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Effect of contact force on pulsed field ablation lesions in porcine cardiac tissue

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Disclosures: Drs. Lars Mattison, Khaldoun Tarakji, Birce Önal, Kevin L. Sack, Megan Schmidt, and Daniel Sigg are employees of Medtronic. Drs. Atul Verma, Gerhard Hindricks, Tobias Reichlin, and Damijan Miklavčič are Medtronic consultants.

Abstract

Introduction: Contact force has been used to titrate lesion formation for radiofrequency ablation. Pulsed field ablation (PFA) is a field-based ablation technology for which limited evidence on the impact of contact force on lesion size is available.

Methods: Porcine hearts ($n = 6$) were perfused using a modified Langendorff set-up. A prototype focal PFA catheter attached to a force gauge was held perpendicular to the epicardium and lowered until contact was made. Contact force was recorded during each PFA delivery. Matured lesions were cross-sectioned, stained, and the lesion dimensions measured.

Results: A total of 82 lesions were evaluated with contact forces between 1.3 and 48.6 g. Mean lesion depth was 4.8 ± 0.9 mm (standard deviation), mean lesion width was 9.1 ± 1.3 mm, and mean lesion volume was 217.0 ± 96.6 mm^3. Linear regression curves showed an increase of only 0.01 mm in depth (depth = 0.01 × contact force + 4.41, $R^2 = 0.05$), 0.03 mm in width (width = 0.03 × contact force + 8.26, $R^2 = 0.13$) for each additional gram of contact force, and 2.20 mm^3 in volume (volume = 2.20 × contact force + 162, $R^2 = 0.10$).

Conclusion: Increasing contact force using a bipolar, biphasic focal PFA system has minimal effects on acute lesion dimensions in an isolated porcine heart model and achieving tissue contact is more important than the force with which that contact is made.

KEYWORDS

cardiac ablation, contact force, irreversible electroporation, pulsed field ablation

1 | INTRODUCTION

Thermal-based catheter ablation technologies (e.g., radiofrequency and cryoablation) are the cornerstone of treatment modalities to treat cardiac arrhythmias. The catheter-to-tissue contact force, measured via displacement of small springs or optic fibers placed in catheter tips, has become a primary driver of radiofrequency lesion size.[1–5] Excessive contact force however is associated with potential complications such as cardiac perforation and phrenic nerve injury.[6,7]

Pulsed field ablation (PFA) is an emerging non-thermal energy modality for catheter-based treatment of cardiac arrhythmias.[8–10] PFA therapy involves the application of an electric field to tissues

leading to cell death through the mechanisms of irreversible electroporation.[11–13] The lesion formation in response to PFA is a function of the electric field distribution applied to the ablation electrodes.[11,14,15]

Preliminary work was reported where the role of contact force in an in vivo endocardial application with a focal PFA system was described.[16] These results indicated that lesion depth increases with increasing contact force, and electrode-tissue contact was required for effective lesion formation with the tested PFA system. The relationship between contact force and lesion size is still not fully understood and has yet to be evaluated using a bipolar PFA system.

Prior work has established that close electrode-tissue proximity optimizes lesion creation and increases the likelihood of achieving transmural lesions by maximizing electric field-tissue penetration.[17] As a follow-up to this initial characterization of proximity of the PFA ablation electrodes to cardiac tissues, the aim of the present preclinical study was to evaluate the effect of contact force on lesion depth, width, and volume using a prototype focal biphasic, bipolar PFA catheter. This study design allows for precise control of offset distance and contact force compared to an in vivo model where minor offsets are difficult to control and contact forces are averaged.

