The New Microwave Ablation Catheter for Varicose Veins: An in Ex Vivo Pilot Study

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Research

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Abstract

Purpose: To improve the current microwave ablation catheter from causing injury by the over-temperature of catheter during the therapy. A new microwave ablation catheter with water-cooling circulation system and temperature-monitoring system was designed. Its effectiveness was verified in an ex vivo study.

Materials and Methods: According to the theory that the heat can be transferred by convection between different mediums to balance the temperature. Designing water-cooling circulation system and temperature-monitoring system based on the microwave ablation catheter. Comparing the temperature of the catheters with or without water-cooling circulation system and comparing the range of ablation tissues by testing on the pork to verify its effectiveness.

Results: The temperature of the MWAC without water-cooling circulation system would increase as using times increased. It would be over 45°C after using the instrument for 3 times continuously, and the range of ablation tissues extends with injury. The temperature of the microwave ablation catheter with water-cooling circulation system would not be over 45°C after using it for 50 times continuously, and it would not cause injury.

Conclusion: The new microwave ablation catheter with water-cooling circulation system and temperature-monitoring system can constantly monitor the temperature and lower the temperature while using the instrument to prevent the patients' native issue and medical staffs from burning, it can control the ablation range more efficiently and safer.

Background

Primary VVs of lower extremity are the common clinical type of chronic venous disease (CVD) with higher prevalence. VVs occur in 25%-33% of female adults and 10%-40% of male adults [1]. VVs cause varying degrees

of discomfort and cosmetic concern. Some patients' legs may swell, and their skin may change. In more severe cases, the veins may burst and bleed, and the disease significantly decrease the quality of life of affected patients. In recent years. The treatment methods of great saphenous vein (GSV) surgery change from dominating by high ligation and stripping into dominating by endovenous ablation. Also recommending endovenous ablation for the patients with VVs(C2-C6) [2].

In the therapy of Lower-limb varicose veins (VVs), endovenous thermal ablation (EVTA) has been regarded as the first option for superficial venous insufficiency (SVI) [3–4]. It creates intense local thermal heat in the VVs or incompetent vein to cause the damage of vascular endothelial cells and endangium. This treatment causes vascular fibrosis and closes off the problem veins. Nowadays thermal ablation treatment of VVs like EVTA and radiofrequency ablation were more effective in the treatment of GSV [5–7].

Microwave ablation, (MWA) is the most development in the field of tumor ablation at the beginning. As the progress of MWA catheter technology, the indication has been spread to minimally invasive surgery for VVs of lower extremity. It shows good clinical effect [8–11]. However, the VVs of lower extremity are different from tumor. Tumor ablation uses a single point of bypass temperature measurement probe to control the edge of ablation. However, EMWA of VVs needs to close the veins by thermal coagulation, and according to the length of the diseased veins, the number of ablation times make great differences in every surgery. In the tumor ablation surgery, percutaneously insert an ablation probe and a temperature measurement probe in the target of tumor, it's not suitable for EMWA of VVs with long distance and multiple ablation points. But they are not suitable for long distance surgery and EVTA of VVs with multiple ablation positions. So, it's necessary to design a new microwave ablation catheter (MWAC) and temperature measurement method according to the shape, length and location of VVs.

Current MWAC lack of water-cooling circulation system. It could result in over temperature of catheter, and the problem of damaging the patients' normal tissues become increasingly prominent. To solve the above problems, Beijing Sanhe Dingye Technology Co., Ltd has designed and produced a new MWAC with water-cooling circulation system. This new catheter includes microwave radiation, water-cooling circulation system and thermistor to measure temperature. And verified its effectiveness in ex vivo study.

Materials And Methods

Microwave ablation system

This system (Fig. 1) consists of MWAC (UM-200, Beijing Sanhe Dingye Technology Co. China) with water-cooling circulation system and microwave ablation instrument (MWAI) (MC-1150, Beijing Sanhe Dingye Technology Co. China) (Fig. 2). The main parts are temperature-monitoring system and water-cooling circulation system. Peristaltic pump and its actuation control electricity provide power to water-cooling circulation system. It can help water fluid recycling in the cooling circulation catheter and accelerate the convection of the heat from MWAC into the air. Thermistor can measure the temperature of catheter and show the specific numbers. Water-cooling catheter consists of MWA inner catheter and exterior catheter, connect by Lure fitting.

