Endocardial vs. Epicardial Ventricular Radiofrequency Ablation:

Utility of in vivo Contact Force Assessment

Running title: Sacher et al.; Utility of contact force for VT ablation

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Abstract:

**Background** - Contact force (CF) is an important determinant of lesion formation for atrial endocardial radiofrequency (RF) ablation. There are minimal published data on CF and ventricular lesion formation. We studied the impact of CF on lesion formation using an ovine model both endo and epicardially.

**Methods and Results** - Twenty sheep received 160 epicardial and 160 endocardial ventricular RF applications using either a 3.5 mm irrigated-tip catheter (Thermocool, Biosense-Webster, n=160) or a 3.5 irrigated-tip catheter with CF assessment (Tacticath, Endosense, n=160), via percutaneous access. Power was delivered at 30 watts for 60 seconds when either catheter/tissue contact was felt to be good or when CF>10g with Tacticath. Following completion of all lesions acute dimensions were taken at pathology. Identifiable lesion formation from RF application was improved with the aid of CF information, from 78% to 98% on the endocardium (p<0.001) and from 90% to 100% on the epicardium (p=0.02). The mean total force was greater on the endocardium (39±18g vs 21±14g for the epicardium, p<0.001) mainly due to axial force. Despite the Force-Time-Integral being greater endocardially, epicardial lesions were larger (231±182mm³ vs 209±131mm³; p=0.02) probably due to the absence of the heat sink effect of the circulating blood and covered a greater area (41±27 vs 29±17mm²; p=0.03) due to catheter orientation.

**Conclusions** - In the absence of CF feedback, 22% of endocardial RF applications that are felt to have good contact didn’t result in lesion formation. Epicardial ablation is associated with larger lesions.

**Key words:** ablation; endocardium; epicardial; ventricular tachycardia; Contact Force
Introduction

Contact force (CF) is an important determinant of lesion formation for endocardial atrial catheter ablation\(^1\). However little is known about its impact on ventricular radiofrequency (RF) ablation (particularly epicardial ablation). We investigated ventricular lesion formation after RF ablation on the epicardium (EPI) and endocardially (ENDO) in a sheep model using standard irrigated-tip catheter vs a contact force sensing catheter.

Methods

Animal Preparation

The experimental protocols were handled in compliance with the Guiding Principles in the Use and Care of Animals published by the National institutes of Health (NIH Publication No. 85-23, Revised 1996).

Twenty-two sheep (6 ±1yo, 55 ±10kg) were sedated with an intramuscular injection of 20 mg/kg ketamine hydrochloride and anaesthetized with sodium pentobarbital (10 mg/kg). Slow intravenous infusion of saline maintained hydration throughout surgery, and anaesthesia was maintained using continuous intravenous infusion of ketamine (500 mg/h) and pentobarbital (150 mg/h). The trachea was intubated through a midline cervical incision for connection to a respirator (Siemens Servo B, Berlin, Germany). Sheep were then ventilated using room air supplemented with oxygen. An intravenous access was placed in the internal jugular vein for infusion of drugs and fluids. Arterial blood gases were monitored periodically (Radiometer, Copenhagen, Denmark), and ventilatory parameters were adjusted to maintain blood gases within physiological ranges.

Access to the right ventricle (RV) was performed via femoral vein and a long steerable 8.5 Fr sheath (Agilis, St Jude Medical) was inserted. The left ventricle (LV) was accessed via a
retrograde aortic approach and a short 7 or 8 Fr sheath was placed in the femoral artery. Epicardial access was performed with a tuohy needle (Braun, Germany) via a subxyphoid approach as previously described\textsuperscript{2,3}. A 8.5 Fr Agilis (St Jude Medical) sheath was used to manipulate the ablation catheter in the pericardium. Intra-pericardial fluid was drained continuously with a vacuum system connected to the epicardial sheath.

Two sheep were excluded from this study: one because of an epicardial access problem and the second one due to intractable VF that could not be converted by several DC shocks after the initial endocardial LV lesion.

