THE DEVELOPMENT OF A MINIMALLY INVASIVE RADIOFREQUENCY ABLATION COIL ELECTRODE

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1. INTRODUCTION

Radiofrequency Ablation (RFA) is currently the most widely used minimally invasive ablation technique and has established its role in the treatment of primary and secondary malignancies unsuitable for resection. [1] Efforts have been made to produce larger ablation volumes by improving the design of the electrode (umbrella-shaped array, starburst cluster, and cooled-tip), but the treatment time is often extended as the devices require multiple cycles and repositioning of the probe. [2]

In previous work, McCann and Sherar demonstrated the ability of a RFA electrode with solenoid geometry to ablate large tissue volumes. [3] The present study evaluates the feasibility of deploying a large coil through a cannulating delivery needle, into tissue. The objective of the study was to determine the ideal geometry and material properties of the coil required to ensure successful deployment in tissue.

2. MATERIALS AND METHODS

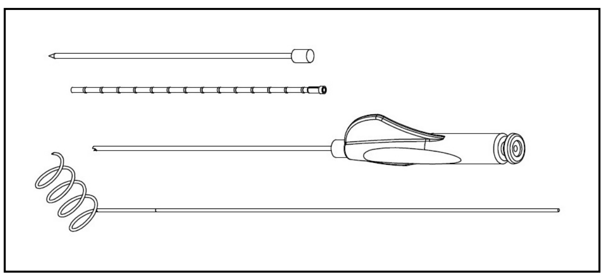

Figure 1: RF Coil components: Top to Bottom – needle, introducer, applicator with cannula, and coil electrode

Figure 1 displays the components of the RF Coil device. Coil parameters that were evaluated included wire diameter and cross-sectional shape, coil diameter, material grade, and annealing time. Shape memory alloy Nitinol was chosen because of its superelastic ability to recover from high strains of 6-7% and electrical conductivity.

2.1 Coil Electrode Geometry

Successful deployment, characterized by maintenance of the coil's shape was evaluated with a digital camera by recording the deployment of the coil into a translucent tissue mimicking gelatin phantom. (Figure 2) The phantom mimics the frictional properties of hepatic tissue based on characterized needle penetration forces into porcine liver parenchyma.

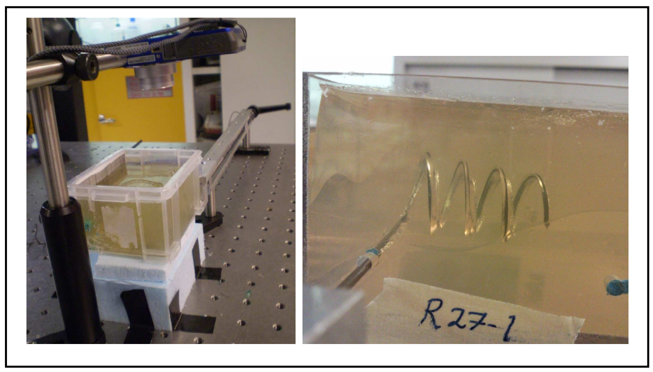

Figure 2: Phantom and Linear Stage Setup

A selection of coils of varied geometries made of either Nitinol SE508 or SE510 (NDC, CA, USA) were deployed through a 14ga needle in a reproducible and controlled manner with a custom fabricated linear stage at a constant speed of approximately 6 mm/s. The expansion and permanent deformation of each coil's diameter and pitch were evaluated.

2.2 Nitinol Coil Annealing Time

Nitinol SE510 coils with a set geometry (18mm diameter, 40mm length x 10mm pitch) were treated at the recommended transformation temperature of 600C [4] for various annealing times (ranging from 9-14 minutes). The coils were deployed five times through a 14ga needle also with a linear stage but into air. The coil's outside diameter was measured after each deployment.

2.3 Ex vivo Deployment Experiments

Two wire cross-sections (circle and segmented circle) and corresponding cannula tip designs were evaluated to determine the error associated with coil deployment trajectory. (Figure 3) The error was taken to be the angle between the planned trajectory (fin direction) and actual trajectory (coil direction). (Figure 3) Ideally the fin and coil should be parallel. This testing was completed in *ex vivo* bovine liver tissue with the aid of a Siemens DIS Orbit C-Arm. To determine the angles the CT images were analyzed with Solidworks (DS, MA, USA).