Temperature test system

Semiconductor device (thermistor) (Fig. 3) can change along with the temperature, so MWAI adopt anti-interference 3-wire resistance temperature detectors (RTD) to measure the specific temperature of MWAC. It has the advantages of miniaturization, specific measurement and strong anti-interference ability.

Selection and installation of thermistor: Temperature measurement probe and microwave radiator are in the same catheter, the space left is limited, so we select a tiny, packaged thermistor with a diameter of 0.43mm. It packaged in glass to prevent inductive currents from being generated in microwave fields. The thermistor resist heat with high stability. Thermal time constant τ = 1S (in still air), temperature ranges from – 50°C to 250°C, dissipation constant: Approx. 0.25mW/℃ insulation resistance: Min. 10MΩ at DC 50V (between lead wire and glass).

The 3-wire RTD circuit (Fig. 4): Normally, RTD only uses one current source. When measure the voltage generated by the constant current source in the thermistor, it can be converted into the corresponding temperature parameters. The 3-wire RTD with two matched current sources are required for measuring the data more accurate. Current from current source (IOUT1) flows through lead resistor (RL1), thermistor (RTD), lead resistor (RL3), precision resistor (Rref) to earth. Current from current source (IOUT2) flows through lead resistor (RL2), thermistor (RTD), lead resistor (RL3), precision resistor (Rref) to earth. Assuming RL1equal to RL2 (same material and length), IOUT1 matches to IOUT2, error voltage from RL1 and RL2 are equal, and there is no error voltage between AIN1(+) and AIN1(-). Reference voltage is developed across precision resistor (Rref), the reference voltage REFIN = REFIN (+)-REFIN (-), there are no errors. AIN1 changes according to REFIN. Reference voltage compensated the error voltage caused by temperature drift of the RTD current source [12].

Lead resistances: RL1、RL2、RL3; Thermistor: RTD; Constant current sources: IOUT1、IOUT2; Sampling voltage: AIN1(+)、AIN1(-); Reference voltage: REFIN(+)、REFIN(-).

Figure 4. 3-wire RTD

Water-cooling circulation system

The water-cooling circulation system consists of peristaltic pump, cooling water circulation tube and inlet and outlet tube. The peristaltic pump (BT100, the pump head is YZ1515X) flow rate is 50ml/min, and the outlet pressure is 460Kpa. The principle of water-cooling circulation system designation: Peristaltic pump pushes the cooling water in the pump tube and flow into the MWAC. The cooling water absorbs the heat from the microwave coaxial cable. After the peristaltic pump rollers alternately extrudes the pump tube, the cooling water flows out of the tube and returns to the water bag (water container), and the low-temperature water flows back into the tube. In this way, the MWAC can be cooled.

The peristaltic pump and its drive control circuit provide the power source for the water-cooling circulation system. It transports cooling water by alternately extruding the pump tube (silicone tube). The peristaltic pump head is divided into two parts: the rotors and the pump shell. The pump tube (silicone tube) is fixed between the rotor and the pump shell. The rotors successively extrude the tube to cause negative pressure, and the cooling water flows into the tube (the blue part is the cooling water). Due to the elastic recovery of the rolled tube, a vacuum is formed in the tube (silicone tube), and then the cooling water flows. There is a distance between rollers, which makes the tube form a closed space (pump chamber). The volume of the tube chamber is related to the inner diameter of the tube and the rotary diameter and quantity of the rollers. The flow rate depends on the rotation speed of the pump head and the volume of the pump chamber. The water in the chamber is alternately extruded and transported to the MWAC by rollers (Fig. 5).

a b c d

1.pump tube (silicone tube) 2. pump shell 3. rotor 4. Cooling water 5. pump chamber (between the rotors)

Figure 5. The working principle of peristaltic pump.