**Contact Force Measurement**

The Tacticath catheter (Endosense, Switzerland) displays CF information owing to a force sensor incorporated into its distal part between the second and third electrode. The force sensor consisted of a deformable body and 3 optical fibers to measure microdeformations that correlate with force applied to the catheter tip. Infrared laser light is emitted through the proximal end of the 3 optical fibers. The light is reflected by fiber Bragg gratings on the deformable body at the distal end of the optical fibers, near the tip of the catheter. Applying CF to the tip of the catheter produces a microdeformation of the deformable body, causing the fiber Bragg gratings to either stretch or compress, which changes the wave length of the reflected light. The change of wave length is proportional to the CF applied to the tip. By monitoring the wave length of the reflected light in the 3 fibers, the system is able to calculate and display the vector of the CF (magnitude and angle).

**Ablation**

Two operators (FS &PJ) performed both endocardial and epicardial ablation of the right and left ventricle with a 3.5 mm open irrigated-tip catheter (Thermocool, Biosense Webster, Diamond
Car, USA) [THERM group] or a 3.5 mm open irrigated-tip catheter enabling contact force information (Tacticath, Endosense, Switzerland) [Tacticath group]. In each sheep, a mean of 16 RF applications were performed (4 at the ENDO of the left ventricle (LV), 4 at the ENDO of the right ventricle (RV), 4 at the EPI of the RV and 4 at the EPI of the LV, going from apical to basal for each series of 4 (figure 1a). Epicardial lesions were performed anteriorly and endocardial lesions were performed inferiorly to give separation between the lesions at pathology ensuring a perfect match between RF applications and lesions found at necropsy in the absence of electro-anatomic system. The order of RF application (RV vs LV, ENDO vs EPI) was randomized for each animal.

RF was delivered when electrode contact was achieved as assessed by recording high amplitude potentials, tactile feedback and fluroscopy or when contact force > 10g (when possible) for the Tacticath group. Energy was delivered in power control mode at 30W for 60 seconds with a flow rate titrated to obtain a target temperature between 39-43°C.

Impedance was recorded and the percent of impedance drop at 10 seconds was calculated. Impedance was taken just before RF delivery (baseline impedance) and 10 seconds after RF start (impedance t10). Difference of local ventricular bipolar amplitude before and after each application was measured with the caliper function of the Labsystem Pro (Bard, USA). A cut-off value of 50% amplitude reduction was arbitrarily chosen to identify a presumed effective lesion. In the Tacticath group, CF as well as Force-Time Integral (FTI) (area under the curve of CF for the duration of RF delivery) were monitored continuously.

In case of steam “Pop” or sustained polymorphic ventricular tachycardia (VT)/ ventricular fibrillation (VF) requiring defibrillation, RF was stopped immediately and the RF duration was noted.
Necropsy

After completion of the lesion set, the sheep was sacrificed and the heart explanted. In situ lesions on lung and/or mediastinum were examined. Gross anatomical examination was performed immediately to identify and measure lesions. Measurements were performed with a micrometer (±0.1mm). Inflammation (red collar, figure 1b) was excluded from the lesion size. In case of RF application on epicardial fat, the myocardial lesion sizes were not included in the analysis.

Lesions volume was calculated according to the formula of Yokoyama et al. The maximum depth (a), maximum diameter (b), depth at the maximum diameter (c), and surface diameter (d) of the lesion were measured. Lesion volume was calculated as: volume = \( \frac{1}{6} \pi \times (A \times B^2 + C \times D^2)/2 \)\(^5,6\).