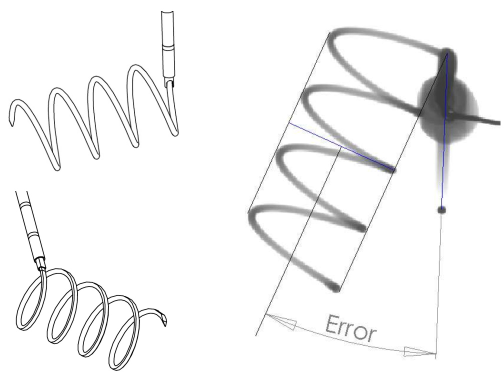

Figure 3: Round Wire with slotted cannula tip, segmented circle wire with flattened cannula tip and CT image indicating the angle of error in the deployment trajectory

2.4 Ex vivo Thermal Ablation Experiments

The selected coil geometry was evaluated in excised bovine liver surround by a polyacrylamide bovine serum albumin phantom. The phantom, measuring L 210 mm x W 160 mm x H 120 mm, was based on an ultrasound phantom recipe developed by McDonald et al (2004). [5] A 100mm x 100mm section centered along the short edge of the phantom was removed and replaced with tissue and tap water. Two grounding pads (Valleylab, CO, USA) were casted bilaterally in the phantom located furthest from the coil approximately 16 cm from the middle of the coil perpendicular to the coil axis. Temperature was measured inside the coil's centre and next to the electrode in the same plane using a fluoroptic-based thermometry system (Luxtron 3100; Luxtron, CA, USA) with SMM Probes.

The device was operated at 27.12 MHz for approximately 10 min with a net input power of 200 W using a Dressler Cesar 273 Power Generator and Matching Network (Advanced Energy, CO, USA). The distal end of RF device was connected to the generator via a flexible, coaxial cable. Heating performance was evaluated by recorded temperatures and gross measurement of the ablation zone. Tissue temperatures greater than 60℃ immediately result in coagulation necrosis. [6]

4. RESULTS

4.1 Coil Electrode Geometry

Minimal expansion and permanent deformation of the coil's diameter and pitch was exhibited in a coil with an 18mm diameter, 40mm length and 10mm pitch fabricated from 1.35mm Nitinol SE510 round wire. (Figure 4 and 5) Although the 17mm coil and 18mm coil with 1.1mm wire diameter exhibited lesser permanent deformation, the measured coil expansion took president.

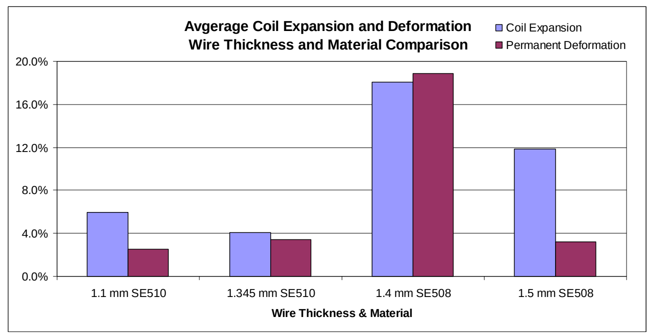

Figure 4: Measured coil diameter expansion and permanent deformation of various wire diameters (1.1-1.5mm) and grades of Nitinol (SE508-SE510)

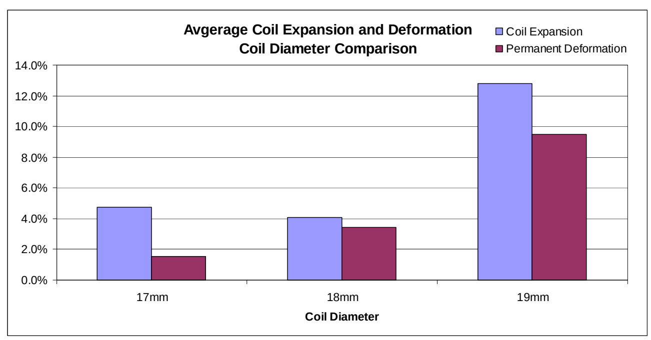

Figure 5: Measured coil diameter expansion and permanent deformation of various coil diameters (17-19mm) for 1.345 mm Nitinol round wire

Testing revealed that as the coil deploys, its long axis tends to turn in relation to the cannula to reduce torsion stress. It was also discovered that Nitinol is sensitive to creep. Therefore, the coil should not be left retracted in the cannula except for immediately before insertion. A 5.5% (±0.2) permanent expansion was measured when coil was left in the cannula for 2hrs, which was equivalent to deploying the coil 5 times consecutively.

4.2 Nitinol Coil Annealing Time

Coils treated at 600C for 12 minutes resulted in the lowest coil expansion when deployed multiple times into air. As shown in Figure 6, heat treating for 14 minutes results in a coil that has difficulty maintaining its shape even after a single deployment.

