Electronic sensing and ablation needles for medical diagnosis and treatment

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Abstract

Electronic biopsy sensing needle caught researchers’ interest as they cause minimal damage to patient’s viscera and vascular tissues and utilize AC voltage to measure the bioimpedance changes in pathological tissue. Researchers have studied the application of bioimpedance sensing in needle-based devices to diagnose cancer, extravasation, and neuromuscular disease. Electrical Impedance Spectroscopy and Electrochemical Impedance Spectroscopy (EIS) have been selected technique to analyse the electrical properties of bio-tissues. Biopsy sensing needles are classified into conventional needles and novel needles, differing in their structure and technique application. Conventional needles consisted of an inner element (a metal wire) and an outer element (a metal cannula), which are electrically isolated. The majority of novel needles are comprised of new sensors/electrodes on the surface of the needle shaft, with the needles being fabricated using new materials and methods. Novel techniques such as RF wirelessly powering, ultrasonic wirelessly powering, and electrolytic non-thermal ablation were researched in RF ablation. This review paper focuses on presenting the applications of electronic needles in medical diagnosis and treatment. The experiment results of pathological detection by conventional sensing needles are presented. Then, the structure, material, fabrication methods, and test results of novel sensing needles are introduced. Furthermore, novel tissue discrimination methods and novel RF ablation needles are introduced. Finally challenges and future work are discussed.

I. Introduction

According to Global Cancer Statistics 2022, approximately 19–20 million people are diagnosed with cancer, and about 10 million people lose their lives due to cancer, annually worldwide[1]. The development of novel cancer therapeutics has become significant in the past decades. With previous reports suggesting that early cancer diagnosis and treatment could efficiently increase the survival rate of cancer patients [2]. Therefore, early cancer detection is an essential topic in cancer treatment. Early detection approaches have been presented, such as screening tests, cancer biomarkers, cancer imaging, and so on [3]. However, some of these approaches carry high costs, such as the lung cancer screening [4, 5]. The utilisation of electric properties of biological tissues in clinical diagnosis has been mentioned previously [6]. The impedance values in the cancerous tissues and normal tissues were detected to be different in previous reports; therefore, bioimpedance sensing can be used in the detection of cancer [6–10]. Besides, tumour ablation is another efficient method to decrease the risk of metastasis. This review introduces the electronic needle-based device for cancer diagnosis and other medical treatments. The bioimpedance can be measured by electrode configuration [11] and using a fine needle as the detector can minimize the damage to viscera and vascular tissues during treatment. As a result, needle-based bioimpedance measuring devices and their application have been well researched in the past decades [12–14].

Needle-based bioimpedance sensing devices commonly consist of a bioimpedance measuring needle, an impedance analyser, a microcontroller, and a display device. To increase the accuracy of tissue discrimination, EIS has been studied by many researchers to create a cancer diagnosis system. This is
due to EIS having the potential to differentiate healthy tissue from unhealthy tissue by observing the variation of multiple references of impedance data (real/imaginary part of magnitude and phase angle) at different frequencies [8, 9, 15–18]. On the other hand, radio frequency (RF) in medical engineering refers to the frequency range of electromagnetic waves that lie about 900Hz to 2500MHz. These high energy waves can be applied in many fields. In the application of medical devices, RF ablation was widely used in tumour ablation surgery. Radiofrequency ablation (RFA) is a technology used to ablate tumours by utilizing an electrical current. The tumour ablation methods are classified into thermal ablation and non-thermal ablation. Thermal ablation is a minimally invasive medical produce that heats the lesion tissue to a cytotoxic temperature with a radiofrequency catheter. Non-thermal ablation is also a minimally invasive medical procedure but utilises non-thermal approaches to cause the destruction of cell structure, such as changing the pH of tumour cells by electrolytic ablation. The following sections will introduce the novel thermal RFA needle-based devices that apply wirelessly powering technologies and other non-thermal ablation methods [21, 22].

II. Methodology

The keywords “Impedance sensing RF needle”, “Radiofrequency ablation”, and “Bioimpedance cancer diagnosis” were used in the specific search engine Google Scholar between March 2013 and March 2023. In total, 118 initial papers were generated to be reviewed, t. Afterwards, filter papers not relative to clinical radiofrequency technologies, resulting in 57 papers. Next, filter the papers discussing the novel bioimpedance sensing approaches for cancer detection and RF ablation. Finally, generated 29 papers as the core of this review (Fig. 1). This study only focusses on reviewing the research outcomes from other papers in the past decade. Therefore, all human and animal experiments from the reviewed papers mentioned in this paper are not involved in this study.