Statistical analysis

Quantitative variables were expressed as mean +/- standard deviation. We compared characteristics of RF applications/lesions performed with the 2 types of catheters (Thermocool™ and Tacticath™) on the endocardium and then on the epicardium. We also compared all RF applications/lesions performed on the endocardium (whatever catheter used) to those performed on the epicardium. Comparisons of quantitative variables between groups were performed using linear mixed models where correlation between animal values were handled through the unstructured covariance matrix of random effects through autocorrelated error structures. Comparison of the number of lesions found at necropsy and transmurality of the lesions between groups were performed using marginal logistic regression models. Bivariate correlation between axial force and lesion depth, lateral force and lesion depth/surface area/volume were performed with the Pearson test. A value p<0.05 was considered statistically significant.
Results

A total of 320 RF applications were performed (80 on the endocardium and 80 on the epicardium with each catheter). There were no differences in terms of actual power delivery, RF duration, irrigation rate according to either catheter or ventricular surface (table 1). Contact force achieved was greater endocardially with a total contact force of 39 ±18 vs 21 ±14 grams epicardially (p<0.001) and a force time integral (FTI) of 2338 ±1076 vs 1163 ±705 g.sec. This was mainly due to axial force (28 ±19g vs 11 ±9g; p=0.005) although lateral force was also higher endocardially (22 ±12g vs 16 ±10g; p=0.008). Of note, catheter orientation was mainly parallel to the tissue epicardially whereas, endocardially, it was predominantly perpendicular to the tissue.

Mean impedance drop at 10 seconds was lower on the endocardium (12 ±7%) vs. epicardium (17 ±10% ; p<0.001) as well as the percentage of applications with an impedance drop >10% at 10 seconds (54% vs 71%; p=0.004). No difference was found, between EPI and ENDO, in term of EGM decrease.

Steam pops occurred 13 times in 4 sheep (ENDO=7, EPI=6) during RF application, predominantly with the thermocool catheter (12 vs. 1 with Tacticath). When the steam pop occurred with the Tacticath catheter the total force was 60g and FTI 3300g.sec.

Thirteen applications (ENDO=5 and EPI=8) in 6 sheep induced VT/VF that required external cardioversion.

Necropsy

A total of 293 RF applications were identified at necropsy (92%). On the endocardium, 62 ventricular lesions were identified on 80 RF (78%) applications in the THERM group whereas 78/80 (98%) were identified in the Tacticath group (p=0.007) (Table 1). Epicardially, 20 ablation
sites were identified on fat; and therefore were not included in the analysis (12 in the THERM
group and 8 in the Tacticath group). Sixty-one of 68 (90%) RF applications in the THERM

group vs 72/72 (100%) in the Tacticath group (p=0.02) were identified. Of note, when local fat

thickness was ≤1mm, 6 myocardial lesions out of 7 RF applications could be identified.
Maximal myocardial lesion depth was 2mm. But when fat thickness was >1mm, no myocardial

lesion could be identified (maximal CF 16g).

A 50% decrease in electrogram amplitude (before and after RF applications) was in favor

of lesions found at necropsy: 156/159 [98%] vs 80/114 [70%] in the absence of EGM amplitude
decrease (p<0.001). However lesions sizes were not statistically different depending on this
dercrease nor on the impedance drop.

Lesions were larger epicardially (231 ±182 vs 209 ±131 mm³; p=0.02) and covered a
greater area (41 ±27mm² vs 29 ±17 mm², p=0.03). There was a trend toward deeper lesions
when applications were performed endocardially (ENDO: 4.6 ±1.7mm vs EPI: 4.1 ±1.5mm;
p=NS) with a weak correlation (r=0.19, p=0.03) between axial force and lesion depth, but not
between lateral force and lesion depth, surface area or volume. There was no difference in

achieving transmural lesions between epi and endocardial RF delivery (ENDO: 23% of
transmural lesion vs EPI: 13%; p=NS) nor depending on the catheter used. Transmural lesions
were mainly found in the right ventricle (n=40) or at the left ventricular apex (n=17) where
ventricular wall are thinner. Endocardial LV lesions were larger than RV endocardial ones
despite identical RF settings (irrigated tip catheter, 30Watts for 60 seconds) but with a trend to
higher contact force (mainly due to axial force) and FTI (Table 2).

