Ablating with Irrigated RF Safely and Effectively Using Microwave Radiometry Sensing Technology

Objectives: A novel technology for radiofrequency catheter ablation (RFCA) has been designed to maximize the effectiveness and accuracy of ablation therapy. The irrigated Tempasure™ temperature-sensing catheter has a chip based instrumented tip which measures and interprets microwaves emitted from heated tissue during RFCA in order to measure temperature at depth in the tissue treated. **Background**: RFCA is the standard of care in the treatment of patients with arrhythmias. Ablation systems allow for temperature-controlled energy delivery and rapidly curtail energy delivery for an impedance rise. Irrigated saline-cooling of the distal electrode helps minimize impedance rises but interferes with the ability of the thermistor at the tip of the electrode to record temperature at the tissue level. Innovative catheters based on microwave radiometry measurements are not affected by saline-cooling and are able to accurately evaluate tissue temperature and ablation lesion volume during irrigated RF ablation.

Summary: Microwave radiometry technology allows the electrophysiologist real-time feedback on catheter-tissue contact, and temperature at 3 mm depth in tissue. Providing complete control of the lesion formation with an irrigated ablation catheter enables the operator to confidently plan and control the lesions — the definitive key to performing safer, more effective procedures.

Introduction

Cardiac ablation treats various arrhythmias including atrial fibrillation (AF), a condition that currently affects more than two million patients in the United States alone, with 500,000 new cases annually. The numbers in Western Europe are similar. It is anticipated that over 200,000 ablation procedures will be performed in 2010 worldwide, with the number expected to rise to over 350,000 in less then five years.

As a widely recognized and useful form of treatment for patients with arrhythmias that are refractory to medical and ICD treatment, RFCA (radiofrequency cardiac ablation) is becoming increasingly more popular in this chronic population and is used earlier in the treatment of these patients. Catheters were first used for intracardiac recording and stimulation in the late 1960s, but surgical treatment for refractory tachyarrhythmia was the mainstay of nonpharmacologic therapy until it was superseded by catheter ablation. The initial energy source used was direct current (DC) from a standard external defibrillator. A shock was delivered between the distal catheter electrode and a cutaneous surface electrode; however, this high-voltage discharge was difficult to control and could cause extensive tissue damage.

Radiofrequency (RF) energy, a low-voltage, high-frequency form of electrical energy familiar to physicians from its use in surgery (eg, electrocautery) quickly supplanted DC ablation. The relative safety of this energy source contributed to the widespread adoption of catheter ablation as a therapeutic modality. Current standard of care for catheter based procedures can be illustrated by one of two methods. An electrophysiologist (EP), who specializes in the treatment of atrial fibrillation and arrhythmias, uses catheters and an energy source to create lesions in the tissue causing the arrhythmia. A linear approach uses balloon catheters to ablate large areas of tissue while a point-to-point treatment (a more recent development) is a more precise delivery of energy to specific locations in the heart.

Challenges in RFCA

RF energy produces small areas of cardiac tissue destruction by heating tissue. RFCA lesions are typically about 5-7 mm in diameter and 0-5 mm in depth. The mechanism by which RF energy current is able to heat tissue is ohmic (resistive). This form of heating is dependent on current density, which decreases rapidly with distance from the ablating electrode. The amount of conventional RF energy delivery is limited by a critical impedance rise at the electrode/tissue interface due to coagulation of blood or carbonization depending on electrode temperature. Therefore, the creation of deep and homogenous lesions is often impossible with conventional RF. For the creation of transmural lesions, the delivery of high energy to the endomyocardial tissues is needed.

The temperature at the electrode-tissue interface must be approximately 55°C or higher to cause tissue necrosis. As the temperature approaches the boiling point of 100°C, the delivery of current is impeded by coagulum (eg, denatured proteins) on the tip of the catheter. This coagulum may predispose the patient to thromboembolic complications.