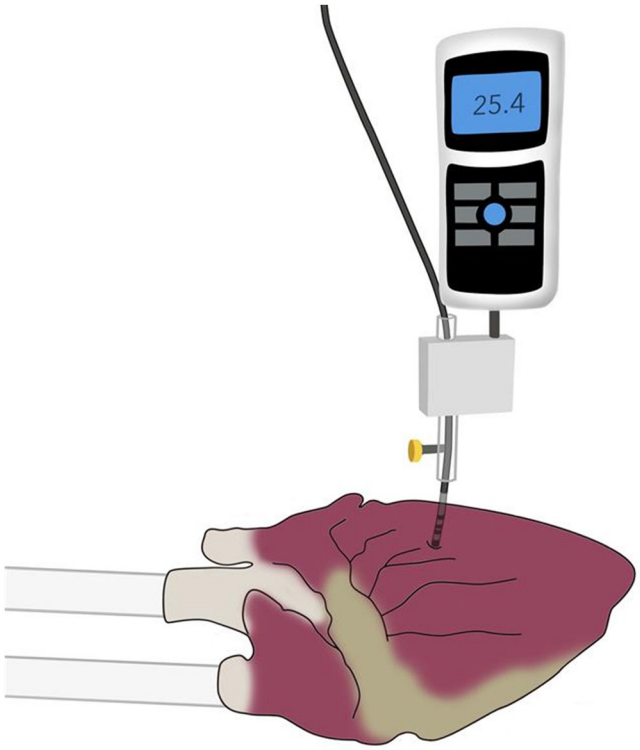

FIGURE 1 Modified Langendorff experimental set up with porcine heart. A focal PFA (pulsed field ablation) catheter attached to a force gauge was held perpendicular to the ventricular epicardium. The catheter was lowered until contact was recorded on the force gauge, and biphasic, bipolar PFA waveforms were applied to the tissue using different applied forces.

2 | METHODS

2.1 | Experimental design: Overview

This research protocol was approved by the Institutional Animal Care and Use Committee of the University of Minnesota. The data that support the findings of this study are available from the corresponding author upon reasonable request.

2.2 | Isolated heart preparation

Isolated hearts were prepared from swine ($n = 6$, mean weight 73.9 ± 10.6 kg [standard deviation]) as previously described.[18] In brief, the isolated heart preparation was perfused using a modified Langendorff set up with Krebs–Henseleit buffer. Sinus rhythm and physiological temperatures (37°C) were maintained throughout the experiment. After cardiac function was reestablished, the preparation was modified by injecting 25–50 mg (8–16 uM) of blebbistatin retrograde through the aorta to the coronary arteries. Blebbistatin is an excitation-contraction uncoupling agent that is typically used to immobilize the heart for optical mapping.[18] The exact amount delivered was determined by observed effect (i.e., when cardiac motion ceased, while electrical cardiac activity could still be observed). Once cardiac motion stopped, the heart was submerged in half normal saline (0.45% saline to mimic blood conductivity) at 37°C.

2.3 | Experimental set-up

A prototype 8 Fr focal PFA catheter (4.1 mm split tip design [0.6 mm tip, 3 mm barrel] with three 2 mm ring electrodes) was held perpendicular to the ventricular epicardium (Figure 1) using a manual micromanipulator (World Precision Instruments) and lowered until contact was made while attached to a force gauge (Mark-10). The micromanipulator enabled precise lowering of the catheter tip toward the epicardial surface of the isolated heart while observing the force values. Once the catheter was in place, 1500 V biphasic PFA waveforms were applied eight times in a bipolar manner (vectored from the split tip electrodes to the three ring electrodes) using a previously described PFA generator.[10,19–21] The number of trains and the selected voltage was chosen as a means to optimize lesion depth using this particular catheter and vectoring configuration (data not shown). Force was applied in a randomized fashion between desired force ranges (0–50 g) to ensure an equal distribution. Each heart had a random distribution of forces (random.org) to ensure an even distribution of forces were applied to each heart. Contact force was set at a certain value, then recorded during each waveform delivery using a custom LabView (National Instruments) program and averaged over all eight deliveries.

A subset of lesions was created with the tip of the catheter positioned 2 mm from the loss of measured contact (i.e., 2 mm offset condition) to determine if lesions can be detected without direct tissue contact using a bipolar focal PFA system. The micromanipulator enabled precise setting of the offset distance of 2 mm from the epicardium. Multiple locations on the epicardium of the right and left ventricle were ablated, avoiding coronary arteries and thick (>1 mm) epicardial fat.

