



Assessing the Relationship of Applied Force and Ablation Duration on Lesion Size Using a Diamond Tip Catheter Ablation System

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BACKGROUND: Contact force has proven to be influential for lesion formation in power-controlled radiofrequency ablation. Lesion formation and morphology from a temperature-controlled diamond tip radiofrequency ablation catheter is not well described. We hypothesize that lesion formation from a temperature-controlled radiofrequency system is independent of applied force over short application durations.

METHODS: This study examined lesion depth, surface width, temperature, and ablation parameters of the DiamondTemp Ablation (Medtronic, Inc) system for ablation applications delivered with varying application duration (5, 10, and 15 s) and applied force (5, 10, and 30 g). Lesions from perpendicular radiofrequency applications were analyzed in a stepwise fashion from a computational model, thermochromic gel data (n=36), and porcine thigh preparation (n=231) experiments.

RESULTS: Varying applied force across each application duration consistently generated comparable lesion dimensions for each model. In the computational model, lesion depths from a 5 s application with 5, 10, and 30 g of applied force were similar (2.3, 2.6, and 3.0 mm, respectively). Also, the 5 s lesion depths in the gel model were consistent across applied force (5 g, 3.2±0.1 mm; 10 g, 3.5±0.1 mm; 30 g, 3.5±0.2 mm). In the thigh model, the 5, 10, and 30 g applied forces for 5 s created lesion depths of 3.1±0.5, 3.2±1.0, and 3.2±1.1 mm, respectively. For the 10 and 15 s durations, the lesion depth and width remained consistent for the 10 and 30 g applied forces. Increases in lesion depth and width, percentage of impedance reduction, minimum power, and maximum temperature were only significant when application duration increased (from 5 to 15 s).

CONCLUSIONS: Lesion dimensions with the DiamondTemp Ablation temperature-controlled radiofrequency ablation system showed no marked change with increased applied force. Short application durations generated consistent lesion dimensions across computational, thermochromic gel, and thigh models.

GRAPHIC ABSTRACT: An online [graphic abstract](#) is available for this article.

Key Words: atrial fibrillation ■ catheter ablation ■ electrode ■ heating ■ platinum

Radiofrequency ablation has become commonplace in the treatment of atrial fibrillation (AF). While this technology has been widely adopted, the recurrence of AF postablation is still 30% to 50%.^{1,2} Significant development efforts have gone into technologies and algorithms, such as contact force (CF) and ablation

indices, to indirectly inform operators of complete lesion formation.³⁻⁷ However, these remain surrogate measures and do not guarantee durable lesion sets.

A diamond tipped ablation catheter and a dedicated radiofrequency generator were developed to accurately measure tissue temperature in real time, which enables

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WHAT IS KNOWN?

- The relationship between contact force and lesion dimensions has only been evaluated for longer radiofrequency ablation durations.
- Higher power shorter duration radiofrequency ablation can create shallower and wider lesions when combined with temperature-controlled ablation and lower irrigation.
- A diamond tip catheter ablation system was specifically designed to facilitate accurate temperature control and low irrigation for higher power and shorter duration radiofrequency delivery.
- The effect of contact force on such lesions, given the short durations of energy delivery, is not well known.

WHAT THE STUDY ADDS?

- The study combines a computational model, a thermochromic gel model, and a porcine thigh preparation model.
- Lesion depth and surface width do not vary across applied forces of 5 to 30 g for short durations of diamond tip catheter radiofrequency deliveries (5–15 s).
- Only ablation time affects lesion depth and width for these shorter duration deliveries.

Nonstandard Abbreviations and Acronyms

AF	atrial fibrillation
CF	contact force
DTA	DiamondTemp Ablation system

energy delivery in a temperature-controlled mode. The diamond material in the tip allows for rapid heat dissipation to maintain temperature accuracy, allowing power modulation to avoid tissue over-heating. This closed-loop approach to radiofrequency delivery leads to power titration in a short period of time while maintaining the target tissue temperature for lesion formation. Recent data from the DIAMOND-AF trial (DiamondTemp Ablation System for the Treatment of Paroxysmal Atrial Fibrillation) demonstrated DiamondTemp Ablation (DTA) is noninferior to CF-sensing technology with remarkable 12-month outcomes.⁸

Higher radiofrequency power delivered over short durations has been shown to create lesions with comparable volume, but with varied lesion morphology to those of traditional application parameters.^{9,10} However, the impact of CF on lesion formation for such short applications, especially with a temperature-controlled ablation system, is not well known. In this study, we characterize the lesion formation using a diamond tipped ablation system under progressively shorter applications while applying a low, medium, and high tip-tissue force.

METHODS

Ablation Catheter

The diamond tipped catheter used in this study (DTA; Medtronic, Inc) has been previously described.^{8,11} The data herein are inclusive of Medtronic proprietary information regarding a commercially available product; and therefore, will not be made available. In brief, the system components include the DTA catheter (7.5 F, 4.1 mm split-tip radiofrequency electrode), dedicated radiofrequency power generator, and an irrigation pump (flow rate of 8 mL/min). The primary feature of this catheter is its diamond network of chemical vapor deposition which act as a heat-shunt that has a thermal energy transfer which is 200 to 400× higher than platinum-iridium.¹² This prevents the tip from over-heating during energy delivery, which allows for accurate real-time temperature readings and a reduced irrigation flow. Additionally, the catheter has 6 external thermocouples, 3 of which are located on the distal tip, and 3 are proximal to the composite radiofrequency electrode. The generator records the temperature from each thermocouple every 20 ms and reports the highest temperature reading. The generator then rapidly modulates radiofrequency power in response to changes in tip-to-tissue temperature during ablation to maintain a constant tissue-tip temperature.