In the CF group alone, the mean total contact force and force time integral were higher in
RF applications with lesions found at necropsy than those where no lesion was identified (33
±18g vs 7 ±0.5g; p<0.001 and 1941 ±1068g.sec vs 404 ±32 g.sec; p<0.001). The relationships between CF, FTI and lesion depth/volume are reported in figure 2. On the endocardium, the mean lesion depth and size increase with the FTI (figure 2A). However this visual correlation was not present on the epicardium (figure 2B) where a FTI between 1000 to 2500g.sec resulted in the same lesion volume in average. The maximal total CF and FTI for RF applications not resulting in lesions at necropsy were 7 gram and 439 gram.sec. The minimal total CF and FTI for RF applications resulting in lesions at necropsy were 10g/609g.sec on the endocardium and 5g/273g.sec on the epicardium.

Of note in 3 sheep (2 with Thermocool 1 with Tacticath), pulmonary lesions facing the epicardial RF ablation site were identified (Figure 3). For the Tacticath patient, the force was not directed toward the heart.

Discussion
This study provides a number of unique insights into acute ventricular lesion formation:

1. Even with experienced operators a fifth of ventricular endocardial RF applications do not result in lesion formation when fluoroscopy, tactile feedback, and EGM amplitude are used to assess contact

2. The addition of CF information dramatically decreases the number of RF applications that do not result in lesion formation.

3. Absence of circulating blood on the epicardium (no heat sink effect) allows creating larger lesion on the epicardium. Lower axial CF achieved epicardially associated with parallel catheter orientation alters the lesion geometry to being broad and shallow. These changes in geometry could have important implications for VT ablation.
Lesion Formation

In the Thermocool group, 22% of RF applications did not result in lesion formation. This was despite the impression of being in good contact based on tactile feedback, fluoroscopy and high amplitude electrograms. The 2 RF applications with CF information (Tacticath group) which did not result in lesion at necropsy had a low CF <10g and/or a FTI <500g.s due to catheter instability or displacement meaning that the amount of energy received to the tissue was too low to create lesion. Interestingly in the Toccata study, 12% of RF applications (operator blinded to CF information) were performed with a CF <5g. In an oral communication, showing the 12 months follow-up of the AF population of this Toccata study, all patients with a mean CF <10g during RF applications experienced AF recurrence. CF feedback seems less crucial in the pericardial space because this is a virtual space, so in the absence of fluid, the catheter is in contact with the tissue. Whereas a CF <10g resulted in the absence of lesion on the endocardium, this was not the case on the epicardium. On the epicardium, limitation of RF efficacy by fat occurred for 20/160 RF applications. However, these 20 applications could be identified on epicardial fat. A limited myocardial lesion could even be identified when local fat thickness was <1mm but in these cases the maximal lesion depth seen was 2mm.

The mean impedance drop during the first 10 seconds was more important during ablation on the epicardium vs endocardium whatever the catheter used (Thermocool p<0.001 and Tacticath p<0.001) but was not able to predict lesion size. A decrease ≥10% of impedance during the first 10 seconds of RF application was not able to predict lesion at necropsy, neither was the decrease >50% of the electrogram. Yokoyama et al. emphasized that the magnitude of impedance decrease during RF applications increased significantly with increasing CF. However, at the same CF, there was no difference in the magnitude of impedance decrease between 30 and
50W whereas these applications resulted in different lesion volume. We also reported a poor correlation between impedance drop and lesion depth. Concerning the EGM amplitude, although a reduction of electrogram amplitude was in favor of lesion formation, 2% of applications with lesion found at necropsy did not have a EGM amplitude reduction >50%. This may be due to the fact that RF applications were performed in healthy ventricular myocardium whereas spatial resolution of the catheter allows recording of normal tissue activities outside the lesion. Looking at CF information, total force was much higher when ablation was performed on the endocardium (39 ±18 vs 21 ±14g) due predominantly to an increased axial force whereas on the epicardium lateral force was superior to axial force (Table 1). Whereas the catheter tip was mainly oriented parallel on the epicardium due to its constraint from the parietal pericardium, this was not the case on the endocardium. The electrode orientation has previously been shown to influence lesion characteristics in a bench model. In atrium, optimal contact force has been evaluated around 20g. Concerning safety, minimal forces to mechanically perforate ventricles (without RF delivery) are higher than for atria (131 g (RA), 159g (LA),168g (RV) and 227g (LV)), however the force required to perforate when RF is delivered can be as low as 77g in the atrium.

