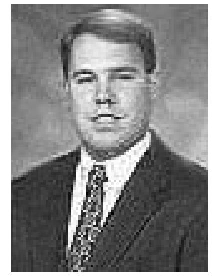


Irrigated Bipolar Radiofrequency Ablation with Transmurality Feedback for the Surgical Cox-Maze Procedure



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ABSTRACT

Background: Nonirrigated radiofrequency ablation (RFA) has been used to replicate the surgical scars of the Cox-Maze procedure. This study aimed to demonstrate that an irrigated, bipolar RFA energy source could also effectively replicate Cox-Maze lesions with impedance monitoring to predict the transmurality of ablated tissue.

Methods: A complete Cox-Maze lesion pattern was created ex vivo on fresh porcine atria using an irrigated, bipolar RFA system. Tissues were clamped between opposing electrodes with steady pressure to ensure an intimate tissue-electrode interface during ablation. A proprietary feedback and control algorithm monitored tissue impedance and terminated ablation when lesions were deemed transmural by a plateau in impedance decline. Ablation time and power, lesion width and length, and tissue thickness were recorded. Lesions were stained with 1% triphenyltetrazolium chloride and sectioned for gross assessment of transmurality.

Results: One hundred thirty-seven lesions were created on 11 porcine hearts. The total ablation time per lesion was 14.8 ± 1.2 seconds (range, 10.0-19.0 seconds). Lesions averaged 4.2 ± 1.3 mm (range, 1.3-10.2 mm) in width. Average tissue thickness was 3.0 ± 1.7 mm (range, 0.5-9.9 mm). Cross-sectional examination revealed that 100% of lesions were transmural (n = 718), and no tissue defects were observed.

Conclusions: These results indicate that irrigated bipolar RFA energy can produce transmural Cox-Maze lesions ex vivo on intact porcine atria and that impedance monitoring is a reliable predictor of lesion transmurality. Additional in vivo studies are under way to further demonstrate the efficacy and safety of irrigated, bipolar RFA technology.

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INTRODUCTION

The Cox-Maze procedure is a surgical technique developed to eliminate atrial fibrillation and reduce the risk of associated morbidity, especially stroke. A successful Cox-Maze procedure partitions the atria with multiple electrically isolating scars that create a preferential path for electrical signals to travel directly to the atrioventricular node while complete, synchronized activation of the atrial myocardium is maintained. Favorable results have been reported in patients who have undergone this procedure [Arcidi 2000, Cox 2000, Schaff 2000]; however, the risks associated with open heart surgery and cardiopulmonary bypass as well as the expense and technical complexity of the procedure have prohibited its widespread application.

There has been much recent interest in simplifying the Cox-Maze procedure by replacing the multiple surgical incisions with linear lesions created by alternative energy sources. Our laboratory has focused on radiofrequency ablation (RFA) techniques to create continuous transmural linear lesions as an alternative to the traditional incision and suture method [Caccitolo 2001]. Early clinical results with RFA devices have been promising [Sie 1997, Thomas 1997]. Unfortunately, most of these RFA devices use unipolar catheters that produce broad lesions without any reliable way to determine lesion transmurality. As a result, partial-thickness ablation can frequently occur [Melo 2000, Thomas 2003]. Operators have resorted to multiple applications and long ablation times for individual lesions to better ensure transmurality, but the high temperatures generated during prolonged RFA energy transfer have produced collateral tissue damage, and there are reports of serious complications with the use of nonirrigated unipolar systems [Gillinov 2001, Sonmez 2003].

Newer instruments are currently being developed that use bipolar RFA to overcome the limitations of unipolar ablation. Bipolar devices deliver energy focused between two apposing electrodes embedded in the jaws of a clamp. Focused energy delivery shortens ablation times, minimizes lesion width, and reduces the potential for adjacent tissue injury. In addition, these devices can be coupled with computer software platforms that monitor tissue impedance at the site of ablation to provide an immediate assessment of lesion transmurality. This study was undertaken to evaluate the effectiveness of irrigated bipolar RFA coupled with a transmurality feedback algorithm in creating a complete set of Cox-Maze lesions ex vivo.

