diverse participant population that represents the broader patient population can be difficult. In breast cancer detection clinical trials, the target population must include diverse age categories, breast type, breast cancer types, breast size, and even underrepresented groups, such as racial and ethnic minorities. Achieving population diversity in breast cancer detection clinical trials is essential for ensuring that research findings are relevant, generalizable, and equitable. Efforts to enhance diversity should be integrated into the trial design, re-

cruitment strategies, and participant engagement processes, with a focus on addressing barriers to participation and promoting inclusivity in breast cancer research.

In (Laila Fadhillah et al., 2018) and (Elouerghi et al., 2022)'s work, authors used only physical or numerical simulation in tests. While these simulations can help collect and assess the device's performance, but are not enough to validate its use for diagnostic purposes. Creating accurate breast tissue models is challenging. Tissue composition can vary widely between individuals, and accurately representing this variability in simulations is complex. Simulations also should replicate the diversity of breast cancer types in size, shape, and location, which is also very complex due to tumor diversity and inter-individual variability. Due to these simulation complexities, clinical trials with a sufficient and diverse population are mandatory to validate wearable devices for breast cancer detection.

Ethical and privacy considerations are of paramount importance when developing and using breast wearable devices for breast cancer detection. These devices collect sensitive health data, and their usage must adhere to strict ethical and privacy standards. Obtaining informed consent from users is crucial, users should fully understand the purpose of the wearable device, how their data will be collected and used, and any potential risks or benefits. Breast wearable devices should employ robust encryption and data protection measures to safeguard user information from unauthorized access or breaches. Ensuring data security is particularly important in the healthcare context, where data can be sensitive and personally identifiable.

Apart from diagnostic accuracy, clinical validation should assess the device's usability in real-world clinical settings. Factors such as ease of use, integration into existing healthcare workflows, and user acceptance are important considerations to take in future works.

6 CONCLUSION

In conclusion, the field of smart wearable devices equipped with thermal sensors represents a promising frontier in breast cancer detection. These innovative technologies offer a multitude of advantages, from non-invasiveness and early detection to accessibility and cost-effectiveness. However, as with any new technology, there are many challenges to overcome. Clinical validation, population diversity in trials, ethical considerations, and privacy safeguards are among the critical issues that demand careful attention.

Through this review, we can say that smart wearable devices with thermal sensors for breast cancer detection projects are not mature enough to be clinically and widely used, but addressing the challenges can make these devices more effective, accessible, and user-friendly. These devices hold the promise of detecting breast cancer at earlier stages, reducing healthcare disparities, and transforming breast health awareness. With continued research, validation, and collaboration between the medical community and technology developers, they may well become an accurate and validated breast detection method.

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