Lesions were allowed to mature for 90 min, cross sectioned, and stained with triphenyl tetrazolium chloride to evaluate tissue viability.[22] The lesions were photographed, and the widths and depths were measured in triplicate and averaged using ImageJ (NIH) (Figure 2).[23] Lesion volume was calculated assuming a half ellipsoid shape using the following formula: $V = \frac{1}{2} \times \frac{4}{3} \times \pi \times \text{depth} \times \left(\frac{1}{2} \times \text{width}\right)^2$.

Peak current, measured internally in the PFA generator, was recorded during each PFA delivery.

To aid in the interpretation of our results, we introduced computational modeling to isolate effects of biomechanical tissue displacement. Specifically, we sought to better understand the interaction between the forces exerted by the focal catheter onto the epicardial layers, whether changes in local myocardium dimensions due to tissue displacement can explain the changes in lesion size observed experimentally. The computational modeling methodologies and results can be viewed in the Supporting Information: Figures 1–3.

2.4 | Statistical methods

Statistical analysis was conducted with GraphPad Prism (version 9.4.1) and involved linear regression, one-way ANOVA with Tukey HSD and *t*-tests. Statistical significance was defined as a $p < .05$.

3 | RESULTS

3.1 | Lesion assessment in response to contact force

A total of 82 lesions were evaluated with contact forces between 1.3 and 48.6 g. The mean lesion depth was 4.8 ± 0.9 mm (range from 2.1 mm to 7.4 mm, Figure 3A). Lesion width was 9.1 ± 1.3 mm (range 5.3–13.5 mm, Figure 3B). Lesion volume was 217 ± 96.6 mm^3 from (range 31.3–579.2 $mm,^3$ Figure 3C). Linear regression showed an increase of 0.01 mm in depth (depth = 0.01 × contact force + 4.41, $R^2 = 0.05$), 0.03 mm in width (width = 0.03 × contact force + 8.32, $R^2 = 0.13$) for each additional g of contact force, and 2.20 mm^3 in volume (volume = 2.20 × contact force + 162, $R^2 = 0.10$).

A total of eight lesions were created with the catheter positioned 2 mm from the tissue (2 mm offset). Lesion depth was 3.33 ± 0.49 mm (range 2.57–4.22 mm, Figure 4A). Lesion width was 7.04 ± 0.89 mm (range 6.04–8.41 mm, Figure 4B). Lesion volume was 89.97 ± 34.92 mm^3 (range 49.24–156.2 $mm,^3$ Figure 4C).

According to the 2017 HRS guidelines, we pooled the contact force lesion dimension data into three groups: a low force group (<10 g), a medium force group (10–30 g), and a high force group (>30 g).[24] Lesion depths using 2 mm distance were significantly lower compared to lesions that applied low, medium, and high contact forces ($p < .05$). No significant differences were detected between the contact groups. A similar trend was observed for the lesion width, with a significant difference also observed between the medium and high contact force groups (Figure 4B). Lesion volume showed significant differences between the medium and high groups compared to the offset group as well as between the high and low group (Figure 4C).

3.2 | Numerical modeling results

Simulated contact forces on the tissue slab tracked closely with the mean trend of experimental data, suggesting that the biomechanical displacement of the tissue due to the force exerted by the catheter explains the slope of the experimental data (Supporting Information: Figure 3C).

3.3 | Comparison of left and right ventricular lesion dimensions

An additional subanalysis was performed comparing lesion dimensions between the left and right ventricle to determine whether the data from left and right ventricle could be pooled. A similar distribution of contact

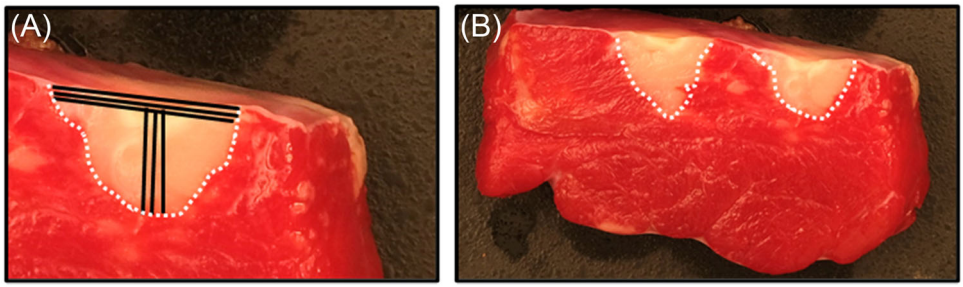

FIGURE 2 After a 90 min maturation period, lesions were cross-sectioned, stained with triphenyl tetrazolium chloride (TTC), and imaged. Depths and widths were measured in triplicate using ImageJ (A). Representative left ventricular lesions (B).