Study Design and Ablation Protocol

This examination included 3 separate phases of data evaluation. Phase I was a 3-dimensional computational model of the thermal propagation and subsequent lesion dimensions (depth and surface width). Phase II was a thermochromic gel model to evaluate temperature distribution. Phase III was a porcine thigh prep to assess pathology and histological lesion morphology and geometric characteristics. All ablations were delivered in a perpendicular orientation, conducted with a target temperature of 60°C, maximum power of 50 W and ablation duration of 5, 10, or 15 s. Included in this study was an assessment of clinically relevant tip-tissue applied forces (5, 10, and 30 g).¹³ Phases II and III maintained a constant tip-tissue applied force with calibrated weighted introducers.

Phase I—Computational Model

The COMSOL Multiphysics software program (COMSOL v5.6a; Burlington, MA) was used to simulate the multiphysics of the solid mechanics and heat transfer of radiofrequency energy delivered into cardiac tissue.¹⁴ The material characteristics and temperature-controlled power modulation of the DTA system were incorporated into the thermal boundary conditions Figure 1. A structural analysis was conducted with 5, 10, and 30 g of applied force to assess the myocardial deformation from the catheter tip which became the foundation for the thermal and the electromagnetism analysis. Simulations were then conducted with radiofrequency application durations of 5, 10, and 15 s. The heat transfer equations was used to determine the responses of the modeled cardiac tissue when radiofrequency energy was applied.¹⁵ The thermocouple temperature reading at the tip-tissue interface was calculated over time and lesion dimensions were estimated by measuring the 50°C isotherm.

Phase II—Thermochromic Gel

A temperature sensing medium composed of 3 layers of 40% polyacrylamide gel (2 clear gels on the outside and a

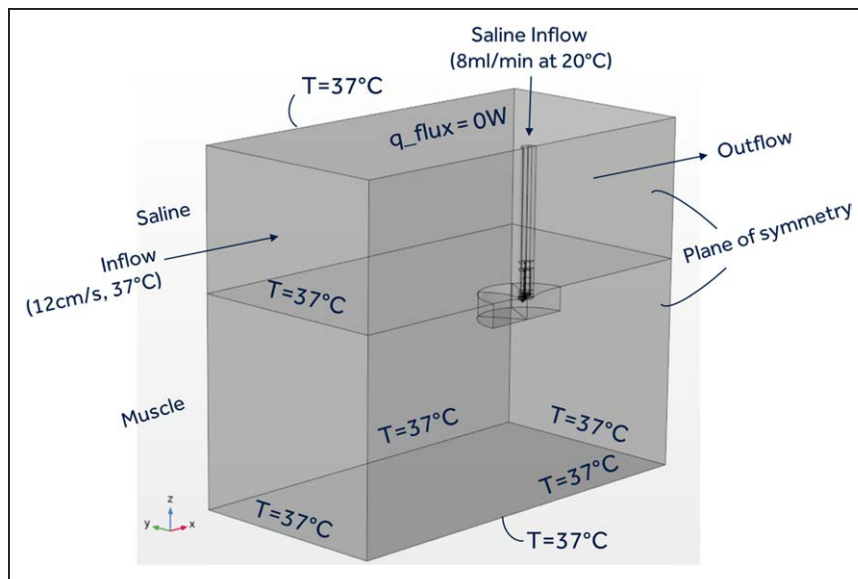


Figure 1. Computational model boundary conditions.

All boundaries were maintained at a temperature of 37°C with parameters consistent with that of the other experimental models. Physical and functional characteristics of the DiamondTemp Ablation system were used when delivering energy into the tissue.

thermochromic opaque gel in the middle) was used in this study. The thermochromic layer contained temperature sensitive crystals (LCR Hallcrest, IL) attuned to 50°C, 60°C, 70°C, 80°C, and 90°C and was added in 75 μ L aliquots. The gel model was submerged in a water bath, and a flow chamber was placed on top of the gel to control half normal saline flowing at 12 cm/s over the ablation site (Figure 2). The 50°C isotherm distances for depth and width were measured along with the generator temperature. Ablation durations and applied force were randomized for all applications. Images were collected immediately after each application. ImageJ software (Version 1.51, National

Institutes of Health; Bethesda, MD) was used for color correction and temperature penetration measurements.

Phase III—Thigh Muscle Preparation

The experimental protocol was approved by the Institutional Animal Care and Use Committee of Medtronic Physiological Research Laboratory. Three adult swine were housed and received humane care in accordance with the Guide for Care and use of Laboratory Animals and the Animal Welfare Act as amended. After intubation, animals were placed on their left

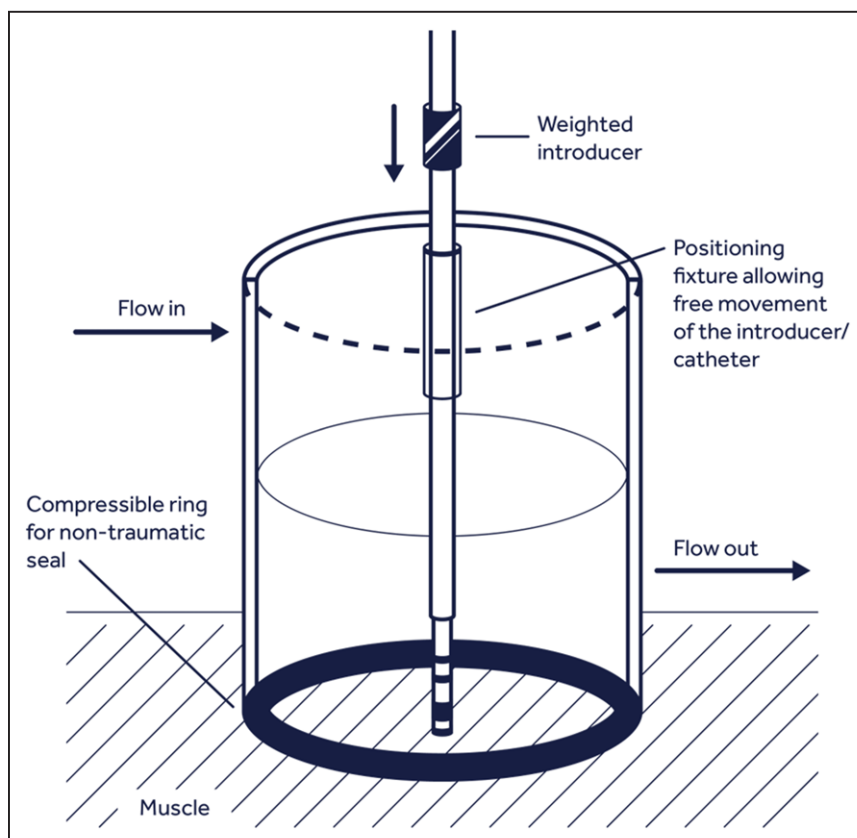


Figure 2. Application apparatus.

