CLINICAL IMPLICATIONS

electrodes with bipolar energy is beneficial, as it creates a contiguous lesion in the myocardium, rather than a collection of point lesions that is created with a traditional unipolar RF ablation catheter. Similarly, the ability to simultaneously create lesions from multiple electrodes reduces the number of catheter manipulations required and leads to procedure times that are reported to be comparatively short (84-201 minutes).[7]

Unipolar RF energy has been successfully delivered through focal tip catheters to treat cardiac arrhythmias for decades. However, the complexity of the atrial fibrillation ablation procedure using a traditional focal tip ablation catheter necessitates innovation in catheter design and energy delivery methods. Using multi-electrode catheters to deliver phased duty-cycled energy is a major advance in technology that allows for tailored and efficient lesion creation.

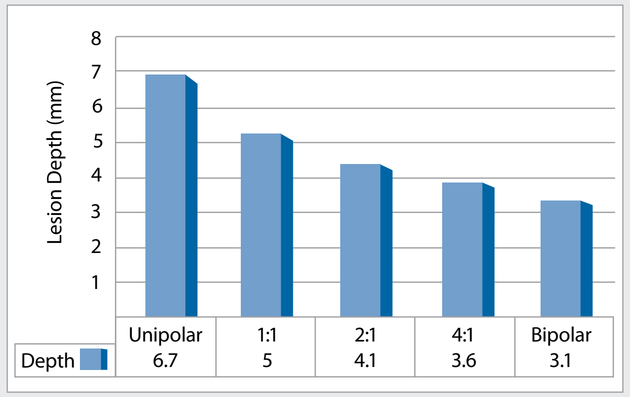

Figure 5. Wijffels, et al. Lesion depth is greater when more unipolar energy is applied.[8]

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Medtronic

Duty-Cycled, Phased Radiofrequency Ablation

Use of Bipolar and Unipolar Energy Delivery to Control Lesion Depth

Technical Bulletin No. 3

INTRODUCTION

Since the first reported case of percutaneous cardiac catheter ablation, clinicians and scientists have attempted to mitigate the complications that accompany the technique. The genesis of catheter ablation was when Scheinman reported using direct current energy applied through the tip of a pacing catheter electrode to a skin electrode to destroy cardiac tissue.[1] Although the focally arrhythmic myocardium was destroyed, the damage to the atrio-ventricular conduction system rendered the patient pacemaker dependent. Huang eventually described using a radiofrequency (RF) generator to deliver electrical energy at 750 kHz frequency in a unipolar manner through percutaneous catheters.[2] This method resulted in well-delineated coagulation necrosis at the target ablation sites. With little modification to the initial system, unipolar RF energy has been used over the years to successfully treat thousands of focal and reentrant tachycardia patients with acceptable complication rates.

Originally, catheter ablation of atrial fibrillation was directed at the AV node in order to control ventricular response. After Haïssaguerre demonstrated that AF is initiated by focal triggers highly concentrated in the pulmonary veins,[3] ablation techniques targeted these triggers. Difficulty in identifying PV triggers led to the technique of electrically isolating the veins from the left atrium using unipolar RF ablation catheters.[4]

However, the extensive lesion set required and the proximity to sensitive anatomical structures has led to complication rates of 3-6% being reported. Solutions have been sought that more efficiently delivered ablative energy to isolate the pulmonary veins.

Catheter ablation of atrial fibrillation using a number of alternatives to unipolar RF energy has been explored. High-frequency ultrasound, microwave, laser, and cryothermic energy have been delivered percutaneously to isolate pulmonary veins. Each ablative energy source has its advantages and disadvantages, striking a delicate balance between efficient lesion creations and causing damage to adjacent structures. Duty-cycled, phased RF is a method of ablating myocardium by using RF energy in such a way that it mitigates potential damage caused by unipolar ablation systems.