MWAC with water-cooling circulation system

In the process of closuring the lower extremity vein, MWAC (radiation ends) continuously radiates microwave energy to vascular tissues, and its temperature rises rapidly. Generally, the temperature of the ablation area reaches 100–120℃ within 3–4 seconds [6], and the thermal microwave effect also expands. Under the effect of heat conduction, the heat at the ablation area spread from the radiation end of the catheter to along the tube, and the temperature gradually increases. The high temperature of the tube would hurt normal tissues and operators' hands. Meanwhile, the temperature of the coaxial cable of the MWAC would increase, and it would aggravate the reflection and standing wave of microwave power. Then the actual output power would reduce and affect the closure of vessels. Therefore, we must adopt effective cooling method to reduce the temperature of the catheter and bring out the heat as quick as possible, so that the catheter can be used safely and effectively [10].

The MWAC with water-cooling circulation system (Fig. 6) includes radiant head, radiation window, copper sleeve, tube, operating handle, water inlet and outlet tube, high-frequency connector, temperature measuring probe, etc. In addition, there are coaxial cable, thermistor, water tank (temporarily collecting the circulating water carrying heat discharged from the tube and discharging it out of the tube), refrigerant tube (capillary stainless-steel tube) and PVC inlet and outlet tubes and other water-cooling circulation components inside (Fig. 7).

A: radiation head B: radiation window C: copper sleeve D: tube E: handle F: water tank G: temperature measuring probe H: High frequency connector I: laser coupling connector J: water inlet and outlet tube K: optical fiber L: refrigerant pipe M: coaxial cable

Figure 6. MWAC with water-cooling circulation system

Test and analysis

Test of temperature-monitoring system

Set the constant temperature water bath (CTWB) temperature, the temperature range is from 10℃ to 80℃, each test interval is 5℃, the MWAI is set to standby mode, fix the temperature probe of MWAI and mercury thermometer of 0.1℃ precision at the same temperature measuring position of CTWB, record the temperature of mercury thermometer and MWAI after the CTWB temperature is stable. Repeat the test for 10 times.

Test of water-cooling system

In order to confirm the effectiveness of the water-cooling circulation system of the MWAC, the catheter temperature was measured by two methods: non-water-cooling mode and water-cooling mode. Using normal saline of 25℃ as cooling water. MWA for VVs of lower extremities in-vitro simulation test was carried out. Setting the temperature measurement probes T1-T8 at the positions 5cm, 15cm, 25cm, 35cm, 50cm, 75cm, 90cm, 105cm away from MWAC head. The catheter was inserted into the high temperature resistant Teflon cannula (simulating human vein blood), the Teflon cannula was injected with 37 ℃ water (simulating human blood), the Teflon cannula was sealed at one end (simulating high ligation), and the 40cm head of the Teflon cannula was placed in the 37 ℃ CTWB (simulating the ablated blood vessel), the rest part is suspended. The experimental test parameters are shown in Table 1, recording the temperature of T1-T8. The actual layout of the experimental test is shown in Fig. 8.

Table 1

experimental test parameters

No.	Power	Time	Ablation interval	Water-cooling circulation system	Time	Speed of peristaltic pump (r/min)
1	70W	4S	2s	Yes	50	60
2	70W	30S	2s	Yes	50	60
3	70W	4S	2s	No	50	0

In ex vivo pilot study

In order to test the effect of MWAC temperature rise on in ex vivo ablation, using the MWAC with or without water-cooling circulation system on fresh pork tissues, setting the output power of MWAI as 70W and ablation time as 5S for both of them, 25 times in a row. Changing the pork tissue at the last ablation. Vernier calipers were used to measure the long and short diameters of the last ablation and record the data. Repeat the above operation for 10 times.

Recording and analysis

Draw the line graph of catheter temperature changing with ablation times. The other results were in the mean ± standard deviation (SD). Using T method to evaluate the difference between the two groups. SPSS software (version 23.0) was used for all statistical analysis. The difference was statistically significant when p was less than 0.05.

Result

Test of temperature-monitoring system

Under the temperature range of 10 ℃ to 80 ℃, the temperature measurement error of thermistor is ≤ ± 0.5 ℃. There are no significant differences compare with Mercurial thermometer (Table 2).