Flow rate was maintained over the ablation location while the operator stabilized the ablation catheter for all ablation applications of the thermochromic gel and porcine thigh models. The calibrated weighted introducer generated the applied force that transmitted from the catheter to the model surface.

side and a large portion of the hind thigh muscle was exposed. A grid pattern was sewn into the tissue for easier identification of lesions postprocedure. Flow chamber setup used during phase II was replicated. Similarly, ablation duration and applied force were randomized for all applications. Upon completion of ablation applications, the skin flaps were closed, and the procedure was repeated on the opposite thigh. One hour after the completion of the final lesion, 20 mL of 10% triphenyl tetrazolium chloride was administered intravenously before euthanasia. The thigh muscles were fixed in 10% formalin before histological sectioning. Depth and width measurements of the lesions were recorded using histology methods.¹⁶

Statistical Analysis

Lesion measurements were summarized by their means and SDs. For statistical comparisons, 1-way ANOVA *P* values were obtained with the lesion measurements as the dependent variable and either applied force or application duration as the independent variable, and the results were stratified by contact duration. Post hoc pairwise comparison via Tukey test was performed in response to ANOVA significance. With a 1-way ANOVA, $P < 0.025$ was defined as statistically significant.

RESULTS

Phase I—Computational Model

The structural analysis resulted in a mesh of 47 k elements with a sensitivity analysis that converged within 5%. When the geometry was coupled with the heat transfer of the thermal conditions, the tip-tissue interface temperatures and the distance of the 50°C isotherm measurements were similar between the 5, 10, and 30 g applications (Figure 3). Distal thermocouple temperature calculation was 52.7°C, 54.6°C, and 57.5°C when 5 g of applied force was introduced during a 5, 10, and 15 s application, respectively. When 10 g of applied force was modeled, surface temperature registered by the catheter

distal thermocouples for the 5, 10, and 15 s applications were 54.8°C, 57.1°C, 59.6°C, respectively. Lastly, when 5, 10, and 15 s applications were modeled with 30 g of applied force the thermocouple readings were 55.7°C, 58.3°C, 60.3°C, respectively. The maximum internal tissue temperatures across the simulations ranged from 82.8°C to 94.0°C.

When delivering a 5 s application, the lesion depths from the 5, 10, and 30 g were similar (2.3, 2.6, and 3.0 mm, respectively), and the lesion widths were also similar (4.2, 4.3, and 4.5 mm, respectively). When delivering a 10 s application, the lesion depths from the 5, 10, and 30 g were similar (3.1, 3.3, and 3.7 mm) and the lesion widths were also similar (4.3, 4.4, and 4.6 mm). Finally, when delivering a 15 s application, the lesion depths were 3.6, 3.9, and 4.2 mm from the 5, 10, 30 g and the lesion widths were 4.3, 4.4, and 4.6 mm.

Phase II—Thermochromic Gel

A total of 12 lesions were created for each application duration (four with each applied force). The temperature recorded by the generator during the 5, 10, and 15 s applications were consistent ($64.1 \pm 0.6^\circ\text{C}$, $64.2 \pm 0.5^\circ\text{C}$, and $64.4 \pm 0.4^\circ\text{C}$, respectively), and no application produced an 80°C isotherm band. Lesion depths and widths are described in Figure 4 and Table 1. When delivering 5 s applications, the lesion depths from the 5, 10, and 30 g force were similar 3.2 ± 0.1 , 3.5 ± 0.1 , and 3.5 ± 0.2 mm, respectively. The 5, 10, and 30 g lesion widths from 5 s applications were different (4.9 ± 0.2 versus 5.0 ± 0.1 versus 4.7 ± 0.1 mm, $P < 0.025$); and via pairwise comparison the 10 versus 30 g combination presented as different. The 10 s applications produced similar lesion depths at 5, 10, and 30 g (4.1 ± 0.1 versus 4.2 ± 0.2 versus 4.3 ± 0.2 mm) and similar lesion widths (5.6 ± 0.1 versus 5.6 ± 0.8 versus

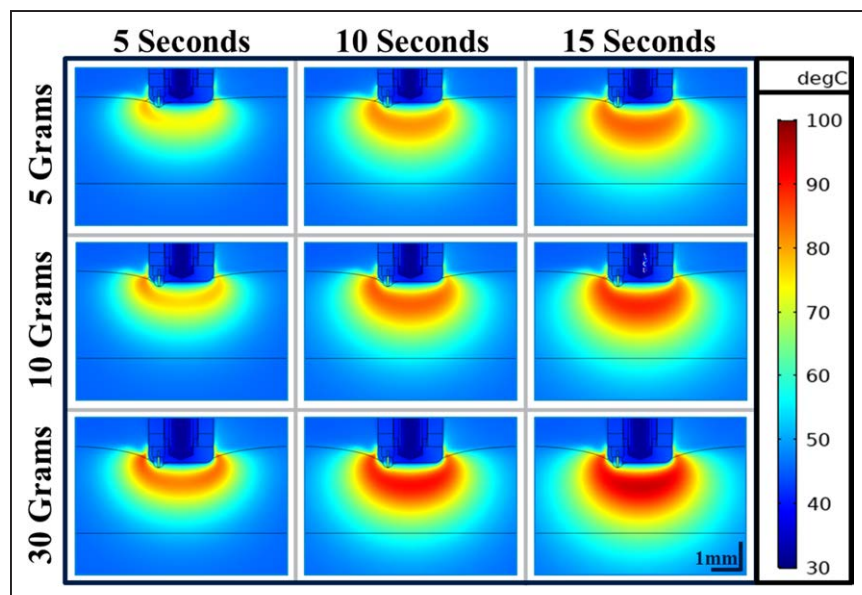


Figure 3. Computational model thermal profile.