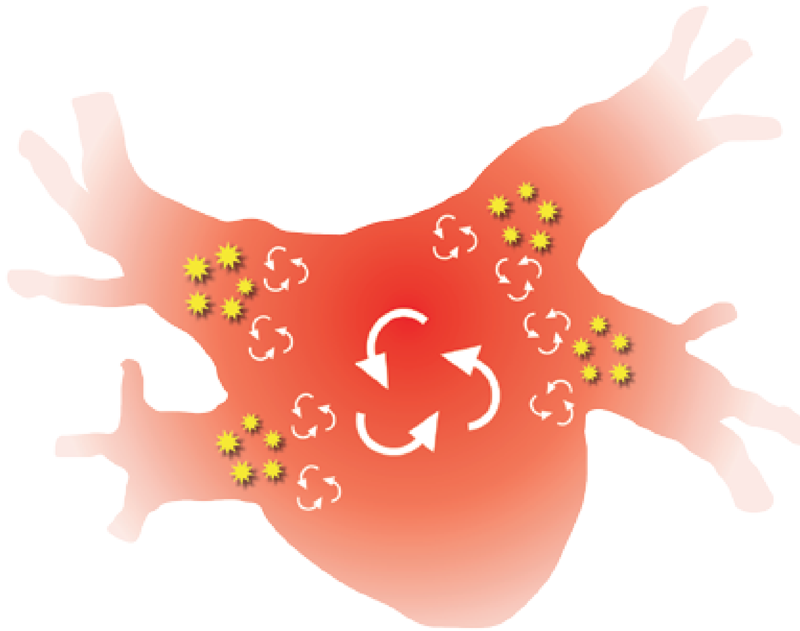

Figure 1. Starbursts represent the location of triggers in the pulmonary veins. The large and small reentrant wavelets represent initiating and sustaining AF in the atrial body.

TECHNICAL INSIGHT

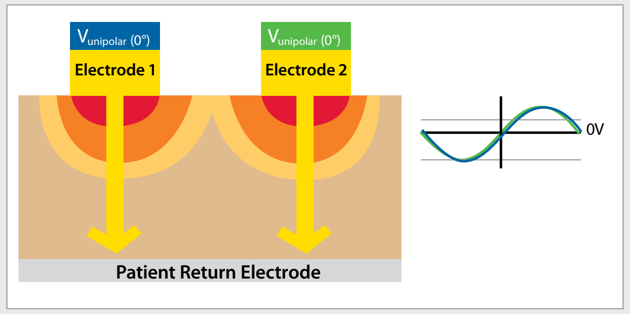

Figure 2a. Schematic demonstrating unipolar energy delivery.
Unipolar circuit/path: potential difference (Vp-0V) = Vp
Bipolar circuit/path: no potential difference (Vp- Vp) = 0

Conventional RF ablation catheters are only capable of delivering RF energy from the ablation electrode to a patient return electrode. This type of RF energy delivery is called unipolar because there is only one ablation electrode involved in the ablation circuit. On the other hand, bipolar energy delivery is RF energy delivered between a pair of ablation electrodes.

Duty-Cycling

The GENius® Multi-Channel RF Ablation Generator delivers power in a fashion known as duty-cycling. In addition to enhancing electrode cooling and allowing optimal power delivery, duty-cycling allows each electrode to be controlled separately and independently from its neighbors.

Temperature-controlled systems modulate power output to achieve a defined target temperature. However, in a multielectrode system, modulating the power output by varying the voltage amplitude of each electrode may create unintended potential differences to neighboring electrodes, leading to power dissipation. By implementing duty cycles and modulating power output to each electrode by varying the length of the 'on' portion of the cycles, power output can vary from electrode to electrode without causing unexpected leakage current.

Phasing

The GENius RF generator is capable of delivering RF power to up to 12 ablation electrodes simultaneously. RF power is delivered in unipolar, bipolar, or combination modes (1:1, 2:1, 4:1 ratio of bipolar to unipolar power). The RF generator's ability to deliver both unipolar and bipolar power concurrently comes from a feature called phasing. The phase of the alternating current that is delivered to each electrode determines the ratio of bipolar to unipolar power.

In the unipolar mode, there is no phase shift between electrodes in a pair; therefore power dissipation occurs only between the ablation electrode and the patient return electrode (see Figure 2a).

In a combination mode, there is a phase shift between electrodes in a pair causing a potential difference. As a result, power dissipation occurs between electrodes as well as between each ablation electrode and the patient return electrode (see Figure 2b).