Table 2

Temperature comparation between CTWB and Mercurial thermometer

Temperature of CTWB (°C) (N = 10)	Mercurial thermometer (°C) (mean ± SD)	Device display (°C) (mean ± SD)	T value	P value
10	10.09 ± 0.15	10.07 ± 0.16	0.327	0.751
15	15.04 ± 0.15	15.03 ± 0.19	0.128	0.901
20	20.07 ± 0.34	20.07 ± 0.32	-0.375	0.718
25	25.03 ± 0.33	25.04 ± 0.3	-0.08	0.938
30	30.07 ± 0.33	30.03 ± 0.38	-0.279	0.786
35	34.9 ± 0.27	34.98 ± 0.34	0.596	0.566
40	39.9 ± 0.23	39.86 ± 0.32	0.322	0.747
45	45.01 ± 0.31	44.89 ± 0.32	0.472	0.648
50	49.92 ± 0.29	50.03 ± 0.25	0.706	0.498
55	55.06 ± 0.34	55 ± 0.22	0.449	0.664
60	59.85 ± 0.24	60.07 ± 0.28	0.768	0.462
65	65.06 ± 0.23	65 ± 0.39	0.441	0.669
70	69.85 ± 0.27	70.05 ± 0.32	-1.747	0.115
75	75.13 ± 0.29	75.07 ± 0.27	0.41	0.691
80	79.95 ± 0.33	79.98 ± 0.3	-0.224	0.828

- **Test of water-cooling system result.**

Under the water-cooling mode, the temperature of the tube reaches dynamic balance with the increase of ablation times, and the temperatures at the eight positions are always less than 40 °C (Fig. 9).

In the test of limit parameters (70W, 30s), the tube temperature of MWAC is ≤ 45 °C (Fig. 10).

In the non-water-cooling mode, the temperature of the tube grows with the increase of ablation times. After three times of ablation, the temperature at eight positions of the tube all exceeds 45 °C. In addition, the temperature of the suspended part of the Teflon tube reaches 100 °C (Fig. 11). There are risks burning medical staffs and patients.

In ex vivo pilot study result

It can be seen from the test that when the continuous ablation times exceed 25, the head of the MWAC without water-cooling circulation system is close to 60°C, leaving burning marks during in ex vivo pork tissue ablation (Fig. 12), but there is no significant difference in the ablation range between the catheter with and without water-cooling circulation system (Table 3).

Table 3

Ablation ranges

N = 8	Water-cooling	Non-water-cooling	P
Length (mm)	16.356 ± 1.344	17.072 ± 0.726	0.325
Width (mm)	8.02 ± 0.77	7.55 ± 0.43	0.268

Discussion

The therapeutic principle of EMWA on VVs of lower extremity is the effectiveness of microwave on the thermal coagulation of vascular tissues, which directly treats on the veins of patients, so that it can produce a penetrating high temperature in a small range to solidify the vessel, and then make it gradually fibrosis and finally completely close. Because of its unique advantages, such as high efficiency of thermal ablation, small influence by blood-flow and carbonization. The EMWA on VVs of lower extremity has been recognized by clinicians.

The results show that: the measurement of thermistor temperature of MWAI is more accurate, the measurement error is ± 0.5°C; The temperature of the catheter can reach 100°C without water-cooling circulation system under the same power, time and times. Improper treatment in clinical operation may cause the risk of patients and operators being burned by the high temperature of the catheter. The temperature of the catheter is less than 45°C under the water-cooling circulation system, which meets YY0838-2011 microwave coagulation equipment standard [13]. MWAI can monitor the temperature of ablation catheter, ensure the treatment's effectiveness. In addition, while the temperature of the catheter exceeds 45°C, the microwave output can be stopped automatically to prevent the catheter from overheating to scald patients and medical staffs.

Conclusions

The new MWAC has been verified that the temperature of the water-cooling circulation system is always lower than 45 °C while it works, which meets the clinical requirements and avoids burning the patients and medical staff. However, there are few tests in the simulation test of CTWB. The next step is to verify the effectiveness and safety of new MWAC in animal test.