Simulated temperature distribution from ablation applications of 5, 10, and 15 s durations with 5, 10, or 30 g of applied force (Scale in Celsius). These are representative images showing larger lesion sizes as application duration is increased, with minimal visual change with an increase in applied force at each duration.

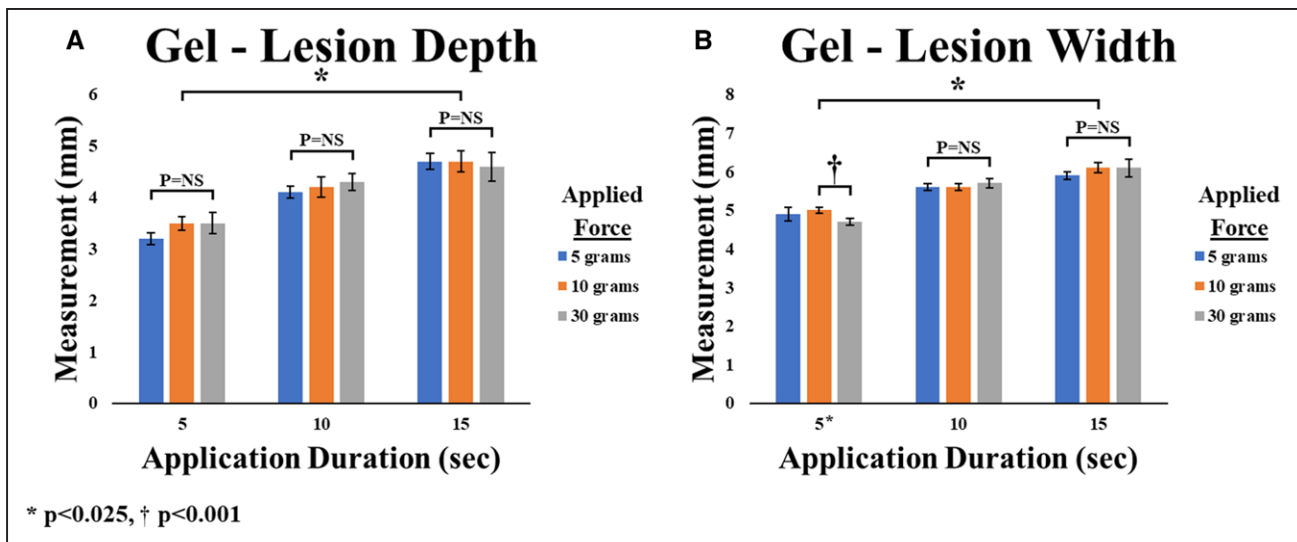


Figure 4. Thermochromic gel model lesion dimensions.

A, Lesion depth from ablation applications of 5, 10, and 15 s durations with 5, 10, or 30 g of applied force. **B**, Lesion width from ablation applications of 5, 10, and 15 s durations with 5, 10, or 30 g of applied force. There were no statistically significant differences in lesion depth or width according to applied force for the 10 and 15 s durations; 5 s presented a difference ($P<0.025$) and subsequent pairwise comparison identified the 10 vs 30 g lesions were different ($P<0.025$). However, mean depth and width for each duration were statistically significant with increased depth and width with longer durations of delivery (ANOVA $P<0.001$; pairwise comparison $P<0.001$ for all).

5.7±0.1 mm). When delivering 15 s applications, the lesion depths (4.7±0.2 versus 4.7±0.2 versus 4.6±0.3 mm) and lesion widths (5.9±0.1 versus 6.1±0.1 versus 6.1±0.2 mm) were all similar at the 5, 10, and 30 g forces, respectively.

Application duration did create differences in both lesion depth and width. The average lesion depth for the application durations were different (5 s, 3.4±0.2 mm; 10 s, 4.2±0.2 mm; and 15 s, 4.7±0.2 mm). The average lesion width for the 5, 10, and 15 s application durations varied significantly (4.9±0.2, 5.7±0.1, and 6.0±0.2 mm, respectively). Pairwise comparisons demonstrated for all lesion depth and width combinations each increased significantly as the application duration increased ($P<0.001$ for all combinations).

Phase III—Thigh Model Preparation

Across 3 swine (6 thigh preps), 248 ablation applications were delivered in a randomized fashion. During histology, 17 lesions were excluded from analysis due to experimental complexity, including (1) the lack of identification (typically due to superficial fat or poor dispersion of the triphenyl tetrazolium chloride stain); (2) delivery across the border of 2 muscles leading to abnormal lesion formation; or (3) incomplete recordings of ablation parameters (ie, impedance, temperature, power). In total, 231 lesions were included in this analysis. The application durations of 5, 10, and 15 s were delivered with varied applied forces (n=76, 79, and 76, respectively).

The lesion characteristics are described in Figure 5 and Table 2. When evaluating lesion depth as applied force changes, there was no difference across the ablation durations. Lesion depths created by a 5 s application

with varying applied forces were comparable (5 g, 3.1±0.5 mm; 10 g, 3.2±1.0 mm; and 30 g, 3.2±1.1 mm). A 10 s application created consistent lesion depths with 5, 10, and 30 g of applied force (4.6±0.4, 4.3±0.7, and 4.6±0.6 mm, respectively). Consistency of lesion depth was demonstrated with the 15 s applications as well (5 g, 5.2±0.8 mm; 10 g, 5.2±0.9 mm; and 30 g, 5.3±0.8 mm).

