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The effect of elastic modulus on ablation catheter contact area

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Abstract

Cardiac ablation consists of navigating a catheter into the heart and delivering RF energy to electrically isolate tissue regions that generate or propagate arrhythmia. Besides the challenges of accurate and precise targeting of the arrhythmic sites within the beating heart, limited information is currently available to the cardiologist regarding intricate electrode-tissue contact, which directly impacts the quality of produced lesions. Recent advances in ablation catheter design provide intra-procedural estimates of tissue-catheter contact force, but the most direct indicator of lesion quality for any particular energy level and duration is the tissue-catheter contact area, and that is a function of not only force, but catheter pose and material elasticity as well.

In this experiment, we have employed real-time ultrasound (US) imaging to determine the complete interaction between the ablation electrode and tissue to accurately estimate contact, which will help to better understand the effect of catheter pose and position relative to the tissue. By simultaneously recording tracked position, force reading and US image of the ablation catheter, the differing material properties of polyvinyl alcohol cryogel^[1] phantoms are shown to produce varying amounts of tissue depression and contact area (implying varying lesion quality) for equivalent force readings. We have shown that the elastic modulus significantly affects the surface-contact area between the catheter and tissue at any level of contact force. Thus we provide evidence that a prescribed level of catheter force may not always provide sufficient contact area to produce an effective ablation lesion in the prescribed ablation time.

1. INTRODUCTION

Cardiac ablation consists of navigating a percutaneously inserted catheter into the heart and delivering RF energy to electrically isolate tissue regions that generate or propagate arrhythmia. Reported ventures into the treatment of cardiac arrhythmias, especially atrial fibrillation, have been discouraging, with a fairly high number of patients requiring revision^[2]. Besides the challenge of inadequate visualization for accurate and precise targeting of the arrhythmic sites within the beating heart, limited information is currently available to the cardiologist regarding intricate electrode-tissue contact which directly impacts the produced lesions and the extent of induced tissue damage. Recent advances in ablation catheter design provide intra-procedural estimates of tissue-catheter contact force which are a valuable guide to the cardiologist in producing high-quality lesions. Contact force, however, is only a part of the equation. The most direct indicator of lesion quality for

any particular energy level and duration is the tissue-catheter contact area, and that is a function of not only force but catheter pose and material elasticity as well.

In this experiment, we have employed real-time ultrasound (US) imaging to determine the complete interaction between the ablation electrode and tissue to accurately estimate contact, which will help to better understand the effect of catheter pose and position relative to the tissue. By simultaneously recording tracked position, force reading and US image of the ablation catheter, the differing material properties of polyvinyl alcohol cryogel^[1] phantoms are shown to produce varying amounts of tissue depression and contact area (implying varying lesion quality) for equivalent force readings. This will facilitate achieving deeper, larger and more fully developed lesions for enduring suppression of the arrhythmic pathway.

2. MATERIALS AND METHODS

2.1 Polyvinyl alcohol cryogels

Three polyvinyl alcohol cryogel phantoms were created at a concentration of 6% and underwent a varying numbers of freeze-thaw cycles. Gel 1 underwent 2 freeze-thaw cycles, gel 2 underwent 3 cycles and gel 3 underwent 4 cycles. The elastic modulus of the gels was tested on a Bose ELF 3200 using a 3mm indenter. Two 2.5cm disks of 1.5cm mean height were cut from each gel phantom. Each disk was tested at two locations to determine elastic modulus.

2.2 US Imaging

Ultrasound images were taken using the 6L3 hand-held probe of an Acuson Sequoia 512 imaging system at 6.0 Mhz.

2.3 Ablation System

The Biosense ThermoCool SmartTouch catheter was used in conjunction with a Carto3 cardiac ablation system to track the location and sense the contact force of the ablation catheter with the cryogel phantoms.

2.4 US mount and catheter guide

A custom-fabricated acrylic fixture provided a mounting structure for the US probe and guide tubes for the ablation catheter. The US probe was attached to the fixture at a 45 degree angle to the horizontal gel phantom, and 2.75mm I.D. rigid acrylic tubing was attached to the fixture at both 90 degrees and 60 degrees to the gel surface to serve as guides for the 8F ablation catheter. The catheter guides ended 5-7mm above the surface of the gel phantoms.