Abbreviations

VVs, varicose veins; CVD, chronic venous disease; GSV, great saphenous vein, EVTA, endovenous thermal ablation; MWA, Microwave ablation; RTD, resistance temperature detectors; EMWA, endovenous microwave ablation; CTWB, constant temperature water bath; MWAI, microwave ablation instrument; MWAC, microwave ablation catheter

Declarations

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Authors' contributions

YL; LX; WW; JL: Conceptualization.

YL; LX; MP; GW; WW: Methodology.

MP; GW; JL; YL: Validation.

MP; GW; YL; JL: Formal analysis.

WW; YL; JL: Investigation.

JL; WW: Resources.

MP; GY; YL: Data Curation Management.

YL; WW; MP; GW: Writing - Original Draft.

All authors: Writing - Review & Editing.

WW; JL: Supervision.

WW; JL: Project administration.

All authors: Final approval.

All authors were fully involved in the study.

All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author upon reason able request.

Ethics approval and consent to participate

No applicable.

Consent for publication

Written consent for publication was obtained from all study participants.

Competing interests

There are no conflicts of interest to declare.

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Figures

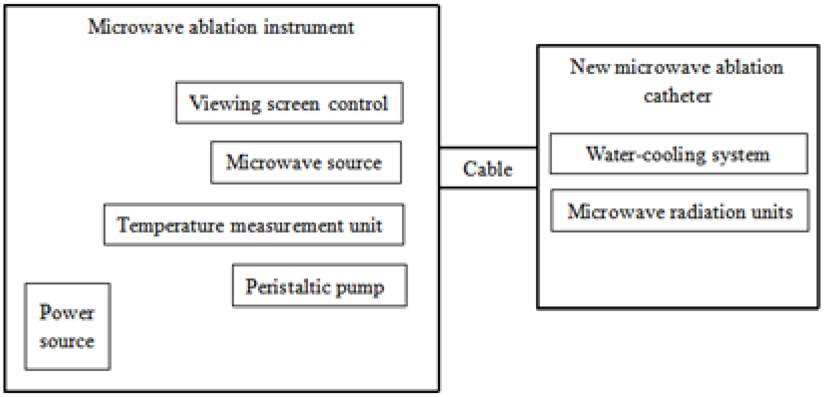

Figure 1

Schematic diagram of the MWA system

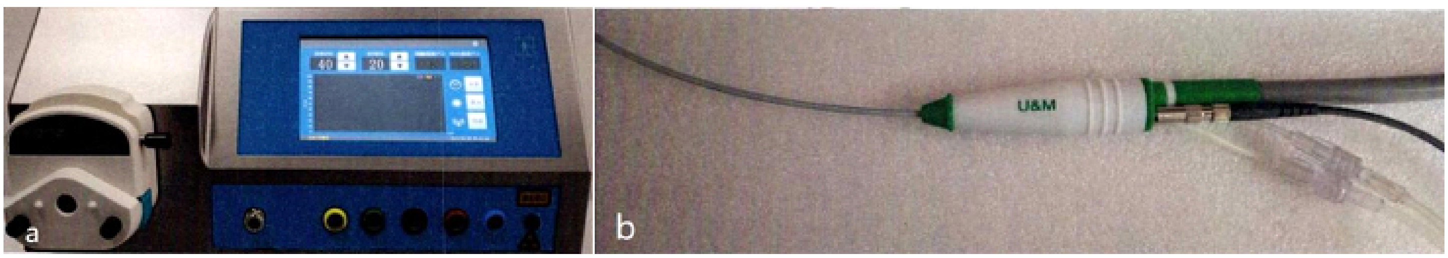

Figure 2

(a) Microwave ablation instrument (b) Microwave ablation catheter with water-cooling circulation system