The lesion width measurements were also consistent within the application durations, Figure 5B. Lesion widths for 5, 10, and 30 g applied forces for a 5 s application

Table 1. Thermochromic Gel Lesion Dimensions

Force	No.	Depth, mm	Surface width, mm
5 seconds	12*	3.4±0.2	4.9±0.2
5 g	4	3.2±0.1	4.9±0.2
10 g	4	3.5±0.1	5.0±0.1
30 g	4	3.5±0.2	4.7±0.1
10 seconds	12*	4.2±0.2*	5.7±0.1*
5 g	4	4.1±0.1	5.6±0.1
10 g	4	4.2±0.2	5.6±0.1
30 g	4	4.3±0.2	5.7±0.1
15 seconds	12*	4.7±0.2*	6.0±0.2*
5 g	4	4.7±0.2	5.9±0.1
10 g	4	4.7±0.2	6.1±0.1
30 g	4	4.6±0.3	6.1±0.2

Comparison of lesion depth and surface width between applied forces within each delivery duration were nonsignificant. Comparison of lesion depth and surface width between delivery durations were significant with longer deliveries demonstrating increased depth and width (ANOVA $P<0.001$).

*Indicates the mean value of all 12 observations for each duration of radiofrequency (5, 10, or 15 seconds).

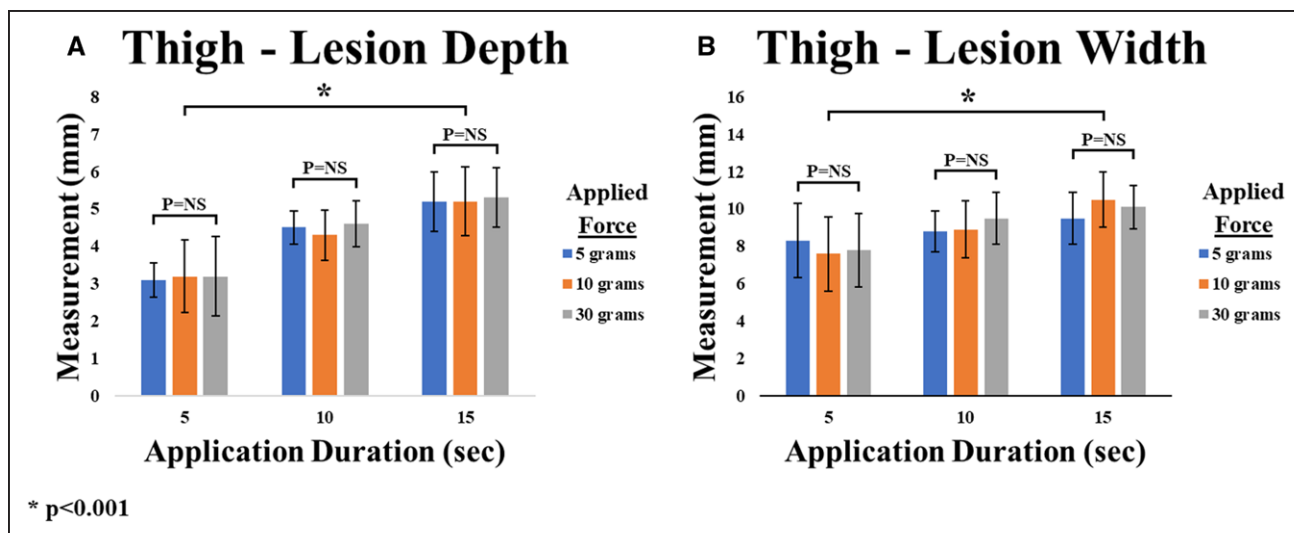


Figure 5. Thigh model lesion dimensions.

A, Lesion depth from ablation applications of 5, 10, and 15 s durations with 5, 10, or 30 g of applied force. **B**, Lesion width from ablation applications of 5, 10, and 15 s durations with 5, 10, or 30 g of applied force. There were no statistically significant differences in lesion depth or width according to applied force. However, mean depth and width for each duration were statistically significant with increased depth and width with longer durations of delivery (ANOVA $P < 0.001$; pairwise comparison $P < 0.001$ for all).

were also similar (8.3 ± 2.0 , 7.6 ± 2.0 , and 7.8 ± 2.0 mm, respectively). When 5, 10, and 30 g of applied force were ablated for 10 s, the lesion widths were similar (8.7 ± 1.1 , 8.9 ± 1.5 , and 9.5 ± 1.4 mm, respectively). The 15 s applications created similar lesion widths (5 g, 9.5 ± 1.4 mm; 10 g, 10.5 ± 1.5 mm; and 30 g, 10.1 ± 1.2 mm).

Application duration did create differences in both lesion depth and lesion width. The average lesion depth for the application durations were different (5 s, 3.2 ± 0.9 mm; 10 s, 4.4 ± 0.6 mm; and 15 s, 5.2 ± 0.9 mm). The average lesion width for the 5, 10, and 15 s application durations varied significantly (7.9 ± 2.0 , 9.0 ± 1.4 , and 10.1 ± 1.4 mm, respectively). Pairwise comparisons

demonstrated for all lesion depth and width combinations each increased significantly as the application duration increased ($P < 0.001$ for all combinations).

Impedance, power, and temperature are described in Table 3. The impedance reduction for the 5, 10, and 15 s grouped application durations were different (12 ± 2 , 15 ± 2 , and $16 \pm 3 \Omega$, respectively). The power titration response (measured by minimum power) to the 5, 10, and 15 s application varied significantly (49.8 ± 1.2 , 48.5 ± 3.1 , and 46.4 ± 4.2 W, respectively). Similarly, the maximum temperature reported by the catheter significantly varied for the application durations (5 s, $55.3 \pm 2.6^\circ\text{C}$; 10 s, $57.9 \pm 2.7^\circ\text{C}$; and 15 s, $59.4 \pm 2.3^\circ\text{C}$). Pairwise comparisons for all combinations, except 5 versus 10 s minimum power, demonstrated significance as application duration increased (Figure 6).