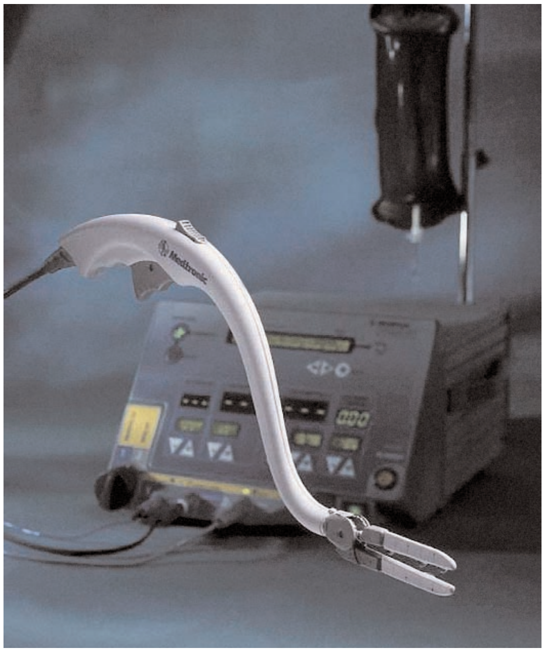

Figure 1. The Medtronic Cardioblate BP Surgical Ablation System.

MATERIALS AND METHODS

Experimental Device

A prototype bipolar RFA device (Cardioblate BP Surgical Ablation System; Medtronic, Minneapolis, MN, USA) was used to create all lesions in the study (Figure 1). The device consists of a handheld surgical clamp and an electrical generator. The clamp contains two bipolar electrodes embedded in apposing malleable jaws mounted on an articulated, rotating platform that provides approximately 90 degrees of flexion away from the long axis orientation and 300 degrees of axial rotation. Each electrode was fabricated from a stainless steel wire mounted in a porous polymer base that delivers uniform RFA energy along its entire length. During energy transfer, the electrode was continuously irrigated through the porous polymer with normal saline (1-2 mL/min) supplied from an external pressurized source. A proprietary transmurality feedback program within the RFA generator monitored tissue impedance between the electrodes and varied the power delivery over the time course of ablation according to a preset algorithm. Ablation was terminated when the transmurality feedback program detected a steady-state plateau in tissue impedance, indicating full-thickness ablation.

Procedure

A complete set of Cox-Maze lesions was fashioned with the bipolar RFA device on fresh excised porcine hearts obtained from a local slaughterhouse. Dissection of the right and left atria was performed as needed to expose the pulmonary veins (PV) and venae cavae. Because mild cardiac hypothermia is generally used in the clinical setting, hearts were cooled to 28°C in chilled lactated Ringer solution prior to ablation. Each lesion was created by manually positioning the area of atrial myocardium to be ablated between the jaws of the clamp to avoid tissue bunching or gapping. Firm clamp pressure was applied while irrigated RFA energy was delivered between the electrodes positioned on the endocardial and epicardial surfaces. The ablation duration and total energy (power × time) delivered to the tissue were recorded for each lesion. In addition, the occurrences of any steam explosions resulting in tissue defects were noted.

The Cox-Maze lesion set consisted of 11 to 12 lesions (Figure 2). First, the right atrial appendage was isolated by ablating obliquely with both electrodes applied to the epicardial surface.