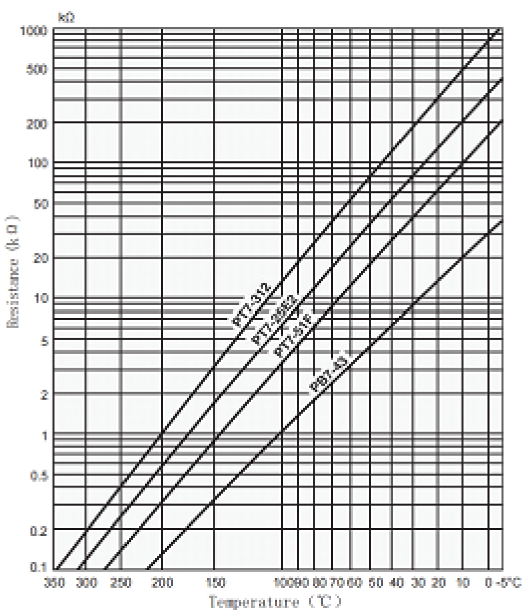

Figure 3

Resistance value and temperature characteristic of thermistor

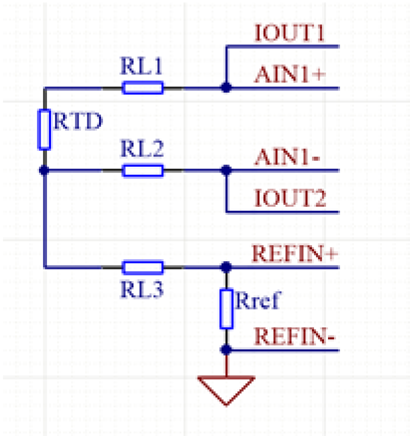

Figure 4

Lead resistances: RL1、RL2、RL3; Thermistor: RTD; Constant current sources: IOUT1、IOUT2; Sampling voltage: AIN1(+)、AIN1(-); Reference voltage: REFIN(+)、REFIN(-). 3-wire RTD

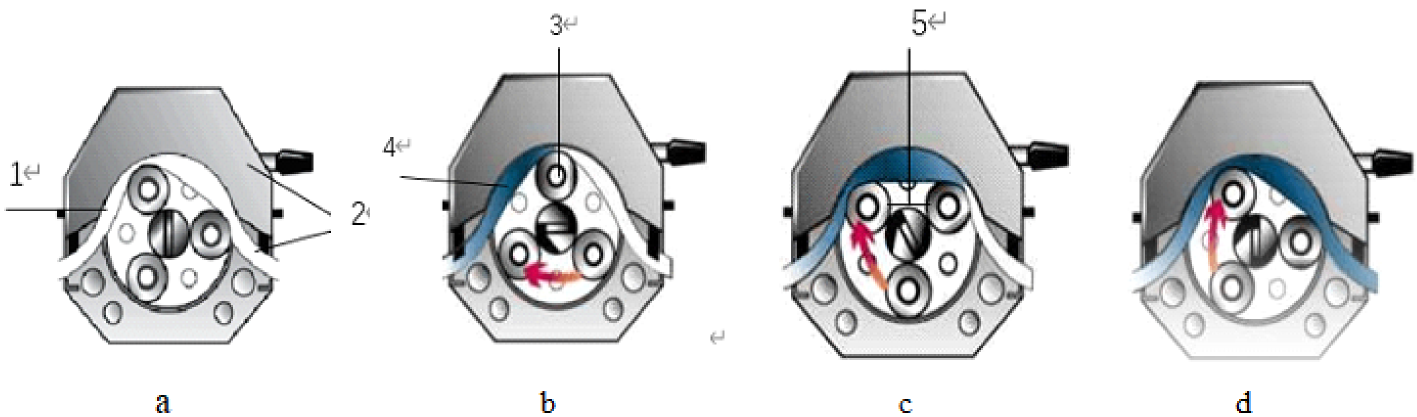

Figure 5

1.pump tube (silicone tube) 2. pump shell 3. rotor 4. Cooling water 5. pump chamber (between the rotors) The working principle of peristaltic pump.