2.5 Experimental Procedure

The gel phantom and mounting structure with US probe affixed were placed within a small water bath filled with an ad-hoc saline solution (25mg table salt in 5.7L tap water) to allow the catheter to sense ~130 Ohm resistance to reference patch ground leads taped to side of the bath below the water line. The water bath had 3 Carto3 reference patches attached to the outside of the bottom of the bath, and three reference patches affixed to the outside of the

bath near the top and was positioned on a non-ferrous procedure table above a Carto3 magnetic location pad below the table. After initializing the Carto3, the catheter was fed through the 90 degree guide tube, and pushed into the gel until a force reading of 60 – 80 gm was achieved. The catheter position and force reading was the recorded with the Carto3 system while an US image was captured simultaneously. The catheter was withdrawn to a force reading of 20-40 gm and another point and US image recorded, then withdrawn to a 10-20gm reading. The final point and image was attempted with the catheter just touching the surface of the phantom without depression. Actual force values at the surface ranged from 0-5 gm.

This sequence of four images, locations and force readings was repeated at four other points (5 total) on the phantom. The catheter was then withdrawn completely and fed through the 60 degree guide tube and the process repeated for another 5 locations on the phantom. All three phantoms were so tested, resulting in a total of 120 images, force readings and locations.

3. RESULTS

3.1 Image analysis

The catheter was segmented manually from the US images and the apparent penetration below the surface of the phantom was measured by calculating the Euclidean distance between manually selected pixel coordinates using the Line Profile tool of Analyze. Figure 7 and Figure 8 represent the segmentation and measurement of the greatest displacement images from gel 1 trial 2 and gel 3 trial 2.

Image based measurements were found to be in agreement with the displacement distances calculated from Carto3 magnetic tracker coordinates as shown in Table 2.

3.2 Force versus displacement

The coordinates of the final test at each site (just touching the surface of the gel) were used as a displacement reference for the other test coordinates for that site. As expected, the stiffer gels exhibited less displacement at similar force readings than the softer gels, and similar displacement required greater force as shown in Figure 3, Figure 4, and Figure 5.

The data collected at 60 degrees of contact yielded similar results. The softest gel imposed the largest displacement. The magnitude of displacement and non-linear effect of force was consistent with the 90 degree data. Figures 6-9 show each of the five trials for the three gels.

3.3 Catheter contact

The displacement values were used as h and the radius of an 8F catheter (1.33... mm) used as r in the cylindrical surface area equation to estimate surface contact area.

$$A=2\pi rh+2\pi r^2 \quad (1)$$

Figure 9 illustrates the comparison of calculated ablation catheter contact area as derived by equation 1 vs force for all three gels at 90 degrees. logarithmic trend lines illustrate that contact area of gel 3 (stiff) is significantly less than that of gel1 (soft) at any catheter pressure. Over the expected working range of 40-60 mg the contact area of gel one is greater by 15 to 30 mm², or 25 to 30%. Figure 10 shows similar relationships at 60 degrees.

4. CONCLUSION

We have confirmed that the elastic modulus of polyvinyl cryogels are increased by additional freeze-thaw cycles, and that the modulus of the gels lies within the range of values expected of human cardiac tissues[3]. We have further shown that the elastic modulus significantly affects the surface-contact area between the catheter and tissue at any level of contact force. Thus we provide evidence that a prescribed level of catheter force may not always provide sufficient contact area to produce an effective ablation lesion in the prescribed ablation time.

This experiment is in support of the ongoing efforts of our laboratory in developing novel image guidance technology that leverages pre- and intra-operative imaging, including ultrasound, as well as real-time modeling of the ablation lesions for online therapy feedback. The overall goal is to improve visualization in therapy delivery and monitoring in order to achieve significantly superior intervention outcomes.

Acknowledgments

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Figure 1.
Measuring deepest displacement for trial 2 of gel 1.

Figure 2.
Measuring deepest displacement for trial 2 of gel 1.

Figure 3.
Displacement vs. force for gel 1 (soft) at 90 degrees.

Figure 4.
Displacement vs. force for gel 2 (medium) at 90 degrees.

Figure 5.
Displacement vs. force for gel 3 (stiff) at 90 degrees.

Figure 6.
Displacement vs force for gel 1 (soft) at 60 degrees.

Figure 7.
Displacement vs force for gel 2 (medium) at 60 degrees.

Figure 8.
Displacement vs. force for gel 3 (stiff) at 60 degrees.

Figure 9.
Surface area vs force for all three gels at 90 degrees.

Figure 10.

Surface area vs force for all three gels at 60 degrees.

Table 1

Gel phantom construction and stiffness

Gel	Freeze-thaw cycles	Elastic Modulus (kPa)
1	2	170.00
2	3	285.75
3	4	315.75

Table 2

Representative image derived displacement values at 90 degrees

Gel	Trial	Force (mg)	Image displacement (mm)	Tracked displacement (mm)
1	2	9.82	2.46	2.55
1	2	20.48	5.50	4.53
1	2	53.04	7.98	7.4
3	2	13.55	3.85	4.04
3	2	25.51	5.09	5.81
3	2	71.89	7.36	7.91