

Review of methods for detecting electrode-tissue contact status during atrial fibrillation ablation

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Highlights

• The effect of electrode-tissue contact force on the efficacy and safety of ablation of atrial fibrillation was reviewed in detail.

● The existing contact force sensing catheters on the market are compared and introduced.

● Three impedance-related methods for assessing catheter adherence are introduced.

Abstract

Atrial fibrillation is a common cardiac arrhythmia with an annually increasing global prevalence. Ablation of atrial fibrillation is a minimally invasive procedure that treats atrial fibrillation by using a catheter to deliver radiofrequency energy to heart tissues generating abnormal electrical potentials. The success of this procedure relies significantly on the adhesion between the catheter and the heart tissue, presenting a challenge in accurately assessing the contact force (CF) during surgery. To improve the safety and success rate of surgery, researchers are committed to developing various methods to evaluate or detect catheter-tissue CF. Among these, some studies integrated optical fibers or magnetic elements into the catheter tip to create CF sensing catheters that monitor CF in real time; other studies used impedance measurement, electrical coupling index, local impedance and other methods to evaluate the CF between the catheter and the tissue by measuring changes in electrical signals. These methods have achieved certain success in clinical practice, offering new ways to improve the effectiveness and safety of cardiac radiofrequency ablation surgery.

Keywords: Catheter, atrial fibrillation, bioimpedance, contact force

Introduction

Atrial fibrillation (AF) is a common cardiac arrhythmia typically caused by irregular electrical signals generated by the two upper chambers of the heart, causing erratic atrial contractions. This abnormal atrial activity affects the pumping function of heart, and patients may experience symptoms including palpitations, shortness of breath, chest pain, fatigue, dizziness, and other symptoms. AF not only diminishes quality of life but also heightens the risk of severe health problems, including stroke, heart failure, and other arrhythmia diseases. Globally, the incidence of AF is on the rise. Data from the Framingham Heart Study indicate a three-fold increase in the number of AF

patients worldwide over the past 50 years [1]. Research by Miyasaka et al. pointed out that by 2050, the number of patients with AF in the United States could increase to 15.9 million [2]; Krijthe et al. pointed out that by 2060, the number of patients with AF in European Union countries could reach 17.9 million [3]. Asia, the most densely populated region in the world, might experience an even steeper increase, potentially reaching 72 million AF cases by 2050, with around 2.9 million of these patients suffering AF-related strokes [4]. Over time, the probability of AF progressing from initial paroxysmal AF to long-term persistent or permanent AF is as high as 15%, with rates increasing to 27- 36% over ten years of follow-up [5]. Numerous factors contribute to the onset of AF. Age is the

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most important factor affecting AF. The prevalence of AF increases sharply after the age of 65, affecting about 5% of those over 65 [6]. In addition, traditional influencing factors such as diabetes and hypertension also paly roles, with more than one-fifth of AF cases attributed to hypertension and a small proportion to diabetes [7]. Affected by modern life, some mental sub-health states can lead to illness in young people. For example, research by Rosman et al. shows that post-traumatic stress disorder is associated with an increased risk of AF in young people [8]. Some unhealthy lifestyles including alcohol abuse, obesity, smoking, and obstructive sleep apnea also increase the incidence of AF [9].