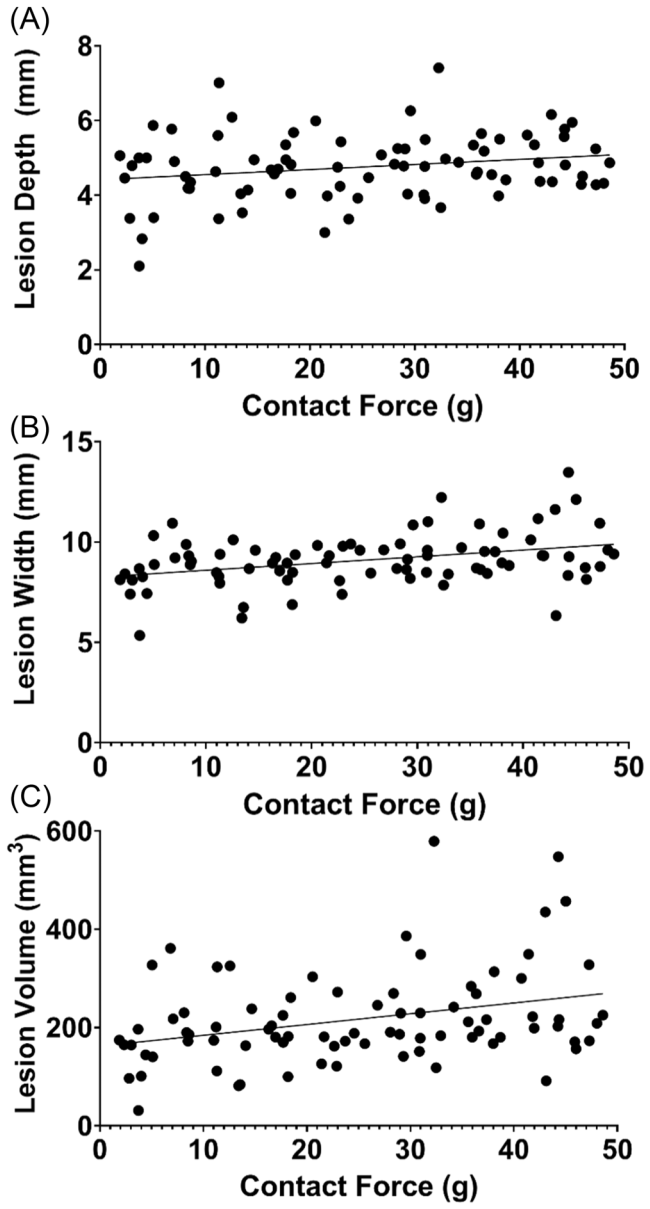

FIGURE 3 Lesion depth, width, and volume assessment for contact force applications of 0–50 g. Shown are linear regression curves ([A] depth = 0.01 × CF + 4.41, R^2 = 0.05, [B] width = 0. 03 × CF + 8.26, R^2 = 0.13, [C] volume = 2.20 × CF + 162, R^2 = 0.10). CF, contact force.

force was observed between the left and right ventricle (p = .86). Lesion depths were similar between the left and right ventricle (LV 4.9 ± 0.7 mm, RV 4.6 ± 1.0 mm, p = .11) (Supporting Information: Figure 4). Lesion widths and volumes were also independent of location with p values of 0.77 and 0.88, respectively.

3.4 | Measured current and contact force

Linear regression analysis of the maximum current and contact force associated with each PFA delivery resulted in the following relationship: Max current = 0.01 × CF + 28.6 with an R^2 value of 0.002 (Supporting Information: Figure 5). This is not significantly different from zero, suggesting no relationship between contact force and maximum applied current has been observed.