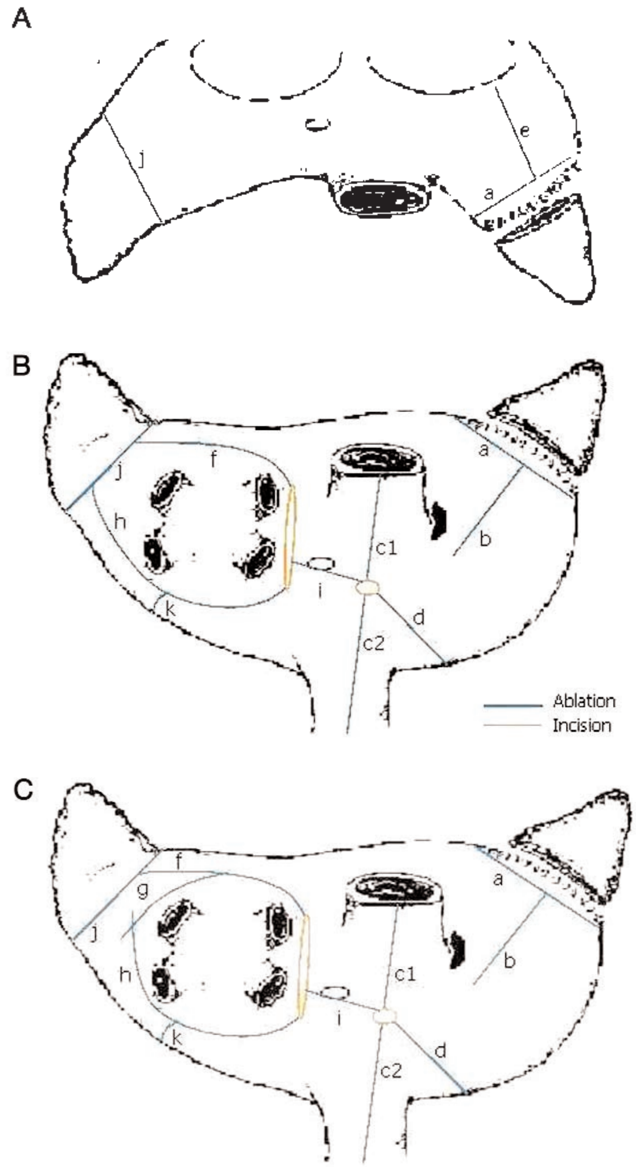

Figure 2. Schematic representation of the anterior surface (A) and posterior surface (B, C) of the atrium and the Cox-Maze lesion set employed in the study. In small hearts, the 2 lesions *f* and *h* were sufficient to completely encircle the pulmonary veins by overlapping lesion *j* (B); in large hearts, an additional lesion *g* was needed to fully isolate the pulmonary veins (C).

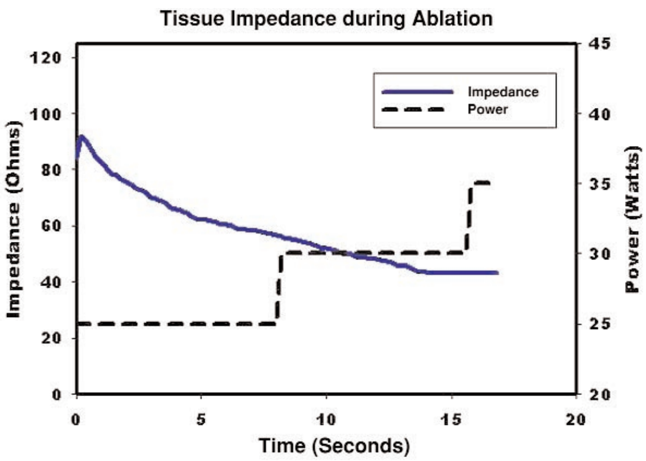

Figure 3. Representative impedance curve and power plot generated during ablation of lesion *a* as depicted in Figure 2. A transmurality feedback program monitors the decrease in impedance as ablation proceeds and increases the power delivered to the tissue in a stepwise fashion until the impedance plateaus; ablation is then terminated. The impedance plateau signifies lesion transmurality.

The right atrial appendage was then excised to provide access to the endocardial surface, and separate linear lesions were applied by passing the clamp through this opening to the mid-portion of the right atrial dome and to the anterior tricuspid valve annulus. A small stab incision was then made in the venous confluence of the right atrium. The instrument was introduced through this stab incision, and separate linear lesions were created that ran obliquely to the posterior tricuspid valve annulus and along the long axis of both the inferior and the superior vena cava. Next, a standard left atriotomy was performed in the interatrial grove to provide access to the left atrial endocardial surface, and a linear lesion was made by inserting the device from the inferior edge of the atriotomy to the midpoint of the posterior mitral valve annulus. A similar lesion was created along the septum just cephalad to the limbus fossae ovalis by simultaneously passing the jaws through the left atriotomy and the right atrial stab incision. Care was taken to avoid the tendon of Todaro. The left atrial appendage was next isolated with a single oblique lesion made with the clamp applied only to the epicardium. Then, the jaws of the clamp were bent to produce a gentle curve, and separate curvilinear lesions were created from each edge of the atriotomy around the superior and inferior PVs toward the left atrial appendage. In small hearts, these two lesions overlapped the appendage lesion and completely isolated the PVs from the left atrium. When necessary to completely encircle the PVs in larger hearts, an additional lesion was placed from the cut edge of the left atriotomy to overlap a portion of the superior PV lesion and intersect the left atrial appendage lesion.