Whereas it has been shown that CF was correlated with lesion volume, it seems that a parameter coupling instantaneous total force and application duration (FTI) was more accurate to predict lesion size. This was visually verified for endocardial ventricular applications in this study but not for epicardial ones. Moreover in the Tacticath group, FTI was twice lower when applications were performed on the epicardium compared to the endocardium however lesions volume were larger on the epicardium (231 ±182mm3 vs 209 ±131mm3; p=0.02 - Table 1).
This was possibly due to the absence of the heat sink effect of circulating blood on the epicardium where energy stays locally.

On the ventricular endocardium, as earlier demonstrated for the atria, a total force<10g or a FTI<500g.sec results in no lesion being identifiable. However optimal CF for ablation seems to be higher than for atria, based on figure 2a. A total force of 30 to 40 g and a FTI between 2000 to 2500 g.sec seem to create optimal lesion.

On the epicardial side, CF information may not be as useful as endocardially, CF <10g or an FTI<500 were enough to create lesion and there was no clear difference of lesion depth or volume using 11-20, 21-30 or 31-40g of force. Moreover it was infrequent to obtain a force >40g on the pericardium when the catheter laid on the ventricles in the absence of adherences. Contact Force >40g was obtained mainly when catheter faced the concavity of the pericardial space. Applying energy when the force is not directed toward the heart may result in lung lesion (Figure 3). It is particularly important that the vector of force is pointing towards the myocardium and not the lung, to prevent/minimize pulmonary lesions.

Limitations

Due to the design of the study, the operators were not blinded to the catheter type. To ensure recognition of the different ablation site at necropsy a systematic approach was performed.

Lesions characteristics, if RF had been applied at different sites, may have been different due to differing loads on the catheter dependent upon the angle at which the catheter tip makes contact with the tissue8. Other variables such as electrode surface area in contact with the tissue and local blood flow known to effect lesion formation could not be controlled for. Prevalence of ventricular arrhythmias during RF application is much higher in animal model compared to patients.
Conclusions

More than 20% of endocardial ventricular RF applications are not associated with tissue lesion in the absence of CF information with experienced operators. Epicardial ablation is associated with wider and larger lesions while endocardial ablation results in deeper lesions.

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Conflict of Interest Disclosures: Frederic Sacher received speaking honorarium from Biosense Webster and Biotronik. Pierre Jais and Michel Haissaguerre are receiving consulting fees from Biosense Webster. Tacticath catheters were given by Biotronik France.

References:


Table 1: Electrophysiological parameters during ablation and lesions characteristics at necropsy depending site of ablation (Endo: endocardium, Epi: epicardium, THERM: Thermocool, RF: radiofrequency)