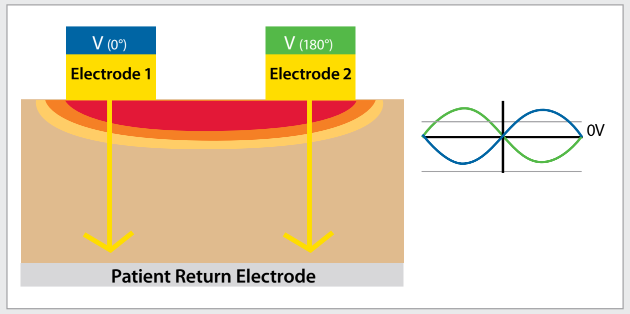

Figure 2b. Schematic demonstrating simultaneous unipolar and bipolar energy delivery.
Unipolar circuit/path: potential difference (Vp-0V) = Vp
Bipolar circuit/path: potential difference (Vp-(-Vp)) = 2Vp

The independent control of power delivery to each electrode results in the ability to respond to local contact, flow, and tissue heating. Though power delivery will vary at each electrode according to its environment, a uniform temperature distribution is created, which results in a uniform lesion.

A 180° phase shift between the electrodes produces a combination field which generates 4:1 ratio. Using the combination fields together with the unipolar fields produce various ratios of 4:1, 2:1, and 1:1 (Figure 3a, 3b, and 3c).

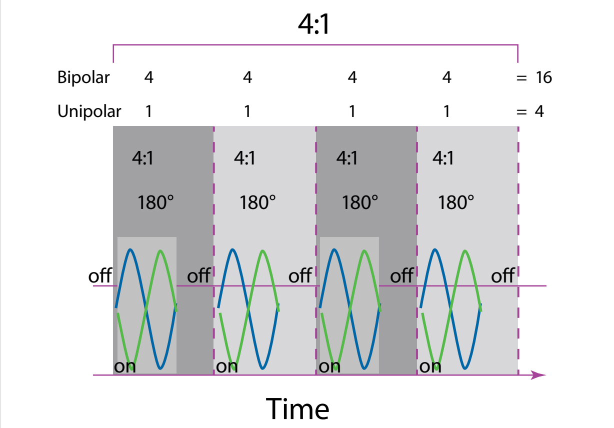

Figure 3a. Chart demonstrating phase shift between electrodes providing unipolar:bipolar ratio of 4:1.

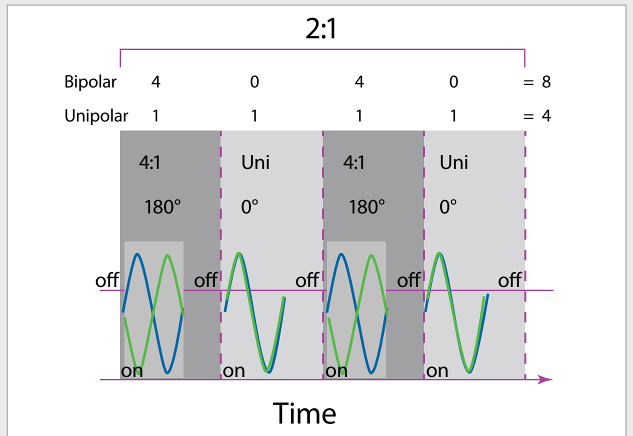

Figure 3b. Chart demonstrating phase shift between the electrodes providing unipolar:bipolar ratio of 2:1.

TECHNICAL INSIGHT

The mixture and direction of power dissipation as determined by energy mode has a strong correlation to lesion depth. A wide range of lesion depths can be generated under identical conditions by varying energy mode; deeper lesions are created with energy modes that contain a higher ratio of unipolar energy. The ability to create shallow lesions with higher ratios of bipolar energy should not be trivialized. By redirecting power from the unipolar path to the bipolar path, lesion contiguity is maintained, along with a notable reduction in depth. Thus, phasing allows a multi-electrode catheter to create a range of deep or shallow lesions without sacrificing lesion quality.

The result of duty-cycling and phasing is greater control over energy delivery. Phasing allows for control of the bipolar to unipolar ratio which governs lesion depth and maintains lesion contiguity. Duty-cycling allows for control of power output of each electrode separately to react to local conditions, resulting in uniform lesion creation.