III. Needle-based Devices In Lesion Tissue Detection

According to a previous report, the changes in cell structure, fluid status, and electrical current can affect tissue conductivity and impedance [19]. Hence many researchers tried to quantify how electrical impedance changes as the tissue becomes pathological. This section will introduce the methods for detecting and distinguishing the lesion tissue by applying electrical impedance sensing techniques.

A. Applications of conventional sensing needles in pathological tissue detection

Conventional sensing needles are currently deployed in the commercial sector. Their structure usually consists of an inner element (a metal wire) and an outer element (the needle cannula), which are electrically isolated. Conventional sensing needles use the bipolar impedance measuring principle. Hence, the inner metal wire is the first electrode, and the needle cannula is the second electrode. According to the setup of electrodes during impedance measuring, the measuring methods can classify into bipolar and monopolar. To evaluate these two different methods, Jack Sharp et al. conducted a comparative study [20]. The monopolar and bipolar setups were used to measure the impedance of a piece of pork. Unlike
the bipolar setup, the sensing needle in the monopolar only contains one electrode on the needle tip and another reference electrode placed on the pork’s skin. Three tests were conducted: method validity, nerve detection, and cerebrospinal fluid detection. According to the presented results, both setups work similarly in inhomogeneous volumes such as biological tissue. However, the current path in the bipolar setup is localized to the smaller tissue volume between two electrodes compared to the monopolar setup. Due to this the bipolar setup is unaffected by other metal implants in the patient’s body (such as pacemakers or cardiac defibrillators). Therefore, the authors indicated that the bipolar setup has one more advantage than the monopolar setup.

In the human liver tumour inquiry, Sanna Halonen et al. measured the human liver and tumour impedance from 26 patients who underwent diagnostic ultrasound-guided liver biopsy by the bioimpedance biopsy needle (IQ-Biopsy, Injeq Oy, Tampere Finland) [21]. The impedance analyzer sent a 1ms (millisecond) long pulse voltage signal through the electrodes on the biopsy needle to the tissue to measure the impedance. According to the data from the experiments, the phase angle of tumour tissue was lower at frequencies below 17kHz and less negative at higher frequencies compared to the phase angle of liver tissue. They also found that the tumour impedance magnitude values were generally lower than normal liver tissue at measurement frequencies of 10kHz to 10MHz.

Camilla Carpano Maglioli et al. detected the bioimpedance of two terms of normal tissue samples taken from six different parts of the animal body by a prototype of a needle-based sensing system [7]. The system consisted of a high-precision impedance converter (AD5933) as the impedance meter, a commercial single-use sterile concentric electrode needle as the impedance sensing probe, and an Arduino DUE. To quantify the ability to distinguish healthy tissues in real organs, an ex-vivo porcine larynx was used for testing. The ex-vivo experiment consisted of ten measurements with frequencies from 10kHz to 100kHz at 200Hz increment, and the Sum of Squared Differences (SSD) of averaged data was calculated at each frequency. The results from their experiments indicated that the values of electrical impedance of tested samples have no overlapping in the magnitude-phase graph; hence they can be easily distinguished.

Zhouqi Cheng et al. created needle-based electrical bioimpedance sensing system called SmartProbe, which is used for clinical studies on the bioimpedance characteristics of both pathologic and healthy tissues from the head and neck region [22]. The system has four main components: a power isolator, the SmartProbe device, a handheld connector, and an Arduino board. Human ex-vivo cancerous tissue and normal tissue from the head and neck were used for the lesion tissue electrical property tests. In total, 586 data of were collected, each data included 10 impedance modules and 10 phase angles at ten excitation frequencies (10kHz to 100kHz). The results generally indicated that healthy tissue has a higher conductivity than pathologic tissue.

H Kwon et al. created an electrical impedance myography (EIM) technique for measuring the electrical impedance of skeletal muscle and its alteration with neuromuscular disease [23]. The needle's electrode was comprised of a stainless steel conductor, polyimide, and medical grade epoxylite varnish as
insulators. The impedance measurement device measured the bio-impedance in a 10kHz and 1MHz frequency range. The leg of male Wistar rats was used as muscle tissue. The results showed that this EIM needle is not affected by the thickness of subcutaneous tissue during the measuring process, and it also showed that 97% of impedivity data of the muscle was measured at a frequency of 10KHz. Further, the contribution of muscle to surface EIM decreased drastically as the thickness of subcutaneous fat increased.