Table 2. Thigh Model Lesion Dimensions

Force	No.	Depth, mm	Surface width, mm
5 seconds			
5 g	25	3.1 ± 0.5	8.3 ± 2.0
10 g	26	3.2 ± 1.0	7.6 ± 2.0
30 g	25	3.2 ± 1.0	7.8 ± 2.0
10 seconds			
5 g	26	4.6 ± 0.4	8.7 ± 1.1
10 g	27	4.3 ± 0.7	8.9 ± 1.5
30 g	26	4.6 ± 0.6	9.5 ± 1.4
15 seconds			
5 g	26	5.2 ± 0.8	9.5 ± 1.4
10 g	27	5.2 ± 0.9	10.5 ± 1.5
30 g	23	5.3 ± 0.8	10.1 ± 1.2

Comparison of lesion depth and surface width between applied forces within each delivery duration were nonsignificant. Comparison of lesion depth and surface width between delivery durations were significant with longer deliveries demonstrating increased depth and width (ANOVA $P < 0.001$).

DISCUSSION

This study evaluated the impact of applied force with shorter ablation durations on lesion size when using a temperature-controlled radiofrequency ablation catheter. The results show that lesion size did not increase as applied force increased during ablation applications ranging from 5 to 15 s. Ablation applications between 5 and 15 s produce lesion depths ranging from 3 mm for a 5 s ablation to over 5 mm for a 15 s ablation, which would be adequate for most atrial ablation (Figure 7).

Across all phases of this study, applied force demonstrated little effect on lesion dimensions with a temperature-controlled ablation system. That would appear to contradict other preclinical studies which have shown that increasing catheter CF leads to increased lesion size

Table 3. Thigh Model Average Lesion Dimensions and Ablation Parameters

Average duration, s	No.	Depth, mm	Surface Width, mm	Impedance reduction, %	Minimum power, W	Maximum temperature, C
5	76	3.2±0.9	7.9±2.0	12±2	49.8±1.2	55.3±2.6
10	79	4.4±0.6	9.0±1.4	15±2	48.5±3.1	57.9±2.7
15	76	5.2±0.9	10.1±1.4	16±3	46.4±4.2	59.4±2.3

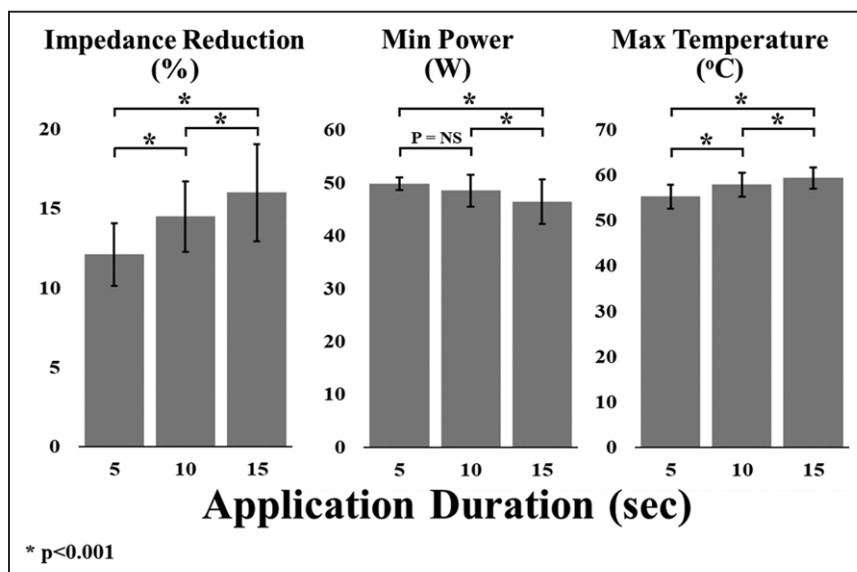
Comparison of depth, surface width, impedance reduction, minimum power, and maximum temperature demonstrated significant differences between the durations of delivery (ANOVA $P<0.001$).

and transmuralty.^{3,7,17} These prior studies suggested that there was a linear relationship between increasing CF and lesion size.⁷ However, they evaluated longer durations of radiofrequency delivery ranging from a minimum of 30 to 60 s.^{3,7,17} These studies did not evaluate short durations of radiofrequency delivery where CF may have less impact on lesion size. In one prior study that looked at shorter lesion durations and CF, there was little effect of increasing force on lesion size for 15 s deliveries, similar to our study findings.¹⁰ Force was a major driver only for lesions 30 s or longer and especially for 60 and 90 s lesions.¹⁰

Comparing thigh model data from similar parameter settings our results compare well. Variations of power and duration have been explored to find the optimal lesion depth, ablation parameters, and efficiency. Preclinical data of 90 W applied for 4 s created lesion depths of 3.62 and widths of 10.36 mm.¹⁰ The same study examined 70 W, 10 g, for 8 s and created lesions of 4.32 mm and 10.79 mm (depth and width, respectively). Borne et al⁹ evaluated 50 W, 10g, at 15 s in an ex vivo model and 50 W, 16 g, for 5 s in a thigh model. In the ex vivo model, 50 W, 10 g, and 15 s produced lesions that were 1.8 mm deep and 6.7 mm wide compared with DTA 50 W, 15 s which produced lesions 5.2 mm deep and 10.1 mm wide. For the in vivo model, 50 W, 16 g, 5 sec produced lesions 2 mm deep and 6.8 mm wide compared with DTA 50 W, 5 s which was 3.2 mm deep and 7.9 mm wide.