There are some commonly used methods to treat AF, including medication, cardiac RF ablation, cardiac ablation, electrical cardioversion and pacemaker. Drug therapy is one of the most common treatments for AF. Antiarrhythmic drugs are usually used to maintain a normal heart rate, while anticoagulant drugs help prevent blood clots and reduce the risk of stroke. Compared with other treatments, drug therapy is simpler and carries lower risks, but long-term use of drugs may lead to some drug resistance and side effects. Defibrillation is a medical procedure in which doctors use an electric shock to reset the heart's electrical signals, restoring a normal heart rhythm. While effective in quickly normalizing heart rate, this treatment is not a cure for AF and carries certain risks, especially for patients with other health issues. For patients requiring long-term heart rate control, a cardiac pacemaker is recommended. This small device, implanted in the chest, primarily adjusts heart rate by sending electrical signals to the heart, effectively alleviating symptoms of AF. However, it does not cure the underlying condition. Cardiac ablation is a procedure that involves destroying or removing heart tissue causing AF, aiming to restore a normal heart rhythm. This method has the potential to completely cure AF, but relatively high-risk due to the open-chest surgical approach, which also extends recovery time. RF catheter ablation, including procedures like AF ablation and catheter ablation, is a minimally invasive surgery that utilizes catheters and RF energy to destroy abnormal tissue in the heart atrium that generates irregular electrical signals. This approach is suitable for patients with inadequate responses or adverse reactions to medication. Compared to drug therapy, this treatment method offers a more enduring effect, potentially reduce dependence on medication, and may also lower the stroke risk when combined with anticoagulant therapy. Compared to open-chest surgical procedures like cardiac ablation, RF catheter ablation has a more precise treatment target and involves lower surgical risks. Studies have shown that ablation, as a first-line treatment for AF, can significantly reduce arrhythmia recurrence, improve arrhythmia-related symptoms and improve patients' quality of life, and reduce the incidence of adverse reactions [10].

The incidence of AF is on the rise worldwide, underscoring the important to improve both the effectiveness and safety of AF surgery. AF ablation, a procedure that uses radiofrequency (RF) energy delivered via a catheter to treat affected areas of the heart, relies heavily on the adhesion between the catheter and heart tissue. This article focuses on the relationship between catheter-tissue adhesion and AF ablation, the impact of catheter adhesion on AF ablation outcomes, and the current characterization of catheter-tissue contact. Research indicates that contact force (CF) is the most intuitive factor characterizing the degree of adhesion, as appropriate CF can significantly improve the effectiveness and safety of treatment. The study of catheter-tissue contact methods can be categorized into four main approaches: CF sensing catheter, electrical coupling index (ECI), electrode-tissue interface impedance (IR) and local impedance (LI).

The relationship between catheter adhesion and AF ablation

Cardiac RF ablation is a minimally invasive medical procedure performed using a thin, long, and unidirectional / bidirectional flexible catheter with one or more electrodes at its tip to record signals and deliver energy to tissue. The catheter is inserted through a small incision in the patient's groin and navigated through the femoral vein to the heart, where the tip is positioned against the target tissue. By releasing RF energy, the procedure aims to destroy the tissue responsible for generating abnormal electrical signals [11, 12]. While cardiac RF ablation offers many advantages compared with traditional thoracotomy and drug treatment, it also presents unique challenges. This remote-controlled surgical operation mode makes it impossible for clinicians to perceive the real force between the treatment instrument and the tissue [13]. This loss of tactile and kinesthetic feedback imposes certain limitations: 1. Doctors may find it challenging to accurately locate certain structures or evaluate certain characteristics of tissues due to the inability to palpate [14]; 2. It is hard to properly

control of the applied force. Excessive force may increase trauma or damage to surrounding healthy tissues, while insufficient force may compromise the effectiveness of the treatment [13]. Therefore, CF is crucial during cardiac RF ablation.

To improve the safety and success rate of surgery, many scholars have analyzed and optimized cardiac RF ablation based on clinical treatment and the results of some in vitro experiments. Yokoyama et al. conducted experiments using canine thigh muscles, and confirmed that CF is the main determinant of the effect of RF treatment [15]. With a fixed RF power output, increasing the CF increases leads to significantly higher tissue temperature and more thermal damage range, as well as a higher probability of thrombus formation and steam burst. Under the condition of 40 g CF and 30 W RF output, the thermal damage depth was greater than that at 10 g CF with 50 W RF output. Reddy et al. followed 34 patients with AF for 12 months and confirmed that the CF between the catheter and tissue affected the treatment results of RF ablation: lower catheter-tissue CF can lead to a higher AF recurrence rate [16]. When the average CF during ablation was <10 g, the AF recurrence rate was 100%. This rate reduced to 47% when the average CF was between 10-20 g, and further reduced to 20% when the average CF exceeded 20 g. Shurrab et al. followed 1,428 adult patients for 10-53 weeks, comparing those who used CF sensing catheters (n=552) with those who used conventional catheters during surgery [17]. The findings indicated that patients undergoing surgery using CF sensing catheters generally have lower recurrence rates and shorter operative time. These catheters also reduce the need for excessive reliance on fluoroscopy during the procedure [17].