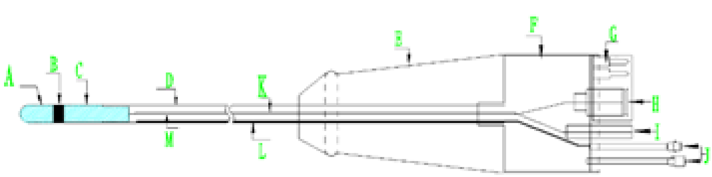

Figure 6

A: radiation head B: radiation window C: copper sleeve D: tube E: handle F: water tank G: temperature measuring probe H: High frequency connector I: laser coupling connector J: water inlet and outlet tube K: optical fiber L: refrigerant pipe M: coaxial cable MWAC with water-cooling circulation system

Figure 7

Water circulation inside the tube

Figure 8

layout of the experimental test

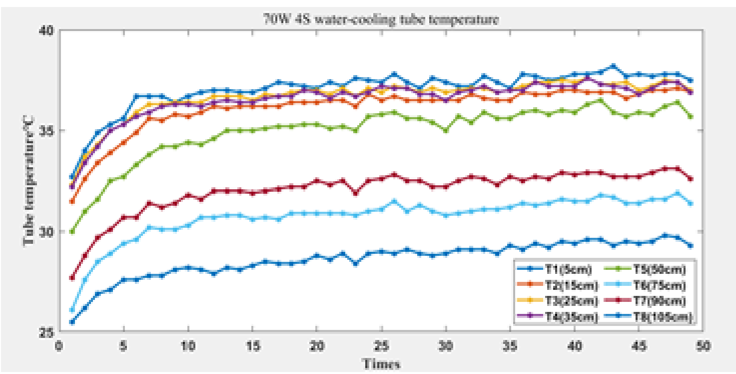

Figure 9

70W 4S water-cooling tube temperature

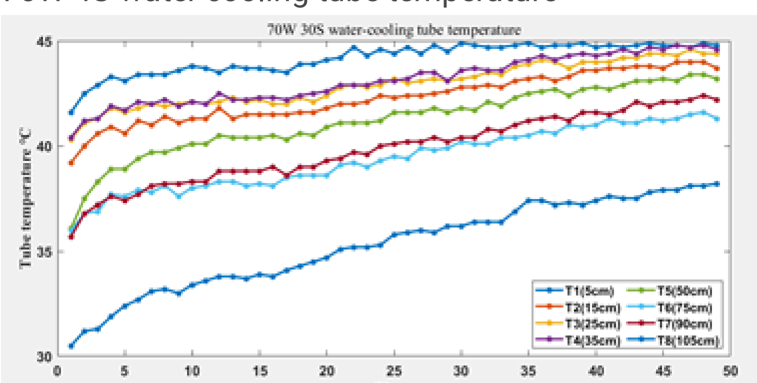

Figure 10

70W 30S water-cooling tube temperature

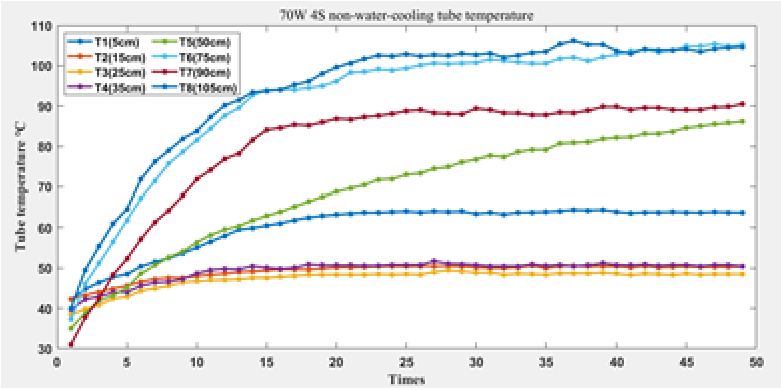

Figure 11

70W 4S non-water-cooling tube temperature

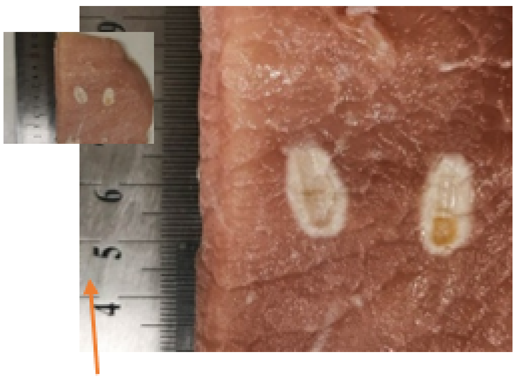

Figure 12

MWA on tissues