Ablation systems allow for temperature-controlled energy delivery and rapidly curtail energy delivery for an impedance rise. The electrode temperature can be influenced by the amount of continuous RF energy delivered and by cooling the electrode. Saline-cooling of the distal electrode helps minimize impedance rises but interferes with the ability of the thermocouple/thermistor at the tip of the electrode to record temperature at the tissue level. Overheating can produce myocardial perforations or damage to unintended tissue such as the esophagus or atrium.

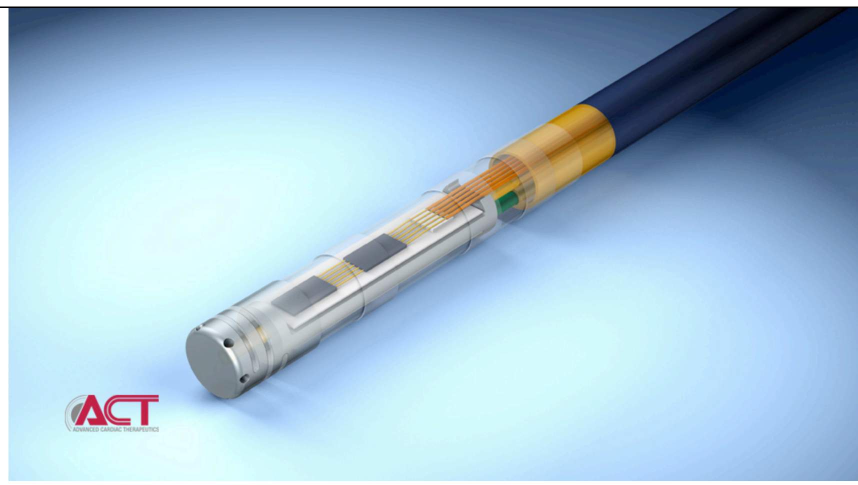
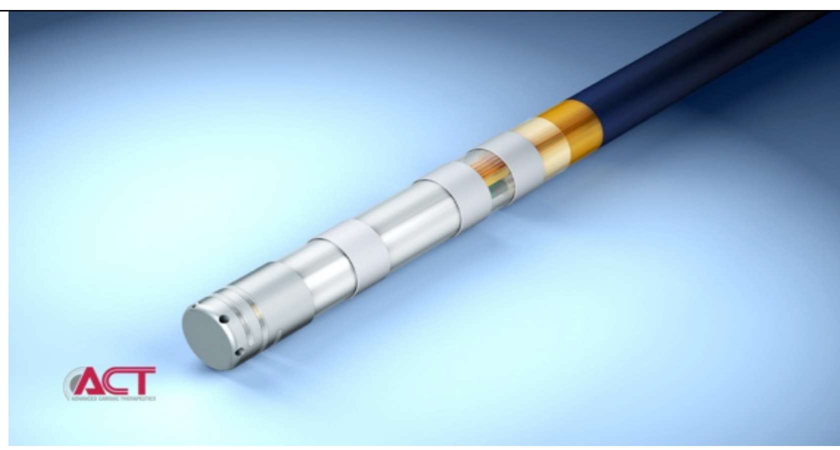
This article describes an innovative technology that has been developed to overcome limitations of current irrigated RFCA catheters. Tempasure™ a new temperature sensing catheter based on microwave radiometry can measure temperature at depth in the tissue away from the electrode tip. The irrigated temperature-sensing catheter has an instrumented tip which measures and interprets microwaves emitted from heated tissue during RFCA.