Moreover, the study suggested that the optimal CF for cardiac RF ablation is approximately 17±5 g, which balances the risks of recurrence and complications such as cardiac tamponade or effusion requiring intervention [17]. Nakagawa et al. proposed that during the treatment process, the RF output power can be controlled according to the CF between the catheter tip and the tissue to prevent steam bursts and impedance rises that affect the effectiveness of the treatment [18]. In their study, 18 patients with symptomatic refractory paroxysmal AF were treated with AF ablation using CF-controlled RF output power. Settings were adjusted based on CF: 35-45 W for <10 g, 25-34 W for 11-30 g, 15-24 W for 31-50 g, and 5-14 W for >50 g. A transthoracic echocardiogram was performed on the second day after surgery to

rule out pericardial effusion and other complications. As a result, no complications such as pericardial effusion, cardiac tamponade, or stroke were observed, except one case developed atrial tachycardia. There were no steam bursts, rising impedance, or electrode eschar during the treatment.

In summary, CF is a crucial indicator of the degree of catheter-tissue contact during cardiac RF ablation, directly impacting the procedure's effectiveness and safety. Conditions such as steam explosion, impedance rise, and electrode eschar that affect RF energy output will gradually increase as the CF increases. Appropriate CF can reduce the recurrence rate of AF and greatly improve the results of cardiac RF ablation. Therefore, ongoing research is focused on refining methods to characterize the catheter-tissue contact to further improve treatment results.

Related studies characterizing catheter-tissue contact

CF sensing catheter

CF measurement has a positive impact on operation time and postoperative recurrence rate, which has made CF sensing irrigation catheters widely used clinically in recent years [19]. Current electrodes for AF ablation catheters include monopolar catheters (usually 3.5-4.0 mm), with or without a CF catheter; and multipolar catheters designed to encircle the pulmonary veins to deliver RF energy to targeted tissue areas [20]. Operating these catheters is highly challenging, typically requiring the operator to control the catheter end effector on the proximal handle by pushing, pulling, rotating, and bending [21]. In view of the difficulty in performing catheterization procedures, there have been many studies on integrating tactile sensors to the catheter tip. CF sensors in catheters are mainly divided into optical fiber CF sensors and magnetic CF sensors [22].

Common designs for fiber optic CF sensors in catheters include intensity-modulated sensors (sensing the CF by measuring changes in the intensity of the optical signal), phase-modulated sensors via Fabry-Perot interferometry (the CF information is inferred by measuring changes in the phase of the optical signal), and a wavelength-modulated sensor with a fiber Bragg grating (a fiber Bragg grating is a periodic structure that senses CF by modulating the wavelength of light. When the abutment force changes, the periodic structure of the grating undergoes slight deformation, resulting in a

Catheter name	Brand	Sensor type	Catheter outer diameter	Force mea- suring range	Deviation	Electrode de- scription	Additional features
Tacticath™ Quartz	Abbott	Optical fiber 8F		Unknown	$<$ 3 g	Unknown	Unknown
AcOBlate®Force	Acutus Medical	Optical fiber 8F		$0 - 60g$	$<$ 3 g	Gold electrode	Rinse and cool
ThermoCool Smart- Johnson&- Touch®	Johnson	Electromag- netic	8F	$0 - 60g$	Unknown	Six electrodes	Embedded temperature sensor
Intellanav Sta- blepoint™	Boston Scientific	Electromag- netic	7.5F	Unknown	5g	Four electrodes	Local imped- ance combined with CF
ThermoCool Smart- Johnson&- Touch [®] SF	Johnson	Electromag- netic	8F	$0-70g$	$<$ 3 g	Six electrodes	Rinse and cool