H. Kalvøy et al. researched an approach for discriminating nerve tissue from other tissue types based on multiple frequency impedance measurements [24]. They created a novel algorithm based on complex impedance measurements to detect different types of tissues by transferring the complex number of impedance data into a vector in a complex plane where the impedance data can be described by modulus (length of the vector) and phase angle. They found the optimal frequency for nerve tissue discrimination by observing the changes in modulus and phase angle of impedance data during the experiment. A new algorithm was also designed to distinguish different types of nerve tissue based on principle component analysis (PCA). A 3-electrode needle-based setup was used to measure the sciatic nerve tissue of eight 3-month-old pigs (4 females and 4 males) in experiments. Samples of intraneural, perineurial, muscle, and subcutaneous fat tissue from porcine were measured at different frequencies. The result of the experiments showed that the optimal frequency range for discriminating intraneural tissue and other tissue types was 126kHz to 158kHz.

The findings presented above show that conventional needle-based devices can distinguish pathological tissues from normal tissues, but the challenge is taking advantage of these findings in experimental medical treatment. Therefore, electrical impedance spectroscopy or Electrochemical Impedance Spectroscopy (EIS) was applied to clinical biopsy sensing needles. Electrical Impedance Spectroscopy is a technique used to characterise the electrical properties of various materials, such as metals, insulators, and semiconductors. It provides many advantages, such as small signal analysis, wide applied frequency range, and commercialized instruments (such as potentiostat). On the other hand, Electrochemical Impedance Spectroscopy is based on the same principle but is more focused on characterising the electrical properties of electrochemical environments such as batteries and fuel cells [25].

The earliest report of EIS needles is from V. Mishra et al., who created an electrical impedance spectroscopy sensing biopsy (EIS-Bx) needle-based device to sense the electrical properties of tissue to provide additional information for doctors [26]. An 18-gauge needle was used as the sensing needle, which also consists of a conventional structure: an inner and an outer element, and they are electrically isolated by adhering a thin-walled tube of polyimide to the inner element (Fig. 2a). Three ex vivo prostate specimens are utilized in an ex vivo prostate tissue experiment. The experiment showed that prostate cancer impedance is more significant than benign prostatic tissues.

To collect more data from prostate cancer tissues, V. Mishra et al. used the EIS-Bx device to measure the bioimpedance, reactance and resistance from 432 cancerous prostate tissue cores from 36 men (12 cores per person) in the frequency range of 100Hz to 1MHz [10]. The result showed that the optimal
frequency to identify cancer is 63.09 kHz using resistance and 251.1 kHz using reactance to discriminate. At these optimal frequencies, the resistive component and reactive component of the EIS-Bx needle provided a sensitivity of 75.4% and 71.4%, respectively, which means the EIS-Bx needle could be a functional real-time cancer tissue discriminating tool.

Muhammad Aitzaz Abbasi et al. researched a new approach for intra-articular space detection by using EIS with a monopolar injection needle and a novel algorithm for inner tissue discriminations [27]. A 7-month-old female pig was used in the in vivo experiment. The device consisted of a monopolar needle-based impedance analyser, DFT-based impedance measurement device, ultrasound transducer, X-ray detector, and Ag/AgCl counter electrode. A new algorithm for detecting the intra-articular space was used. The experimental results indicated a significant difference between the impedance magnitudes of the elbow and knee joints. Conversely, the knee joints showed a higher conductivity.

Reihane Mahdavi et al. researched a new system named Electrical lymph Scoring (ELS) with EIS for the Intraoperative pathologically-calibrated diagnosis of breast cancer by detecting the electrical properties of lymph nodes (LNs)[16]. The ELS system consisted of a needle-shaped 2-electrodes probe and was designed based on the under-test dielectric properties of LNs, including impedance and admittance. The experiments in this study tested the impedance, admittance, and impedance phase slope (IPS) of the LN dissection from 77 patients, of whom 68/77(88.3%) had invasive-type breast cancer, 3/7(3.9%) were ductal carcinoma in situ (DCIS) patients, with 55% of all patients undergoing post-chemo/radiotherapy surgery. According to the results from the experiments, the ELS system presented an electrical diagnostic calibration based on permanent pathology states of LNs in both neoadjuvant and non-neoadjuvant breast cancer cases with sensitivities of 95% and 91%, respectively.