Furthermore, clinical studies are not consistent on whether increasing CF equates to more complete lesions. On the contrary, the EFFICAS I trial (TactiCath Prospective Effectiveness Pilot Study) demonstrated that a median CF of 19.5 g was associated with durably isolated pulmonary veins compared with 15.5 g in those where pulmonary vein reconnections were reported.⁴ The TOCATA trial (TouchPlus for Catheter Ablation) reported higher recurrence at 1 year when CF was <10 g, but better outcomes with a CF between 10 and 20 g, and even better yet with a CF >20 g.⁴ Yet, the SMART AF trial (THERMOCOOL SMARTTOUCH Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation) showed the highest freedom from AF occurred within a tight CF range of 6.5 to 10.3 g, suggesting a U-shaped rather than a linear relationship between CF and AF recurrence.¹⁸ Very high CFs are also associated with increased risk of steam pop and perforation.^{3,17,18} There has also been no randomized trial ever demonstrating the superiority of CF-sensing technology over traditional radiofrequency ablation in terms of patient outcome.^{7,19}

The data from this study suggests lesions created with DTA (a temperature-controlled ablation system) may be independent of clinical ranges of applied force, especially in short duration applications. So long as clinically sufficient contact occurs to enable heat transfer to the tissue, a sufficient lesion may be formed, even across a wide range of applied force from 5 to 30 g. A temperature-controlled

**Figure 6. Thigh model ablation parameters.**

Average impedance reduction, minimum power, and maximum temperatures changed significantly as application duration increased. (ANOVA $P<0.001$; pairwise comparison $P<0.001$ for all, except 5 vs 10 s Min Power, $P=0.034$).

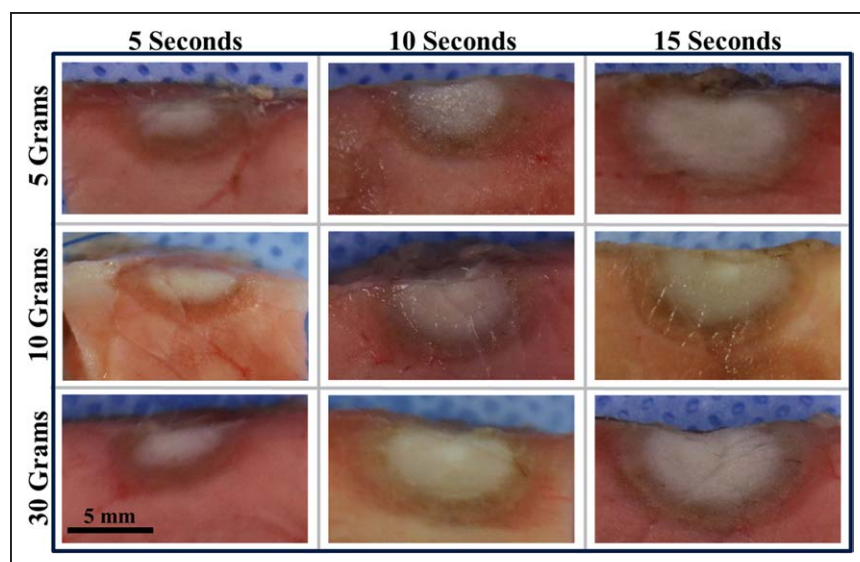


Figure 7. Thigh model lesion histology.

DiamondTemp Ablation generated consistent lesions at each ablation duration, irrespective of increased applied force.

ablation will modulate the power according to the individual circumstances of the lesion. For example, if the applied force is excessive and the catheter is embedded in the tissue, the power will decrease as soon as the target temperature has been reached. If the catheter is barely contacting the tissue, the power will remain high until the targeted temperature is reached. Our results show that the ability to titrate power to a target temperature will ultimately result in more uniform lesion formation independent of clinically relevant ranges of tip-tissue applied force. Leshem et al¹⁰ also showed that temperature-controlled ablation produced similar-sized lesions to nontemperature-controlled ablations and that increasing CF was associated only with increased risk of steam pop but not larger lesion size. The CF range allowed in that study was also very wide, allowing 5 to 30 g. Perhaps, measures of contact (not force) will be sufficient for temperature-controlled ablations, using biophysical parameters (eg, electrogram amplitude, achieving target temperature, and possibly tissue impedance).

Despite the DTA system not having CF, clinical studies using the system have been promising. The TRAC-AF study (ACT DiamondTemp Temperature-Controlled and Contact Sensing RF Ablation Clinical Trial for Atrial Fibrillation) used DTA technology for patients undergoing pulmonary vein isolation and during remapping of the veins at 3 months, they found 85% durability in isolation of the veins.¹¹ Importantly, the recently published DIAMOND-AF study showed that the 1-year outcome of AF ablation with DTA was noninferior to that of traditional contact force guided, power-controlled ablation.⁸ Evaluation of electrogram amplitude and adjustment during ablation to achieve a target temperature >55°C were adequate in driving the outcome.

Study Limitations

This preclinical evaluation has some limitations. First, we only evaluated a narrow range of CFs from 5 to 30

g. We do not know if forces outside of this range may drive differences in lesion size. However, data from clinical studies suggest that forces >30 g may increase the risk of perforation or steam pop, and these higher forces are infrequently used in clinical practice. We also performed all the evaluations with a target temperature of 60°C. Therefore, this study does not provide insight into whether other target temperatures, such as 50 or 55°C, would show similar results. Additionally, imaging processing of the thermochromic gel was focused on the 50°C isotherm and may have reduced resolution at higher temperature bands because of the prespecified composition of the gel. However, no application generated an isotherm >80°C. Finally, the results of this study are specific to the DTA technology and cannot be extrapolated to other technologies using different system designs or components despite the employment of temperature-controlled ablation.

Conclusions

The DiamondTemp Ablation system created consistent lesions with depth ranging from 3 to 5 mm by applying ablation durations of 5 to 15 s. Clinically relevant applied force has little impact on lesion dimensions when radiofrequency is applied using a temperature-controlled ablation method over shorter durations from 5 to 15 s.