Table 1. Comparison of five types of catheters

Note: CF, contact force; SF, surround flow.

change in wavelength, thereby enabling the measurement of the abutment force). These designs enable precise sensing of both axial and lateral forces at the catheter tip [23]. Magnetic CF sensing catheters are usually equipped with magnetic materials such as magnets or magnetic alloys at the tip. These magnetic elements generate an electric field, while magnetic field sensor located at the proximal end of the catheter detects changes in the magnetic field generated by the catheter tip. When the tip contacts tissue, the magnetic field changes, allowing the system to calculate the CF between the catheter and the tissue, thereby enabling real-time monitoring of the CF between the catheter tip and the tissue.

Tacticath™ Quartz (Abbott, Abbott Park, IL, USA) and AcQBlate® Force (Biotronik, Berlin, Germany), which are frequently used clinically, are optical fiber CF sensing catheters. Tacticath[™] Quartz uses the Fabry-Perot interferometry method to measure how a flexible titanium alloy structure deforms upon contact with tissue, from which both the magnitude and direction of the CF can be deduced [22, 24]. The AcQBlate® Force uses a fiber Bragg grating wavelength-modulated sensor that changes its length at the corresponding portion of the fiber when the catheter tip contacts tissue [24]. Magnetic CF sensing catheters include ThermoCool SmartTouch® (Biosense Webster, Diamond Bar, CA, USA), Intellanav Stablepoint™ (Boston Scientific, Marlborough, MA, USA), and Smarttouch® SF (Johnson&Johnson, New Brunswick, NJ, USA). The ThermoCool SmartTouch® is a saline flush catheter with a magnet signal transmitter at the distal end of the spring and three magnetic position sensors near the spring that measure the micro-deflection of the spring to calculate the force magnitude and angle on the tip electrode. The tip of Stablepoint[™] is equipped with a precision-machined spring with

three inductive sensors made of ferromagnetic cores and coils near the catheter tip. Contact with tissue causes the coils to move inwards, and the axial and transverse forces acting on the tip can be calculated from Hooke's law. The tip of Smarttouch® SF is equipped with a machined precision spring with three magnetic sensors distributed in relatively close parts of the catheter. The sensors detect changes in signal received by the sensor coil when the catheter tip encounters force, enabling calculation of the force and direction based on Hooke's law [24-26]. CF-sensing catheters have been used in clinical procedures, which can provide real-time feedback of the force exerted between the catheter tip and the myocardium, improving the effectiveness and safety of complex ablation procedures [26]. See Table 1 for details.

The CF between the catheter tip and tissue is crucial to ablation surgery. In addition to CF sensing catheters, researchers are also working on other characterization methods. Some researchers have proposed that impedance changes can be monitored to estimate the physical contact between the catheter tip and the tissue, as well as the effect of RF ablation [27, 28]. Real-time changes in impedance during ablation are a direct physical consequence of actual lesion formation, and therefore, impedance serves as the only commercially available and clinically accessible indicator that directly reflects real-time biophysical status of the tissue during ablation [29].

The method of ECI

The method of assessing electrode-tissue contact by measuring the LI between the catheter tip and the tissue using a three-terminal circuit model was pioneered by Yokoyama et al., which has been tested in animal studies and demonstrates the feasibility of evaluating the

Figure 1. ECI three-terminal impedance measurement circuit model. ECI, electrical coupling index.