B. Applications of the novel sensing needle in pathological tissue detection

Improvement of the bipolar electrodes was presented by Joho Yun et al., who created a novel needle named EIS on a needle (EoN) by fabricating the bipolar interdigitated electrode (IDE) on the end of a curved surface of a hypodermic needle (Fig. 2b) [28]. The EoN applied a file photomask and photoresist spray coating in photolithography. To minimize unnecessary invasion and reduce the damage to bio-tissue, the location of electrodes is designed as closely as possible. Hence the width of IDE is 400µm, with a needle size of 22-gauge. They used the discrimination index (DI) as the reference value to evaluate the tissue discrimination capability of EoN between different layers, which is an index defined by the ratio of the mean difference (magnitude, phase angle, real part, or imaginary part from EIS data) between dissimilar tissues and the square root of the sum of two variances for each of the dissimilar tissues. Higher DI means two different tissues are easier to distinguish. A three-layers (fat, muscle, and fat) porcine tissue sample was utilized for the experiments, and three layers were measured respectively. According to the results from the experiments, the needle performed the highest DI between the first layer and the second layer at 627Hz (15.772),111Hz (6.978), 627Hz (15.686), and 100Hz (5.235) in the order of real parts of impedance, magnitude, and phase. For the DI between the second and third layers, the highest DI were observed at 111Hz (1.097,1.648 and 1.284) and 177Hz (0.368) in the same order.
According to the previous research of EoN, the electrical properties of bio-tissues can affect the connection part of EoN during penetration, causing a considerable distortion in the sensor output. Therefore, Joho Yun et al. studied applying the incremental compensation method (ICM) on the EoN to overcome the distortion of the sensor output issues from the previous EIS needle [29]. ICM calculates the conductivity and relative permittivity values in different immersions during the insertion, averaging overall steps for the immersion depth. Different types of phosphate buffer saline (PBS) were utilized as the test sample in the experiments. According to the experimental results, the detection accuracies for the conductivity and relative permittivity of the PBS were enhanced by 5.59 times and 2.18 times, respectively, when the EIS needle made use of ICM.

Giseok Kang et al. further improved the IDE by applying a newly developed flexible photomask: Parylene-C film, in the fabrication process [15]. Two types of EoN were designed and fabricated for the comparison experiments, and they were classified into open type (electrodes of open type are exposed to the air) and passivation type (Parylene-C passivates electrodes of passivation type). Furthermore, the ex vivo experiments used the Phosphate-buffered Saline, skin, fat, and muscle of pork, and normal tissue and cancerous human breast tissues to test the tissue discrimination capability of the new needle. Constant voltage was applied to characterize the electrical properties of the bio-tissues in the frequency range from 1kHz to 1MHz. A potentiostat and a laptop were used to measure the electrical signal from the bio-tissues. According to the results from the experiments, the passivation type of EoN performed higher precision and higher capability of tissue discrimination in human normal/cancer tissues measurement experiments, which indicated that the Parylene-C increased the capability of the EoN.

Joho Yun et al. also collected the EIS data from 10 Renal cell carcinoma patients using EoN [9]. They measured the normal and cancer tissues over the frequency range from 100Hz to 1MHz to evaluate the cancer tissue discrimination capability of EoN. The EoN needle-based device showed that the best discrimination frequency is 1MHz because the DI of magnitude (5.15 at 1MHz) was higher than that of phase (3.57 at 1kHz).