4 | DISCUSSION

An experimental procedure was designed to precisely control contact force with biphasic PFA delivered to a bipolar, focal catheter positioned perpendicularly to ventricular epicardial tissue. While lesion dimensions increased with increasing contact force, the observed changes were minimal across a broad range of forces currently used in RFA clinical practice. Lesion depth, width, and volume when the catheter was in contact with tissue were all larger than when positioning the catheter 2 mm away from the tissue. With the 2 mm offset, lesions were still created, however, those lesions were smaller than when the catheter was in direct contact, consistent with recent study devoted to noncontact/proximity.[17,25]

It has been reported in preliminary work that lesion depth increased significantly with increased contact force delivered from a focal current-controlled PFA system (CENTAURI; Galaxy Medical).[16] Deliveries were made with a 7 Fr contact force catheter, with a 3.5 mm saline irrigated (2 ml/min) ablation electrode (TactiCath SE; Abbott). Electrode-tissue contact predisposed lesion formation, and authors reported no lesions were made with electrode-tissue offset which is the main difference between this study and our study. The distance between electrodes and tissue was determined via intracardiac echocardiography. When comparing our data with previously reported data and focusing on lesions with tissue contact, our study shows less effect of increased force on lesion dimensions. It is important to note however that there are several differences between the two studies. An obvious difference was that we used a well-controlled epicardial approach that enabled precise control of force on a per pulse train basis on hearts treated with blebbistatin to avoid cardiac motion, as well as precise control of any offset using a mechanical micromanipulator. The previous in vivo study used a unipolar PFA system and the energy was delivered via an endocardial approach.[16] It is important to note that other unreported aspects of the delivered PFA waveform or experimental set up could also contribute to this observed difference. Our investigation shows that lesion dimensions increased to a small but significant degree only with application of high force, while no significant differences were noted in the range of 0–30 g commonly used clinically with RF catheters.

These results provide important new insights into the biophysics of PFA. When maintaining PFA delivery parameters both computationally and experimentally, there was no correlation between varying levels of contact force within the range of recommended guidelines and PFA lesion dimensions, although a trend was observed. This is in contrast to power-controlled radiofrequency catheters, for which one study reported an additional 2.8 mm maximum depth, 3.5 mm maximum diameter, and 502 mm^3 maximum