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REFERENCES

- Callans DJ, Gerstenfeld EP, Dixit S, Zado E, Vanderhoff M, Ren JF, Marchlinski FE. Efficacy of repeat pulmonary vein isolation procedures in patients with recurrent atrial fibrillation. *J Cardiovasc Electrophysiol*. 2004;15:1050–1055. doi: 10.1046/j.1540-8167.2004.04052.x
- Kuck KH, Hoffmann BA, Ernst S, Wegscheider K, Treszl A, Metzner A, Eckardt L, Lewalter T, Breithardt G, Willems S; Gap-AF–AFNET 1 Investigators*. Impact of complete versus incomplete circumferential lines around the pulmonary veins during catheter ablation of paroxysmal atrial fibrillation: results from the gap-atrial fibrillation-German atrial fibrillation competence network 1 trial. *Circ Arrhythm Electrophysiol*. 2016;9:e003337. doi: 10.1161/CIRCEP.115.003337
- Yokoyama K, Nakagawa H, Shah DC, Lambert H, Leo G, Aebly N, Ikeda A, Pitha JV, Sharma T, Lazzara R, et al. Novel contact force sensor incorporated in irrigated radiofrequency ablation catheter predicts lesion size and incidence of steam pop and thrombus. *Circ Arrhythm Electrophysiol*. 2008;1:354–362. doi: 10.1161/CIRCEP.108.803650
- Reddy VY, Shah D, Kautzner J, Schmidt B, Saoudi N, Herrera C, Jais P, Hindricks G, Peichl P, Yulzari A, et al. The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. *Heart Rhythm*. 2012;9:1789–1795. doi: 10.1016/j.hrthm.2012.07.016
- Kautzner J, Neuzil P, Lambert H, Peichl P, Petru J, Cihak R, Skoda J, Wichterle D, Wissner E, Yulzari A, et al. EFFICAS II: optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. *Europace*. 2015;17:1229–1235. doi: 10.1093/europace/euv057
- Reddy VY, Dukkupati SR, Neuzil P, Natale A, Albenque JP, Kautzner J, Shah D, Michaud G, Wharton M, Harari D, et al. Randomized, controlled trial of the safety and effectiveness of a contact force-sensing irrigated catheter for ablation of paroxysmal atrial fibrillation: results of the TactiCath contact force ablation catheter study for atrial fibrillation (TOCCASTAR) study. *Circulation*. 2015;132:907–915. doi: 10.1161/CIRCULATIONAHA.114.014092
- Virk SA, Bennett RG, Trivic I, Campbell T, Kumar S. Contact force and ablation index. *Card Electrophysiol Clin*. 2019;11:473–479. doi: 10.1016/j.ccep.2019.05.007
- Kautzner J, Albenque JP, Natale A, Maddox W, Cuomo F, Neuzil P, Poty H, Getman MK, Liu S, Starek Z, et al. A novel temperature-controlled radiofrequency catheter ablation system used to treat patients with paroxysmal atrial fibrillation. *JACC Clin Electrophysiol*. 2021;7:352–363. doi: 10.1016/j.jacep.2020.11.009
- Borne RT, Sauer WH, Zipse MM, Zheng L, Tzou W, Nguyen DT. Longer duration versus increasing power during radiofrequency ablation yields different ablation lesion characteristics. *JACC Clin Electrophysiol*. 2018;4:902–908. doi: 10.1016/j.jacep.2018.03.020
- Leshem E, Zilberman I, Tschabrunn CM, Barkagan M, Contreras-Valdes FM, Govari A, Anter E. High-power and short-duration ablation for pulmonary vein isolation: biophysical characterization. *JACC Clin Electrophysiol*. 2018;4:467–479. doi: 10.1016/j.jacep.2017.11.018
- Iwasawa J, Koruth JS, Petru J, Dujka L, Kralovec S, Mzourkova K, Dukkupati SR, Neuzil P, Reddy VY. Temperature-controlled radiofrequency ablation for pulmonary vein isolation in patients with atrial fibrillation. *J Am Coll Cardiol*. 2017;70:542–553. doi: 10.1016/j.jacc.2017.06.008
- Brown AI, Marco SM. *Introduction to Heat Transfer*. 3rd ed. McGraw-Hill Book Company Inc.; 1958.
- Calkins H, Hindricks G, Cappato R, Kim YH, Saad EB, Aguinaga L, Akar JG, Badhwar V, Brugada J, Camm J, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm*. 2017;14:e275–e444. doi: 10.1016/j.hrthm.2017.05.012
- Yan S, Gu K, Wu X, Wang W. Computer simulation study on the effect of electrode-tissue contact force on thermal lesion size in cardiac radiofrequency ablation. *Int J Hyperthermia*. 2020;37:37–48. doi: 10.1080/02656736.2019.1708482
- PENNES HH. Analysis of tissue and arterial blood temperatures in the resting human forearm. *J Appl Physiol*. 1948;1:93–122. doi: 10.1152/jap.1948.1.2.93
- Nakagawa H, Yamanashi WS, Pitha JV, Arruda M, Wang X, Ohtomo K, Beckman KJ, McClelland JH, Lazzara R, Jackman WM. Comparison of in vivo tissue temperature profile and lesion geometry for radiofrequency ablation with a saline-irrigated electrode versus temperature control in a canine thigh muscle preparation. *Circulation*. 1995;91:2264–2273. doi: 10.1161/01.cir.91.8.2264
- Okumura Y, Johnson SB, Bunch TJ, Henz BD, O'Brien CJ, Packer DL. A systematic analysis of in vivo contact forces on virtual catheter tip/tissue surface contact during cardiac mapping and intervention. *J Cardiovasc Electrophysiol*. 2008;19:632–640. doi: 10.1111/j.1540-8167.2008.01135.x
- Reddy VY, Pollak S, Lindsay BD, McElderry HT, Natale A, Kantipudi C, Mansour M, Melby DP, Lakkireddy D, Levy T, et al. Relationship between catheter stability and 12-month success after pulmonary vein isolation: a subanalysis of the SMART-AF trial. *JACC Clin Electrophysiol*. 2016;2:691–699. doi: 10.1016/j.jacep.2016.07.014
- Conti S, Weerasooriya R, Novak P, Champagne J, Lim HE, Macle L, Khaykin Y, Pantano A, Verma A. Contact force sensing for ablation of persistent atrial fibrillation: a randomized, multicenter trial. *Heart Rhythm*. 2018;15:201–208. doi: 10.1016/j.hrthm.2017.10.010