Tissue Analysis

After all lesions were created, each heart was stained with 1% triphenyltetrazolium chloride (TTC) solution for at least 30 minutes [Fishbein 1981, Vivaldi 1985]. TTC staining clearly differentiates viable from nonviable cardiac muscle and was the primary method used to evaluate lesion transmurality. Each lesion was sectioned at 5-mm intervals and grossly inspected for transmurality. Digital photographs were prepared by capturing images of the epicardial and endocardial surfaces of all lesions intact as well as in cross section. A metric ruler was included in each photograph as a reference of scale. Measurements of tissue thickness and lesion length and width were made from the photographs with SigmaScan software (SPSS, Chicago, IL, USA).

Statistical Methods

Ablation duration, tissue thickness, and lesion dimensions are summarized as the mean ± SD. Lesion transmurality is reported as a percentage of cross sections examined with a 95% lower limit tolerance interval. Based on a sample size of at least 130 lesions, the 95% lower level tolerance interval provides 99% confidence that lesions are transmural.

RESULTS

One hundred thirty-seven lesions were created ex vivo on 11 porcine hearts. There were no issues encountered related to device electromechanical operation, and all desired areas of the heart could be reached easily. Electrode malleability and the two degrees of articulation of the clamp jaws helped compensate for differences in atrial size and anatomy. A representative impedance curve generated by the transmurality feedback program is presented in Figure 3. The power of RFA energy supplied by the generator was increased in a stepwise fashion until a plateau in impedance predicting transmurality was achieved, at which point the energy transfer was terminated. The total irrigated RFA power delivered to tissues was 406.4 ± 49.0 joules (range, 255.0-596.0 joules), and the total ablation time per lesion was 14.8 ± 1.2 seconds (range, 10.0-19.0 seconds). Although some bubbling and evaporation of irrigation fluid occurred at the tissue interface, the integrity of the tissue surfaces was maintained throughout the ablation period.

The appearance of all lesions was comparable to that seen in previously reported studies of unipolar RFA [Caccitolo 2001]. Representative gross photographs of intact bipolar RFA lesions and lesion cross sections are given in Figures 4 through 6. Ablated tissue failed to demonstrate any TTC staining and appeared pale white or brown, whereas viable, partially ablated or unablated tissue zones extending away from the lesion stained variable shades of red. No gaps were observed in any lesions. Lesions measured 24.1 ± 8.4 mm (range, 5.3-60.3 mm) in length and 4.2 ± 1.3 mm (range, 1.3-10.2 mm) in width. Examination of cross sections (n = 718) revealed that 100% of lesions were transmural along their entire length regardless of the thickness of ablated atrial tissue (3.0 ± 1.7 mm; range, 0.5-9.9 mm). Based on the sample size of 137 lesions, this result represents a 99% confidence level that at least 97% of lesions created with irrigated RFA energy will be fully transmural.

DISCUSSION

The Cox-Maze procedure has been performed for more than 25 years to treat atrial fibrillation, with multiple institutions including our own reporting excellent long-term results

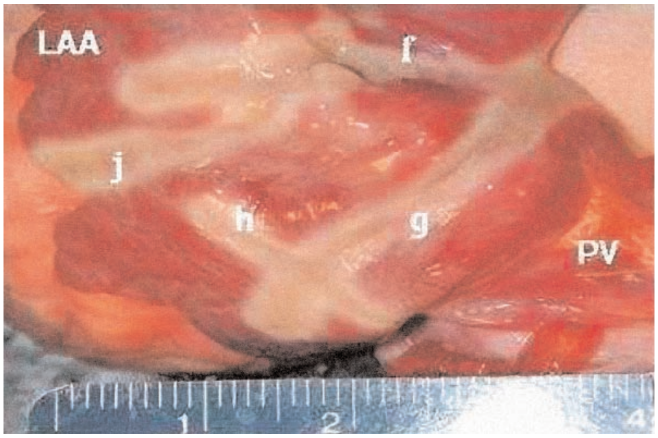

Figure 4. Representative photograph of the left atrium (epicardial view) demonstrating the pulmonary vein–encircling lesions. Letters correspond to the lesions depicted in Figure 2 (1% triphenyltetrazolium chloride stain, original magnification ×1.5). LAA indicates left atrial appendage; PV, pulmonary vein.