Jinhwan Kim et al. researched the utilization of an improved EoN in bioimpedance measurement of hepatocellular carcinomas (HCC), cirrhotic liver parenchyma (CLP), normal liver parenchyma (NLP), and metastatic tumour in normal liver (MLT) [30]. The new EoN was comprised of IDEs and straight electrodes (SEs). Comparing the previous model of EoN in [28], they replaced the IDEs rectangular shape with a triangular shape, significantly reducing the distance between the detection electrode and sharp tip to 280µm, which further minimized the intrahepatic vascular damage cause by the unnecessary excessive penetration (Fig. 2d). The HCC, CLP, NLP, and MLT bio-tissue samples were measured from 100Hz to 1 MHz. According to the experimental results, the optimal frequency range for tissue discrimination is 0.46 MHz to 1MHz. Besides, the largest DI values were obtained at 1MHz. They were 2.71 and 0.96 in the real and imaginary parts of impedance between CLP and HCC, respectively. The values between NLP and MTN were 3.62 and 2.54, respectively. Therefore, the optimal frequency in this research was 1MHz. Furthermore, the result also showed that the conductivities and permittivities of malignant tumours in normal liver and cirrhotic liver had a significant difference.
However, the measuring accuracy of a 2-electrode EIS needle is likely to be affected by the electrode polarization (EP). Therefore, Jaeho Park et al created a new biopsy needle integrated with a novel EIS microelectrode array on the needle’s surface to decrease the EP effect during measurement (Fig. 2e) [31]. The microelectrode array on the needle consisted of a 4-electrode configuration and the whole system consisted of a stainless-steel needle with a diameter of 1.2mm (gauge 18) and a length of 15cm, an LCR meter, and a control PC used for data receiving, displaying, and analysing. After Real-time EIS measurement in the liver-mimicking-hydrogel-phantom, a piece of porcine tissue was measured with the novel EIS needle longitudinally and compared of EIS spectra between normal and fatty liver with EIS needle. The data from the experiments indicated that the EIS needle was able to detect its penetration from the muscle to the fatty tissue in porcine meat, measure the electrical conductivity and distinguish between normal and cancerous tissue in real-time during needle insertion.

Previous reports have shown that the pH and glucose concentrations from cancerous tissue are different from normal tissue[32–35]. Jaeho Park et al. tried to use these unique features to detect cancerous tissues. They created a novel biopsy needle integrated with multi-model sensors (Iridium oxide-based pH sensor, enzymatic glucose sensor, and Au electrode) and tested its capability (Fig. 2f) [36]. The biopsy needle focused on detecting the pH changes, electrical conductivity, and glucose concentration in different tissues. The system was comprised of a biopsy needle integrated with multi-model physical/chemical sensors, a multiplexer, an LCR meter, an electrometer, a source meter, and a control PC. A liver cancer-mimicking hydrogel phantom based on agarose gel was used for dual-modal measurement with pH and electrical conductivity. A porcine liver with internally exchanged physical/chemical parameters was utilized for ex vivo experiments, and its conductivity, pH, and glucose concentration were measured for 30 seconds. Based on the data from the experiments, the conductivity of the mimicking cancer tissue was 1.92 times higher than that of the normal liver tissue, the measured pH difference was 0.49, and the measured difference of glucose concentration between normal and cancer tissues was 2.90mM (millimolar).

C. Applications of sensing needles in medical procedures

Many needle-based devices have been created for further medical trials, such as the needle-integrated ultrathin bioimpedance microsensor array created by Rongzhou Lin et al.[37]. This biopsy needle with sensor arrays is used for early extravasation detection by monitoring the bioimpedance values between veins and tissue. The micro-sensor array consists of 8 electrodes. It was developed using photolithography to pattern Au electrodes on a flexible polyimide substrate and electrochemical deposition to coat them with a porous PEDOT-MWCNT layer (Fig. 3a). In vivo animal experiments (including rat tissue and porcine tissue) tested the capability of the sensing needle, and the results indicated that the PEDOT-MWCNT microsensors could detect local impedance changes in porcine muscle by injecting as low as 20 µL 0.9% NaCl. The microsensor could also detect subcutaneous injections of solutions before visual assessment of skin swelling in a mouse model was possible and sensitively differentiate extravasation from conventional injections in a pig model.
Another similar functioning needle device was created by Zhouqi Cheng et al. [38]. This device was designed to help in the peripheral intravenous catheterization (PIVC) procedure. The main operating principle is to detect bio-impedance differences in the skin, vein wall, and blood to identify the needle's entry into the patient's body. The electrical-bioimpedance sensing device was developed based on a concentric electrode needle (CEN) (Fig. 3b) and an intelligent venous entry indicator (SVEI), where the SVEI lights up a LED to indicate the venous entry when the measured value is within the range of blood. The paper illustrated 2 experiments: The first one aimed to test the effectiveness of the detection method through animal trials; The second one evaluated the effectiveness of the technology to guide PIVC operation on a commercial baby arm phantom. The data from the experimental results showed that 100kHz is the best excitation frequency for identifying the bio-impedance during the PIVC insertion, and it also indicates that the effectiveness of this device for non-experienced people is significant.