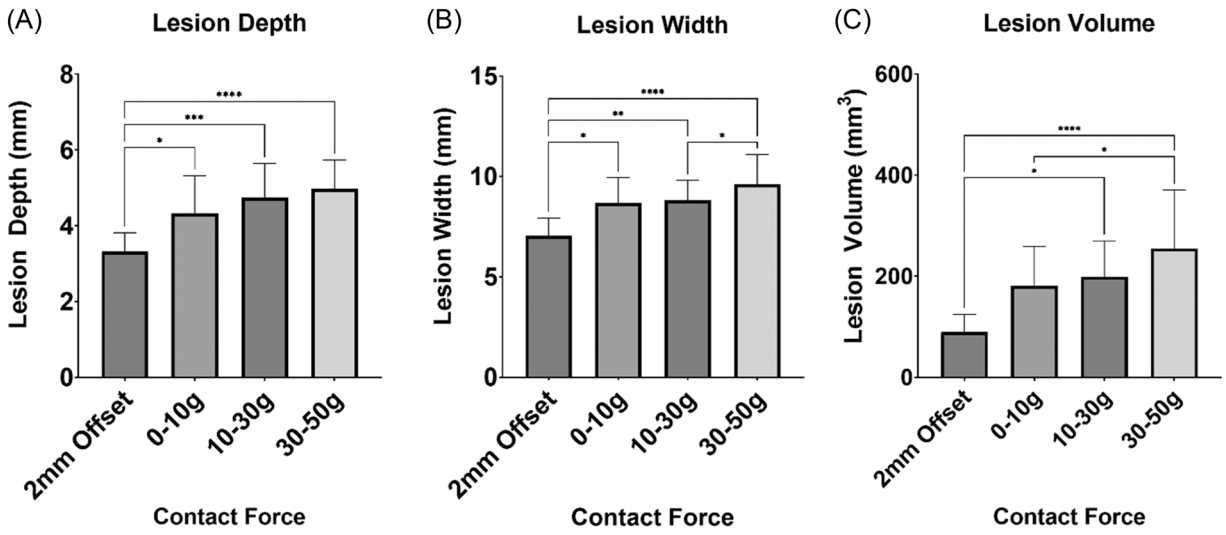

FIGURE 4 A comparison of lesion depth, width, and volume with 2 mm offset (electrode 2 mm away from tissue and not in tissue contact), 0–10 contact force, 10–30 contact force, and 30–50 g contact force (*$p < .05$, **$p < .01$, ***$p < .001$, ****$p < .0001$).

volume at 30 W as contact force increased from 2 to 30 g.[26] While monitoring contact force is also relevant for some radiofrequency catheters due to steam pop incidence, this does not seem to be a relevant safety consideration for PFA deliveries.[7,26] Although contact force is a primary driver for pulmonary vein reconnection in large radiofrequency ablation clinical studies, there is no indication that contact force optimizes PFA delivery to achieve homogenous lesion formation for PFA.[26-31]

Current contact force technologies measure microdisplacement with springs and/or magnetic sensors embedded in catheter tips that correlate with tip force.[7,26,28,29,31,32] It is possible that these technologies and real-time signal processing algorithms which incorporate target tissue movement, result in different contact force measurements compared to the current study. Our study delivered blebbistatin to limit cardiac motion and used an external force gauge to measure contact force, providing precise control, and measurements of contact force.

Modeling results reveal that deformation of tissue due to contact force is a 3D phenomenon, affecting tissue throughout the wall thickness (Supporting Information: Figure 3). Our simulations were designed to evaluate the isolated effect of tissue deformation under the catheter, and they demonstrated that tissue deformation does account for a (slight) increase in lesion depth as contact force increases. Importantly, the slopes of contact force versus lesion dimensions shows very similar trends between experimental data and modeling data (Supporting Information: Figure 3C).

Despite control of experimental conditions, we observed some lesion size variability in the present study. We attempted to identify the cause of this variability by studying the effect of biomechanical displacement of adipose tissue computationally as well as by evaluating delivered currents. Our findings suggest that neither potential biomechanical interference of adipose tissue thickness nor variation of delivered currents had a discernable effect on the observed variability (Supporting Information: Figures 3D, 4). Further analysis of lesion images did identify that lesions with the lowest lesion depths had an adipose tissue layer >0.5 mm despite our best efforts to avoid areas of epicardial fat (Supporting Information: Figure 6). Adipose tissue has a lower conductivity than myocardium and a thicker adipose tissue layer could thus theoretically reduce the effects of pulsed electric fields on the underlying myocardium. However, it is unknown if such interaction was significant in the present study. Further research on understanding the interaction between adipose tissue and pulsed electric field induced lesions is needed. That said, lesion size variability in the present study is within the range of what is reported in the literature for PFA.[16,33-35] For example, previously reported work studying contact force delivered from a unipolar focal PFA system in a porcine model showed lesion size depth ranges from 2.5 to 8 mm.[16]

4.1 | Limitations

This experimental study was conducted under controlled laboratory conditions using an isolated porcine working heart model perfused with Krebs–Henseleit buffer. Only the ventricular myocardium was targeted to facilitate clear lesion visualization and measurements. Applicability of this work to clinical practice will require further studies, including in diseased cardiac tissues (e.g., remodeled atrial tissue, infarcted fibrotic ventricular tissue) and long-term durability of lesions. Reported lesion dimensions of these epicardial lesions may not be directly translatable of endocardial lesion dimensions but are assumed to be relevant.

In the present study, eight pulse trains as well as 1500 V of applied voltage were used per lesion. The impact of a lower number of pulse trains or lower applied voltages has not been assessed.

5 | CONCLUSION

Increasing contact force using a bipolar, biphasic focal PFA system has minimal effects on acute lesion dimensions in an isolated porcine heart model and achieving tissue contact is more important than the force with which that contact is made.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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