[Arcidi 2000, Cox 2000, Schaff 2000]. Surgeons have not widely used this highly successful procedure, however, because of its invasiveness, technical complexity, and the potential risk of morbidity associated with cardiopulmonary bypass and open heart surgery. To overcome these limitations, our laboratory and others have begun to examine simpler, alternative means for creating full-thickness lesions to replace the Cox-Maze incisions while maintaining the efficacy of the technique. Previous studies have demonstrated the effectiveness of unipolar RFA energy to create transmural, linear ablation lines in the clinical setting [Sie 1997, Thomas 1997], but uncertainty regarding the depth of ablation and recent reports of serious injury to adjacent organs, including esophageal perforation, have called into question its clinical utility [Gillinov 2001, Sonmez 2003]. As a result, our laboratory and others have begun examining bipolar RFA energy sources for application in the Cox-Maze procedure.

Several advantages of bipolar RFA technology make it an appealing alternative to unipolar systems. Ablation energy is delivered between two closely apposed electrodes that focus the energy and cause the tissue to quickly reach therapeutic temperatures (40°C-60°C) capable of producing irreversible tissue damage. Focusing deposits the energy efficiently and subsequently reduces the overall energy needed to create a lesion, and it reduces the possibility of adjacent organ or vessel injury seen with unfocused, unipolar sources [Prasad 2002b, Doll 2003]. The clamp design of bipolar instruments ensures consistent tissue contact over the entire length of the electrodes, resulting in more uniform, transmural ablations performed in seconds, not minutes [Prasad 2002a, Prasad 2002b, Gaynor 2003]. Most importantly, bipolar RFA technology provides an immediate, reliable assessment of lesion transmurality through real-time impedance monitoring [Prasad 2002a, Bonanomi 2002].

Unlike previous investigations, this study evaluated irrigated bipolar RFA technology for creating Cox-Maze lesions in an ex vivo model by using impedance monitoring as a predictor of lesion transmurality. A proprietary algorithm built into the radiofrequency generator controlled the amount of energy delivered to the electrodes while continuously monitoring impedance change in the ablated tissue. As shown in Figure 3, the algorithm incrementally increased the power as the impedance declined until a steady impedance plateau predicting lesion transmurality was reached, at which point energy transfer was terminated. Cross-sectional analysis demonstrated that all lesions were completely transmural along their entire length, providing the first evidence that irrigated bipolar RFA energy is capable of producing consistently transmural lesions in cardiac tissues regardless of tissue thickness, which in some areas approached 1 cm. Moreover, these findings validate that the plateau in impedance decline is a reliable predictor of transmural ablation.

For this study, our choice of an irrigated bipolar RFA energy source was based on previous experiments demonstrating the superiority of irrigated unipolar systems. When the electrode-tissue interface temperature exceeds a critical value during nonirrigated ablation, tissue desiccation and protein denaturation form an insulating layer referred to as "coagulum" on the dry electrode surface. Coagulum interferes with energy transfer, resulting in an impedance rise and interruption of further tissue ablation. Furthermore, coagulum is potentially thrombogenic and forms a nidus for future emboli [Haines 1990]. "Microbubble" formation from evaporating interstitial fluid can also accompany increasing tissue-electrode temperatures. The release of accumulated microbubbles cleaves tissue planes and can disrupt tissue surfaces to produce an audible "pop." Continuous irrigation during unipolar RFA prevents or prolongs the time to coagulum formation, impedance rise, and microbubble formation [Demazumder 2001a], and this delay is likely due to the dissipation of heat within the irrigation fluid. Although the present study was not

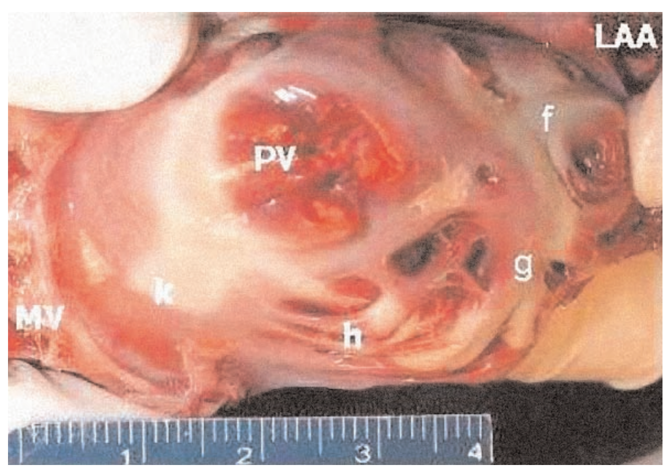

Figure 5. Representative photograph of the left atrium (endocardial view) demonstrating the pulmonary vein–encircling lesions. Letters correspond to the lesions depicted in Figure 2 (1% triphenyltetrazolium chloride stain, original magnification ×1.5). LAA indicates left atrial appendage; PV, pulmonary vein; MV, mitral valve.