Laurent Schoevaerdts et al. created a needle device that applied a new impedance sensor to identify punctures of retinal vessels by detecting the impedance of blood [39]. The new sensor had inner and outer electrodes and they were electric insulated (Fig. 3c). The principle of impedance measurement is by injecting the conductive thrombolytic agent thought the needle lumen in the eye, and observe the impedance variation when the electrode touched the vessel wall. A pig eyeball was used for in vivo experiments. In total, the experiment executed 12 punctures, including five double punctures. The ex-vivo experiment showed the impedance variation with a standard deviation of ± 0.660 kΩ, and the electrical sensitivity was tuned to optimize the impedance; both punctures and double punctures were recognised in 80% of the cases.

D. Combination of Machine learning in tissue discrimination

Previous sections introduced many different sensing needles; most have excellent sensitivity to pathological tissue. However, taking advantage of these new techniques in clinical diagnosis is challenging tissue discrimination forming a significant part of the diagnosis. Ho-Jung Jeong et al. have given a novel method for discriminating between normal and cancerous tissue by combining EIS and Machine Learning (ML) techniques [40]. They created a micro-EIS device equipped with a pneumatic valve for flow cytometry and a pair of electrodes instead of a needle. The Normal (SV-HUC-1) and cancerous (TCCSUP) urothelial cell lines were used for experiments. These two groups of urothelial cells were measured by interfacing the µEIS device with a laptop, an impedance analyzer, a syringe pump, and a pneumatic pump and five samples from each group were measured at five different frequencies (10, 50, 100, 500kHz, and 1MHz). One hundred thirty-five impedance values of TCCSUP and 101 impedance values of SV-HUC-1 cell line were used to feed the machine learning model as the feature vectors. Six well-known ML models: Logistic Regression (LR), K-Nearest Neighbors (KNN), Decision Trees (DT), Radiofrequency (MLRF), Support Vector Machine (SVM), and Back-propagation Neural Networks (BPNN) were selected to be robust when used for classification tasks. The results indicated that the RF performed the best on three of the five performance parameters, and it classified normal and cancerous cells with an accuracy of 91.7%, a precision of 92.9%, a specificity of 90.0%, and an F1-score of 93.8%. Although this
research did not create a needle-based device, the novel ML application in cancer diagnosis still has reference worth in future work of bioimpedance sensing devices.

Iv. Tumour Ablation Needle-based Devices

RF ablation is a minimally invasive medical method to remove lesion tissue, and it has the advantages of low costs and less tissue damage. Some novel approaches were studied in needle-based RF ablation systems, such as the wirelessly powered catheter by electromagnetic induction.

A. Novel ablation catheters

RF ablation catheters using wirelessly powering techniques can provide further convenience for surgeries. Hence, Julian Moore et al. studied a method that uses a wirelessly powered catheter and generator to achieve Liver radiofrequency ablation (RFA) [41]. They aimed to create a wireless power transferring needle-based device that able to transfer 60 W energy for the experimental ablation through the coils and heat the tissue by catheter up between 62 degrees and 102 degrees Celsius in 60 seconds. Electromagnetic induction was used to power an ablation catheter wirelessly. The device consisted of transmitting and receiving circuits, where both circuits have a coil to transmit power by the magnetic resonant theory. The ablation needle is separated into an inside stylet component, an insulation component, and an external sheath component (Fig. 4a). The results showed that a maximum voltage and power of 92Vpp and 60W were received in the receiving coil when a 100Vpp sine wave was applied to the transmitting coil. The temperature of the insertion point of the needle rose 64 to 102 degrees Celsius in 60 seconds, and the power efficiency was recorded at 49% in the case of positioning the catheter at a depth of 10–12 cm at the centre of the transmitting coil.

To research the power transfer efficiency when the angle and distance between transfers, Julian Moore et al. tested another prototype of wirelessly powering radiofrequency ablation needle devices, which utilized the bipolar RF ablation (RFA) technique [42]. The system consisted of two parts: an ablation generator and a wireless catheter, where the ablation generator used an amplification circuit to create an alternating circuit through a coil to create an alternating magnetic field to the wireless catheter part. The catheter part was comprised of a receiving coil connected to a 6.5 gauge and 12 cm in length prototype (Fig. 4b). The experiments tested the power-receiving capability of the received coil at different distances and angles between the transmitting and receiving coil. According to the results, the average maximum received power from the received coil was 15W, and its average maximum efficiency was 63.27%. The system was able to have an ablation zone with a width of 9mm, a length of 18mm when supplied with maximum power (24VDC with transmission coil distance), and an ablation zone with a width of 12mm, a length of 21 mm (12VDC at 0cm coil distance and 24VDC at 6cm coil distance).