Microwave radiometry to optimize RFCA

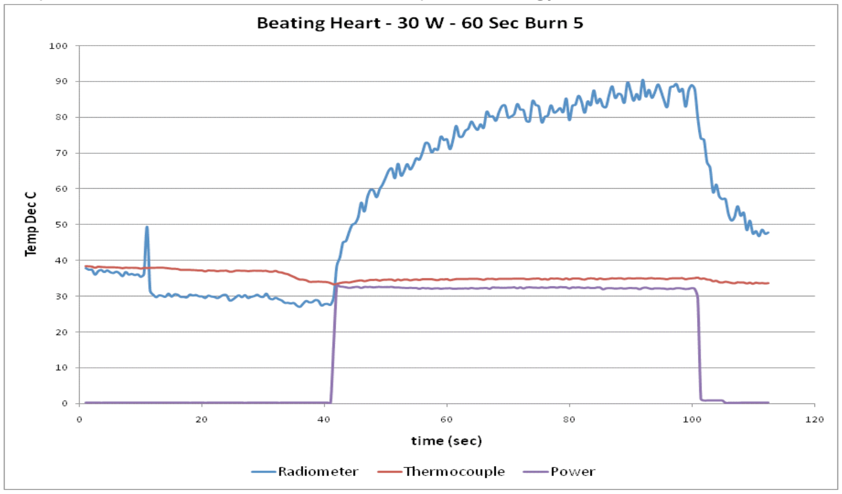
Microwave radiometry is defined as the technique for measuring electromagnetic energy considered as thermal radiation. Developed as a technology by Dr. Kenneth Carr and his colleagues during the Cold War for measuring the thermal activity of the earth from space, microwave radiometry can now be used to detect and measure microwave energy emanating from heat sources.

This novel technology consists of a steerable catheter connected to an electrode RF cap tip which contains a microwave chip set that measures the microwave energy generated by heated tissue and converts that energy value into a temperature measurement value. The system is three components, a catheter, an interface box and a cable. The catheter is a temperature sensing ablation catheter which ablates with irrigated RF (radiofrequency) energy and provides microwave radiometry feedback. This catheter is used with a standard RF generator and is similar to other irrigated EP catheters in terms of technology specifications and performance safety profile. The ICT (integrated catheter tip) contains circuitry for measuring the temperature at depth of the ablated tissue using microwave radiometry and hooks up to an auxiliary device through a cable in order to display this temperature at depth to the user. The innovative aspect of the catheter technology is that it provides the cardiologist with real-time feedback on catheter-tissue contact, temperature at 3 mm depth, and volume of ablated lesion, thus affording complete control of the lesion formation with an irrigated ablation catheter.

The microwave radiometry sensing technology is a passive “listening” system that is fully contained in the “integrated catheter tip” (ICT). Therefore, it is easily compatible with all cardiac ablation technologies and devices on the market today with no changes to catheter or handle design or function.

The ICT is shown here including the irrigated EP ablation tip and microwave radiometry chipset.	
The final tip configuration of the catheter which includes the ICT.	

The diagram below shows feedback from delivery of an ablation lesion. Prior to ablating, there is a mild drop in temperature sensed by Tempasure™ due to the effect of irrigant flow cooling the heart wall. This drop in temperature is only seen when the catheter has good contact with the heartwall and is hence a good contact sensor. When RF is applied the radiometer feedback shows a temperature rise not sensed with thermocouple technology.



System Advantages

By using the at-depth temperature measurement capability of this system, the EP can overcome the three most critical issues of AF ablation procedures.

1. Safety

The system allows the physician to avoid overheating, thus preventing myocardial perforations or damage to unintended tissue such as the esophagus or atrium.

2. Effectiveness for lesion creation

With real-time feedback, physicians using the system will know that the catheter tip has good contact; that energy is properly delivered; that the tissue is truly heated for the required time; and that the size of the created lesion in relation to the location of the heart is correct. This system is designed to impact the long term therapeutic success rate.

3. Duration of procedure

Real-time feedback for catheter-tissue contact, energy delivery and effective lesion creation is designed to minimize time wasted on non-contact or poor-contact lesions and reduce the need for repeat ablation delivery and repeat procedures.

Conclusion:

Enhanced lesion control through Microwave Radiometry technology is designed to increase safety, reduce in-procedure time to achieve complete block, and ultimately achieve greater long term and effective therapeutic success.