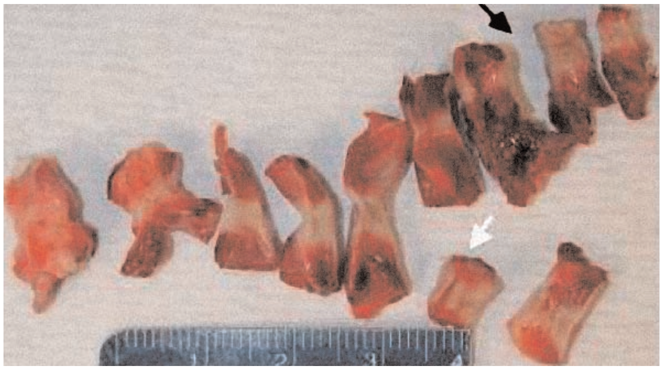

Figure 6. Representative photograph of cross sections from lesions *h* (black arrow) and *k* (white arrow) as depicted in Figure 2. The lesions overlap at the left of the image and diverge at the right. Lesion transmurality is evident from the lack of staining in the ablated tissue zone, compared with the stained, nonablated tissue (1% triphenyltetrazolium chloride stain, original magnification ×1.5).

designed to evaluate these phenomena, there were no audible pops or tissue disruptions observed that would suggest microbubble escape. Finally, the reduction of microbubble formation associated with irrigation also appears to facilitate reliable impedance measurement along the entire length of the bipolar electrode. Despite slower ablation compared with dry RFA, the gradual ablation provided by the cooling of the irrigation seems to consistently provide an accurate measurement of impedance.

Compared with the previous studies of Prasad and colleagues with a similar bipolar RFA system, the total time for ablation (15 seconds versus 9 seconds) and the overall width (4 mm versus 2 mm) were greater for the lesions in our model [Prasad 2002b]. This discrepancy in results may simply be related to differences in the design and size of the electrode filament as well as to the study model. However, dissipation of heat with irrigated RFA energy transfer is associated with a slower rise in tissue temperature and a higher maximum applied power. This heat dissipation is known to result in longer ablation times and more voluminous lesions than with nonirrigated energy sources [Demazumder 2991b]. Therefore, we expect longer ablation times and wider lesions than those that have been reported for a nonirrigated bipolar RFA system. Because the discrepancies in time and width are quite small, we do not expect these experimental differences to have a profound impact in the clinical setting.

Study Limitations

This ex vivo study is the first of a series evaluating the efficacy and safety of an irrigated, bipolar RFA system for replicating Cox-Maze lesions and has several limitations requiring the cautious application of these results to the clinical setting. First, there are considerable differences between the human and porcine anatomies. In addition, normal atrial tissues were studied, which will vary in thickness from diseased human atrial tissue. Although lesions appeared acutely transmural by TTC staining, no functional assessment of electrical conduction could be performed with these freshly preserved hearts. However, since the completion of the original study, similar lesions have been created in vivo with a sheep model of cardiopulmonary bypass and open heart surgery, and preliminary pacing results have demonstrated lesions to be electrically insulating. Finally, this model did not permit an assessment of left atrial transport function, which is an important indicator of the degree of collateral atrial damage produced by RFA energy sources during the creation of Cox-Maze lesions.

CONCLUSION

In summary, this study demonstrated the efficacy of an irrigated, bipolar RFA system in replicating a complete Cox-Maze lesion set ex vivo on fresh porcine atria. The freedom of clamp movement and the malleability of electrodes facilitated the accurate placement of lesions despite variation in atrial anatomy and size. All lesions were transmural throughout their entire lengths, validating continuous impedance monitoring as a reliable predictor of lesion transmurality. Additional studies are currently under way to further assess the efficacy and safety of this technology in clinically relevant in vivo models, including beating heart applications.

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