<table>
<thead>
<tr>
<th></th>
<th>THERM group</th>
<th>Tacticath group</th>
<th>p-value</th>
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<tbody>
<tr>
<td></td>
<td>Endo</td>
<td>Epi</td>
<td>Endo</td>
</tr>
<tr>
<td>RF parameters</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Number of RF</td>
<td>80</td>
<td>80</td>
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</tr>
<tr>
<td>applications</td>
<td></td>
<td></td>
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<tr>
<td>Power (Watts)</td>
<td>30 ±2</td>
<td>30 ±1</td>
<td>30 ±2</td>
</tr>
<tr>
<td>RF duration</td>
<td>57 ±14</td>
<td>55 ±13</td>
<td>59 ±5</td>
</tr>
<tr>
<td>(seconds)</td>
<td></td>
<td></td>
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<tr>
<td>Mean pump flow</td>
<td>25 ±11</td>
<td>23 ±11</td>
<td>25 ±14</td>
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<tr>
<td>rate during</td>
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<tr>
<td>ablation (ml/min)</td>
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<tr>
<td>Percentage of</td>
<td>13 ±8</td>
<td>18 ±10</td>
<td>10 ±6</td>
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<td>Impedance drop</td>
<td></td>
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<tr>
<td>at 10 sec (%)</td>
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<tr>
<td>Contact Force</td>
<td>Total Force</td>
<td>39 ±18</td>
<td>21 ±14</td>
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<tr>
<td>Force data</td>
<td>(gram)</td>
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<tr>
<td>Axial Force</td>
<td>28 ±19</td>
<td>11 ±9</td>
<td>-</td>
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<tr>
<td>(gram)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lateral Force</td>
<td>22 ±12</td>
<td>16 ±10</td>
<td>-</td>
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<tr>
<td>(gram)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Force Time</td>
<td>2338 ±1076</td>
<td>1163 ±705</td>
<td>-</td>
</tr>
<tr>
<td>Integral (gram.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>sec)</td>
<td></td>
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<td></td>
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<tr>
<td>Necropsy</td>
<td>Number of</td>
<td>61/68 (90%) [12</td>
<td>78 (98%)</td>
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<tr>
<td>Lesions</td>
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<td>[12 on fat]</td>
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<tr>
<td></td>
<td>62 (78%)</td>
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<tr>
<td>Lesion Depth</td>
<td>4.7 ±2.1</td>
<td>4.1 ±1.6</td>
<td>4.4 ±1.4</td>
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<td>(mm)</td>
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<tr>
<td>Lesion Width</td>
<td>5.3 ±1.7</td>
<td>6.3 ±1.9</td>
<td>5.1 ±1.6</td>
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<td>(mm)</td>
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<tr>
<td>Lesion Length</td>
<td>7.7 ±2.2</td>
<td>8.4 ±2.6</td>
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</tr>
<tr>
<td>(mm)</td>
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<tr>
<td>Volume (mm³)</td>
<td>229 ±147</td>
<td>249 ±183</td>
<td>209 ±131</td>
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Table 2: Contact Force information and lesions size depending on RF application site. (RV: right ventricle, LV: left ventricle)

<table>
<thead>
<tr>
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<tr>
<td>Total Force</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>(gram)</td>
<td>36 ±15</td>
<td>43 ±20</td>
<td>NS</td>
<td>20 ±12</td>
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<tr>
<td>Axial Force</td>
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<tr>
<td>(gram)</td>
<td>23 ±16</td>
<td>34 ±21</td>
<td>0.006</td>
<td>10 ±9</td>
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<tr>
<td>Lateral Force</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(gram)</td>
<td>24 ±12</td>
<td>20 ±13</td>
<td>NS</td>
<td>15 ±10</td>
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<tr>
<td>Force Time</td>
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<tr>
<td>Integral</td>
<td>2133 ±881</td>
<td>2549 ±1220</td>
<td>NS</td>
<td>1063 ±724</td>
</tr>
<tr>
<td>Necropsy</td>
<td></td>
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<tr>
<td>Lesion Depth</td>
<td></td>
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</tr>
<tr>
<td>(mm)</td>
<td>4.0 ±1.4</td>
<td>5.0 ±2.0</td>
<td>0.001</td>
<td>3.6 ±1.3</td>
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<tr>
<td>Volume</td>
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<tr>
<td>(mm³)</td>
<td>179 ±134</td>
<td>249 ±136</td>
<td>0.003</td>
<td>221 ±178</td>
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Figures Legends:

Figure 1: Panel A represents 4 endocardial lesions performed on the inferior wall of the left ventricle. On panel B, the lesion was sliced in the middle and the depth was measured (black arrow) without taking into account the inflammation (red collar: white arrows).

Figure 2: Mean lesion depth and volume of lesions performed with the Tacticath catheter depending on contact force (CF) and force-time integral (FTI) applied on the endocardium-figure 2A vs epicardium-figure 2B.

Figure 3: Lung lesion due to RF delivered on the epicardium with the catheter not well applied toward the heart.
Lung

Epicardial RF lesion

Heart within Pericardial space
Endocardial vs. Epicardial Ventricular Radiofrequency Ablation: Utility of in vivo Contact Force Assessment
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