degree of contact using LI measurements [15]. Based on this research, Piorkowski et al. employed the EnSite Contact™ system to measure the complex impedance between the catheter tip and the tissue [30]. They mathematically combined the real and imaginary parts of the collected impedance to obtain the ECI. Figure 1 shows the three-terminal circuit model used by ECI. In a clinical application involving 12 patients undergoing RF ablation for AF, various parameters such as electrocardiogram amplitude, pacing threshold, and the impedance at the catheter-tissue interface were concurrently measured [30]. When the catheter touched the tissue, the ECI changed significantly, from $(118±15)$ to $(145±24)$. The average ECI difference between contact and non-contact sites was (32.7±11.6) ECI units, and the ECI of vascular tissue was significantly higher than that of trabecular tissue and smooth myocardium. This study not only confirmed the practicality of measuring catheter LI at the catheter-tip tissue interface during AF ablation, but also explored the impact of patch location, operator, body mass index (BMI), and type of AF on the ECI calculation results [30].

An N-way analysis of variance showed that these factors had no significant impact on ECI. The research by Deno et al. indicated that the ECI could convey information about the effective delivery of RF ablation energy to the tissue, serving as a useful indicator for monitoring the RF catheter ablation process for AF [31]. In their study, the researchers derived a fitting formula for ECI based on pig experiments. They compared ECI with clinical judgments, pacing thresholds, electrogram amplitudes, ablation lesion depth, and transmural effects, affirming the specificity of catheter-tissue impedance and ECI for assessing tip electrode-tissue contact or coupling. Three-terminal impedance

and ECI measurements were taken at non-contact locations during the experiment. The average impedance change was less than 10 Ω over an interval of (6.3±2.2) hours, and the average ECI change was only (5.8±5.6)%. This suggests that ECI measurements are stable over long-term use. Linear regression analysis of the real and imaginary parts of impedance in the experimental data compared to pacing and electrophysiology system yielded an impedance weight of 5.1 times resistance. The relationship between ECI, force,

and catheter position (distance and angle) was validated in isolated bovine myocardium. Impedance and ECI were found to be insensitive to the surface and above distances until the electrode tip was approximately 2 mm from the impedance. In the range of 0-20 g, ECI changes were nearly proportional to the applied force and depth (an increase of 1.5 ECI units per gram of force). The results indicate that the catheter-tissue contact angle has no significant impact on ECI outcomes.

The method of IR

ECI is determined by applying a small high-frequency current between the catheter electrode and the first skin patch, while simultaneously measuring the voltage difference between this electrode and another skin patch. This process calculates the impedance, both resistance and reactance, of the electrode-tissue contact, ultimately determining the ECI value. While ECI provides reliable measurements within the left atrium, it can erroneously indicate good contact even when the electrode is floating within the pulmonary veins, likely influenced by the nearby high-impedance lung tissue. Therefore, Van et al. proposed an improved method for measuring the IR, as depicted in Figure 2 [32]. Unlike ECI, the IR method is suitable for multi-electrode catheters. It involves applying current between the target electrode and adjacent electrodes, simultaneously measuring the voltage between the target electrode and the skin patch to calculate impedance. This method concentrates the driving current in a small area around the target electrode, effectively avoiding the influence of distant tissues on ECI measurements. Researchers compared the IR method with ECI alongside CF sensing catheters in both in vivo and in vitro pig experiments. In vitro experiments used PVC pipes

Figure 2. Comparison diagram of IR and ECI. (A) A schematic diagram of the principle of the IR method. It is necessary to apply a current between the target electrode and the adjacent electrode, to measure the voltage between the target electrode and the skin patch electrode; (B) A schematic diagram of the principle of the ECI method. It is necessary to apply a current between the target electrode and the skin patch electrode, to measure the voltage between the target electrode and another skin patch electrode. IR, electrode-tissue interface impedance; ECI, electrical coupling index.