Maria Moris et al. evaluated the optimal thermal dosimetry of a novel RF ablation needle in pancreatic cysts treatment [43]. A prototype of the ablation needle-based device was built, which consisted of a 22-gauge monopolar needle with a tip electrode connected to a standard electrosurgical unit (Fig. 4c). The cyst model was made of fresh tissues from a pig's small intestines, which was utilized for the ex-vivo
experiment, and each cyst was cut into four different specimens for sub-analysis, and they followed a predetermined order immediately after the ablation. Each ablation in the experiment was performed until a specific, predetermined maximum temperature (50°C, 60°C, 90°C, and 97°C, respectively) was reached. As a result, 23 cyst segments were ablated, and the maximum temperatures reached were 50°C, 60°C, 90°C, and 97°C in 8, 11, 11, and 2 cysts, respectively. The results showed that the needle using low-voltage coagulation can provide ablation in a temperature-dependent fashion with a threshold of at least 60°C and a safe cyst margin below 97°C.

Another study into thermal ablation was presented by Jannis Dickow et al. who researched the two-dimensional intracardiac echocardiographic (2D-ICE) to guide and validate Saline-enhanced RF (SERF) needle ablation in real-time [44]. The SERF needle ablates the tissue by injecting heated saline into the target with a stainless-steel ablation needle. The SERF catheter had four distal-tip electrodes, and the stainless-steel ablation needle was fitted to the distal catheter (Fig. 4d). Mongrel dogs were used in the ex vivo experiment. The results of the experiments indicated that the 2D-CIE could be used to guide the SERF ablation.

During the RFA procedure, however, many reports pointed out that an unintended audible explosion, called “steam pop”, would happen inside the patient’s tissue during surgery. This phenomenon can induce various thermal and mechanical effects on neighbouring tissue [45–47]. Therefore, Jaeho Park et al. created a sensor-integrated RFA needle (sRFA) [48]. A flexible sensor based on a polymeric platform with pressure and temperature sensing capabilities was integrated into the surface of the RFA needle. The sRFA needle comprised an internal tube and a thermocouple to maintain the temperature as low as possible (Fig. 4c). The steam pop detection test utilised a porcine liver as patient tissue. The result from tests indicated that the sRFA needle could provide insight into the environmental changes during RFA. However, the needle was still unable to give a reliable prediction of occurrence of steam pop.

Another method to avoid “steam pop” is non-thermal ablation. Kim et al. created an electrolytic ablation system powered by an ultrasonic wireless powering technique (Fig. 4e) [49]. EA is a nonthermal method in which a localized PH region is created via two electrodes inserted into a tumour and connected to a direct current (DC) source. The device has in vivo part, and an ex vivo part, where the in-viva part consists of one or multiple implantable EA microprobes, and the out-viva part is the ultrasonic transducer. Compared to inductive wireless powering, ultrasonic powering allows the device to be miniaturized with a longer operation range (> 10cm) and a higher power transfer efficiency. The data from experiments showed that the ultrasonic-powered EA ablation device was wirelessly charged with an average power of over 60mW/cm² at a distance of 60 cm away. Its ablation zones after 30 min of operation for the anode/cathode were 0.25, 0.35, and 0.6 cm³ for intensities of 46, 119, and 190 mW/cm², respectively. The in vitro experiment indicated that a single EA microprobe could kill the cancer cells in a maximum number of 1394 spots (± 241 spots).

V. Conclusion
A. Structures and materials of sensing needle

The structures of sensing needles can be separated into two terms, conventional and novel. The conventional needles use the bipolar impedance measuring principle, so most conventional structures have two electrodes. The needle structure comprises a metal wire inner element (the first electrode) and the needle cannula as an outer element (the second electrode). On the other hand, the structure of novel needles depends on the number of sensors/electrodes. They usually place the electrodes/sensors on the surface of needles, such as EoN, whose structure has sensing and connection parts. The connection part consists of two metal wires integrated into the needle body's surface, connected to the sensing part and PCB. The sensing part is composed of a pair of parallel interdigitated Au electrodes fabricated on the surface of the needle tip. The advantage of EoN is that IDEs on the needle provide higher sensitivity than conventional sensing needles. Another type of novel sensing needle comprised of 4-electrodes was invented because the 2-electrode structure is more likely to be affected by EP. Four wire electrodes made of 1µm thick gold were integrated into the insulation material of the needle's surface. The needle hub capability that connects them has been evaluated that can reduce the effects of EP. Depending on the materials of electrodes from novel sensing needles, the utilization of gold (Au) in fabricating electrodes has been proven to provide higher sensitivity than materials due to its high conductivity.