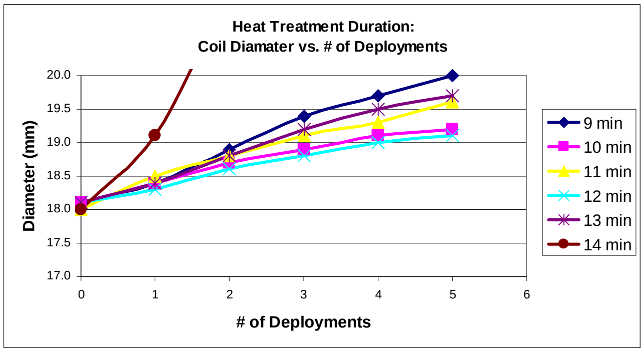

Figure 6: Annealing Time: Coil Expansion vs. Deployments

4.3 Ex vivo Deployment Experiments

The results of the ex vivo trajectory experiment are shown in Table 1. The average error and standard deviation associated with the deployment of the segmented circle shaped wire of 6.3 (±3.6) degrees was lower than that of the round wire. This angle deviation equates to a difference of 2.4 mm between the center of the coil and center of the target. Unlike the round wire coil, the segmented circle wire's inability to twist within the cannula, resulted in a beneficial tactile feedback response within the handle indicative of an obstruction in the coils path.

Table 1: *Ex vivo* trajectory experiment results

Wire Cross-section	**Average Error [deg. (±1 SD)]**
Round (n = 18)	9.2 (±7.3)
Segmented Circle (n = 16)	6.3 (±3.6)

4.4 Ex vivo Thermal Ablation Experiments

The optimal coil design underwent ex vivo testing to validate its ability to coagulate large homogenous volumes in excised bovine liver (n=16). Ex vivo testing was successful with an average ellipsoidal ablation volume of 64.2 (±11.6) cm^3 and treatment time of 8.2 (±3.4) minutes. (Table 2) The ablation zones boundaries were clearly identified by the whitening of the tissue indicating denaturation of the structural proteins. (Figure 7) Temperatures measured in the ablation zone centers and at the coil edge reached plateaus of >90℃.

Table 2: *Ex vivo* Ablation Summary [mean **(±1 SD)**]

Treatment Time (min)	**Ablation Dimensions**			**Mean volume (cm^3)**	**95% CI Range**
	L (mm)	**W (mm)**	**D (mm)**		
8.3 (±3.4)	55.8 (±12.6)	41.8 (±10.6)	41.3 (±9.5)	64.2 (±11.6)	58.5 - 69.9

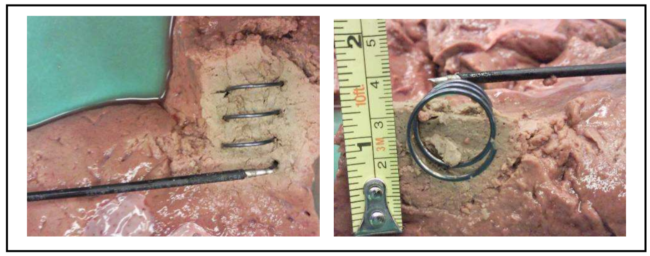

Figure 7: *Ex vivo* ablation volume: Gross inspection.

5. DISCUSSION AND CONCLUSIONS

In this paper, we evaluated and refined a novel minimally invasive RFA device composed of a superelastic coil deployed through a cannulating delivery needle. A Nitinol SE510 coil measuring 18mm diameter and 40mm long with a 10mm pitch into liver tissue was found to be ideal. The refined coil geometry produces minimal coil expansion and plastic deformation when deployed. Furthermore, the Nitinol coil exhibits rapid creep prohibiting the containment of the coil within the cannula for periods of time greater than two hours. The optimal annealing time for the selected coil at 600C was 12 minutes.

The ability to correctly place the RFA electrode within the target to ensure an effective ablation zone is of great significance in percutaneous procedures. [7] This study displayed some of the challenges related to deploying a RFA device with a solenoid geometry into tissue. Although improvements were found by changing the wire cross-section and tip design, more work can be done to further reduce the angle of deviation from the set trajectory and thereby increase the repeatability of deployment.

The RFA coil was able to create large uniform ablation volumes in a single, short treatment time. The mean ablation volumes calculated in *ex vivo* testing are similar to those found in a study by Denys et al., which evaluated four commercially available RFA devices. [8] Further studies in an *in vivo* porcine animal model are required to demonstrate the potential for this device to treat large tumors in a perfused environment. [8;9]

6. ACKNOWLEDGEMENTS

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7. REFERENCES

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