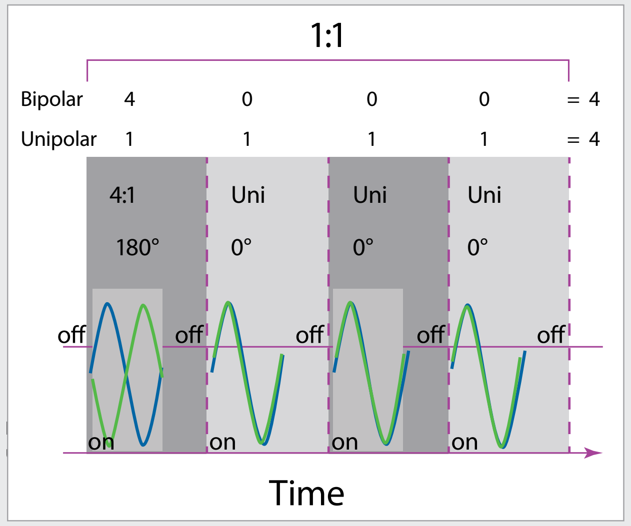

Figure 3c. Chart demonstrating phase shift between the electrodes providing unipolar:bipolar ratio of 1:1.

CLINICAL IMPLICATIONS

The walls of the atrium are composed of one to three or more overlapping layers. The thickest part of the atrium is the anterior wall, which is 3.5-6.5 mm thick in the area of Bachmann's bundle (Figure 4a). The atrial wall behind the aorta is the thinnest, reported to be 1.5-4.8 mm in thickness. Similarly the posterior wall is reported to be very thin (Figure 4b).[5] In thinner anatomies, lesion depth should be reduced to avoid peripheral damage to adjacent structures, such as the esophagus. Current ablation technologies rely on dragging the catheter tip electrode along the atria, reducing power or ablation duration in order to control lesion depth. The challenge in this method is that the catheter design is inherently unstable in the beating heart. Moreover, adjustments to power delivery and/or ablation duration may lead to insufficient lesion formation, which, in turn, may lead to transient electrical propagation, which can result in arrhythmia recurrence and the need for retreatment.

Through phasing and duty-cycling, the GENius RF generator is able to deliver controlled energy delivery to create contiguous, uniform lesions of varying depths (Figure 5). This method is clinically advantageous as it allows for consistent power delivery, regardless of anatomic position of the catheter. By using 4:1 bipolar: unipolar energy in areas of less atrial thickness, it is possible to achieve therapeutic lesions while minimizing the adverse effects of unipolar current density in adjacent structures. Wieczorek, et al.[6] used this system in a series of patients and examined the esophagus with an endoscope to assess damage from the creation of ablation lesions in the left atrium and found normal esophageal mucosa.

Successful ablation of atrial fibrillation requires electrical isolation of the pulmonary veins, and even small gaps can reduce efficacy or lead to the creation of post-ablation tachycardias. The ability to deliver RF energy between the

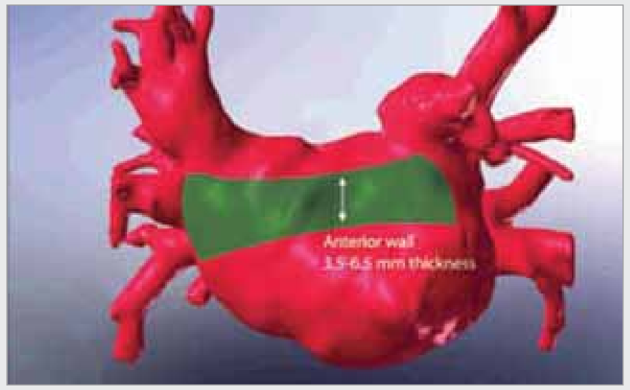

Figure 4a. Anterior projection of left atrium, revealing thickness of anterior wall

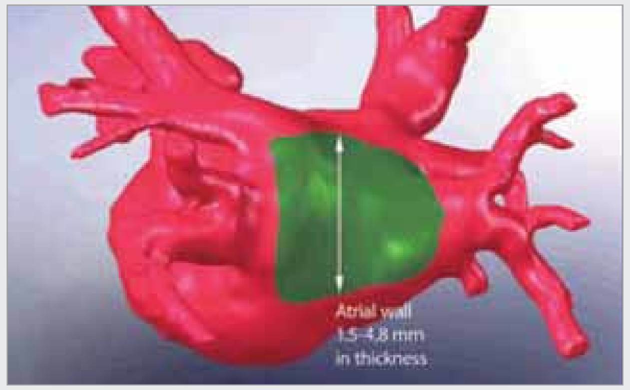

Figure 4b. Posterior projection of left atrium, revealing thickness of atrial wall

(continued on back)