Figure 3. Schematic diagram of local electric field under the action of floating and contact with LI method. (A) A schematic diagram of the electromagnetic field when the electrode is suspended; (B) A schematic diagram of the electromagnetic field when the electrode is in contact with tissue. LI, local impedance.

to simulate high impedance at the distal end. When the catheter was placed inside the pipe, ECI and IR measurements increased by 32.2% and 3.2%, respectively. IR demonstrated a significantly lower sensitivity to distal impedance compared to ECI. In the in vitro experiments, ECI and IR were measured 237 and 288 times, respectively, along with synchronous impedance readings and CF sensor readings. The correlation coefficient (R2) for the fitted power was 0.84, indicating a clear relationship between impedance and force for both measurement methods. The results from in vitro experiments were further validated in in vivo experiments. A total of 373 CF and IR measurements were taken during in vivo experiments, showing a significant correlation (P=0.64) between CF and impedance increases. When the electrode moved in vivo from the inferior vena cava to the right atrium, the ECI value increased by 20%. However, the IR value remained stable when the catheter shifted between the right atrium, inferior vena cava, or superior vena cava. These data suggest that the IR method is convenient for assessing the contact level between circular multi-pole ablation catheters and tissue interfaces, and it is less susceptible to the influence of high-impedance tissues at a distance.

The method of LI

To address the susceptibility of impedance measurements to distant structures such as muscles, lungs, and bones, Sulkin et al. proposed the LI method, which eliminates the need for skin surface patch electrodes [32-34]. This system is applicable to multi-electrode catheters, where the catheter tip is equipped with at least three microelectrodes. The LI method employs a four-electrode impedance measurement technique. A small current (5.0 μA, 14.5 KHz) is applied between the tip electrode and the proximal electrode to generate a local electric field. The microelectrodes and the distal electrode can measure the potential difference generated by nearby heart tissue or high-resistance myocardial tissue contact. The impedance is then calculated by dividing the voltage by the applied current. The schematic diagram in Figure 3 illustrates the local electric field formed by the small current in the LI method during both floating and contact states. This system rigorously tested through in vivo and in vitro experiments. The results demonstrated that the LI method can effectively distinguish healthy myocardium from blood. Importantly,

the measurements provided by LI method are independent of catheter orientation and tissue thickness. The LI method showed high sensitivity to tissues with different resistivities, allowing for a clear differentiation between contact and non-contact states between the catheter and tissue.

Conclusion

Catheter ablation presents significant advantages in treating AF; however, challenges persist during the surgical process, particularly in accurately assessing the degree of contact between the catheter tip and the tissue. This paper views various assessment of catheter tip-tissue contact in AF ablation and introduces existing methods for evaluating contact.

The assessment of contact between the catheter and tissue is crucial in ablation surgery. Appropriate CF can significantly enhance the effectiveness of treatment and reduce recurrence rates. Conversely, excessive CF may increase the risk of thrombus formation and steam pops, while insufficient CF can lead to a higher recurrence rate of AF. This paper primarily delves into the in-depth study of evaluation methods, including CF-sensing catheters and LI, used in current research.

In clinical AF ablation surgeries, operators manipulate the catheter using techniques such as pushing, pulling, rotating, and bending. To improve surgical precision and ease the procedure for physicians, CF sensors are placed at the catheter tip to monitor real-time CF between the catheter and tissue. The sensors employed in CF-sensing catheters, including fiber optic sensors and magnetic CF sensors, such as Tacticath™ Quartz, AcQBlate® Force, and ThermoCool SmartTouch®, are widely used in clinical treatments.

Additionally, three-terminal circuits were utilized to collect LI between the catheter tip and tissue for evaluating CF. The ECI method mentioned in this paper uses a configuration with one treatment electrode and two skin patch electrodes to calculate impedance. The IR method, developed to address the impact of high impedance in pulmonary vein tissue on ECI measurements, uses a configuration with two treatment electrodes and one skin patch electrode to calculate impedance. Some researchers found that, apart from pulmonary vein tissue, other high-impedance tissues in the body, such as bones and lungs, could potentially affect contact assessment. To address this issue, researchers proposed using a configuration with

three intracardiac treatment electrodes to calculate impedance in the LI method.

In summary, various methods for assessing catheter-tissue contact can assist catheter operators in performing AF ablation procedures more easily and accurately. Future research and technological developments will further improve the accuracy of evaluations, allowing these methods to gain broader applications in clinical practice.

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