B. Pathological tissue discrimination methods

Most studies of pathological tissues detection utilized EIS to analyse the electrical property of tissue. Hence, figuring out the correct data from EIS becomes the key to distinguishing pathological tissue from normal tissue. The Discrimination Index was used to test the optimal frequency for tissue distinguishing. The application of Machine Learning was also researched in tissue discrimination through the EIS data, 6 ML models were tested, and they provide very high sensitivity and accuracy in discriminating cancerous (TCCSUP) urothelial cell.

C. RFA needles in medical trials

The studies of wireless RF ablation devices were introduced due to them being able to reduce the risk of wires being damaged or shorted and provide continence to therapy doctors. 2D-CIE was evaluated as a novel approach to guide the RF needle in therapy. However, during RF ablation, an unintended audible explosion called “steam pop” may occur inside the patient's tissue, and this phenomenon can induce various thermal and mechanical effects on neighbouring tissue. Hence, the sRFA needle was created to avoid this issue by monitoring the pressure and temperature of the inner environment of ablated tissues. However, the sRFA needle still needs further research because it can only provide information about the inside tissue environment instead of providing reliable predictions to surgeons. Another solution is to use a non-thermal ablation approach. EA is another choice to avoid the “steam pop”. The prototype of a wirelessly powered EA device was created and tested. However, the ablation time of the prototype is too long for therapy (around 30mins).

D. Challenges, and Future work
Developing an exemplary GUI for sensing needle systems is very useful for training surgeons, and a good display can provide more accurate information for the surgeon to confirm the position of the lesion tissue. Besides, CT scanning might be used during the insertion of the sensing needle to know the position. For the RF ablation needle systems, an exemplary GUI for the RF needles to monitor the temperature and pressure of inner tissue is supposed to avoid the “steam pop” during therapy as well. Furthermore, the two-dimensional intracardiac echocardiographic (2D-ICE) can help the clinical staff get guidance on the needle position in the patient’s body. Novel needles comprised of new sensors were evaluated to have higher sensitivity. However, one of the challenges is fabricating the sensors on the needle surface. Fabricating these sensors requires high precession manufacturing and a complicated process. Hence, finding a simplified sensor manufacturing method might make these techniques more practical. On the other hand, the EIS data are different due to electrochemical environments, and different pathological tissues perform different electrical properties. Hence, building up an EIS data library for diagnosis is essential. ML could be very powerful in studying these data in the future. Besides, many reports mentioned that the cancer tissues also perform different pH and glucose concentration features. Hence, to get higher diagnosis accuracy, the sensing needles might be able to detect these different features of cancer tissue in the future. Smarter RFA needles should be researched to avoid the “steam pop”. On the other hand, non-thermal ablation methods are other options to avoid the “steam pop”. Hence, further non-thermal ablation methods are supposed to be researched in the future.

Declarations

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Data availability statement

The datasets generated and/or analysed during the current study are not publicly available due this is a review paper but are available from the corresponding author on reasonable request.

References


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**Table 1**

Table 1 is available in the Supplementary Files section.

**Figures**
Figure 1

process of selecting papers in this article
Figure 2

EIS on the needles

a) Structure of EIS-Bx needle tip [26]

b) Structural details of the EoN with IDEs at the end of a 22-gauge (diameter = 700 um) hypodermic needle [28].

c) Schematic of contacting process before photolithography when the parylene-C photomask is deflected to contact the curved surface of the needle [31].

d) Schematic design of EoN, comprising a detection part [30].

e) Fabrication process of microelectrode array on the surface of biopsy needle (blue box) and packaging to external connection (green box)(left); Overall structure of biopsy needle(right) [31].

f) The structure of the multi-sensor needle [36].
Figure 3

Needles with bioimpedance sensors in medical trials
Figure 4

Novel ablation catheters

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.
• Table1.docx