Clinical and Experimental Health Sciences

Investigation of Therapeutic Ultrasound Dose on Muscle Phantom: An Experimental Study Investigation of Therapeutic Ultrasound Dose

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ABSTRACT

Objective: The study aims to investigate the standardized, traceable dose amounts that will create the desired therapeutic physiological change in the tissue and prevent the risk of tissue damage in the light of metrology principles

Methods: In the study carried out in TÜBİTAK National Metrology Institute Medical Metrology Laboratory, a muscle phantom simulating the acoustic properties of muscle tissue was created and thermocouples were placed in it. Ultrasound at different intensities and durations at 1 MHz frequency was applied to the phantom. The temperature changes measured by the thermocouples were recorded. Each measurement was repeated three times and averaged

Results: 14 minutes application at 1 W/cm^2 density, 10 minutes application at 1.5 W/cm^2 density, ~7 minutes application at 2 W/cm^2 density, and ~4 minutes application at 2.5 W/cm^2 density have been achieved for the temperature range needed to produce therapeutic effect.

Conclusions: In order to achieve the therapeutic effect, the ultrasound doses used in the procedure should be checked. Measurements in multi-layer phantoms would be useful in future research.

Keywords: Therapeutic ultrasound, muscle phantom, dose, metrology.

1. INTRODUCTION

Therapeutic ultrasound is an accepted therapeutic agent in reducing pain and spasm in tissues. It is a high-frequency current that is preferred because of its thermal and mechanical effects on deep tissues, and it is a frequently used, easy-to-apply, and economical electrotherapy modality (1–3). As a result of the absorption of ultrasound in the tissues, mechanical vibration and sonic energy are transformed into heat energy in proportion to the intensity of ultrasound. Due to the increase in temperature in the tissue, circulation increases, the inflammatory process improves and an analgesic effect occurs (4). To achieve the beneficial therapeutic effect, the tissue temperature must be kept between 40-45°C for at least 5 minutes. Destructive consequences occur when the local tissue temperature exceeds 45°C (5)

Despite its widespread use, there are conflicting results in the literature regarding the therapeutic effect of therapeutic ultrasound. In previous studies to investigate the effectiveness of ultrasound, the duration of application differed, a standard dose data was not found, and quantitative information supporting the effectiveness of application protocols recommended for different clinical conditions was not presented.(6–10) Treatment plan is based on the clinician's individual experience. As a result, therapeutic ultrasound applications do not include standardized, comparable dose concepts supported by traceable measurements. The lack of accurate dose information makes it difficult to determine dose-response curves and to create effective treatment plans (11). This can lead to excessive or inadequate treatment of the tissue and even to the patient's harm.

Test materials that can describe the special characteristics of human tissues in ultrasound applications are called phantoms (12). It is used to test US systems or to investigate the interaction of sound waves with tissue. There are many phantoms in the literature that mimic human tissue. To develop measurement techniques and validate theoretical models, tissue-mimicking phantoms should have acoustic and thermal properties equivalent to human tissues Speed

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of sound, attenuation coefficient, and acoustic impedance of phantom and the tissues must be similiar. (11,13,14)

This study was planned due to the lack of a clear framework for therapeutic US applications in the literature. The aim of the study is to investigate the standardized, traceable dose amounts of therapeutic ultrasound that will create the desired therapeutic physiological change in the tissue and prevent the risk of tissue damage with reference to the temperature increase on the muscle phantom in the light of metrology principles.

2. METHODS

This research was conducted in the TÜBİTAK Metrology Institute Medical Metrology Laboratory from April 8, 2018 to December 31, 2020. The study was conducted under the conditions required for the competence of the test and calibration laboratories. All instruments to be used in measurements were calibrated at first. The algorithm with the study progress steps is given in Table 1.

Table 1. *Study algoritm*

Construction of muscle phantom
↓
Measurement of the acoustic properties of the phantom
↓
Forming the phantom container and inserting thermocouples into it
↓
Pouring the phantom into the container and waiting for it to cool
↓
Applying ultrasound to the phantom
↓
Recording the measured temperature values

2.1. Construction of Muscle Phantom and Measurement of the Acoustic Properties

Materials to be used in phantom construction were prepared and their masses were measured. Agarose powder (A9539-500G Sigma-Aldrich, USA), degassed water, aluminum powder Al2O3 (Nanokar, Turkey), and glycerin (Cleanmaster, Turkey) were used to prepare the muscle phantom.

Speed of sound, attenuation coefficient, and acoustic impedance are the most essential acoustic properties of soft tissue phantoms. The attenuation coefficient and speed of sound of the phantom was then measured ten times and averaged. In the speed of sound and attenuation coefficient measurements, a digital storage oscilloscope (Tektronix TDS 2002C, USA) and a pulser receiver (Panametrics Model 5052 PR, USA) were used, as well as 1 MHz probes (M639 SMN2M5, Meccasonics LTD, UK). Calculations of density and acoustic impedance were carried out. Uncertainty calculations are important in determining how much information is missing from a measurement result JCGM 100: 2008 GUM was used to guide the uncertainty measurements (15). The factors affecting the speed of sound and attenuation coefficient measurements results were identified. The components of the uncertainty budget were determined. Measurement uncertainty was calculated. It was possible to calculate expanded uncertainty, U, by taking the square root of the number of the variances and applying a coverage factor k=2, which corresponds to a coverage probability of approximately 95% for normal distribution.

2.2. Preparation of Phantom Container and Insertion of Thermocouples

A phantom container of 58x108x74 mm was drawn with the SolidWorks application. The center of the area where the ultrasound will be applied was determined. The spaces where the thermocouples will be placed were drawn at a depth of 3 cm from the phantom surface, to the center of the application area and 1cm and 2cm from this point. Then the phantom was removed from the 3D printer (Zaxe X1-Plus ZAXE) and 3 connectable 10 kOHM NTC type thermocouples were placed in the spaces. Thermocouples are directly connected to the temperature measurement device

2.2.1. Pouring the Phantom Into the Container

The level where the muscle phantom will be pour was marked on the container. The prepared muscle phantom was poured into the container where the thermocouples were placed and left to cool.

2.3. Dose Calculations

Acoustic dose is defined as the energy deposited per unit mass of a medium supporting an acoustic wave (16). The minimal amount of energy that was determined to be beneficial for therapeutic ultrasound was 2250 Joules each session. For the calculation of the energy required during the ultrasound application, given formula is used (17).

Total energy per session (Joules) = Intensity (W/cm²) x time (seconds) x US head size (cm)

2.4. Applying Ultrasound to the Phantom

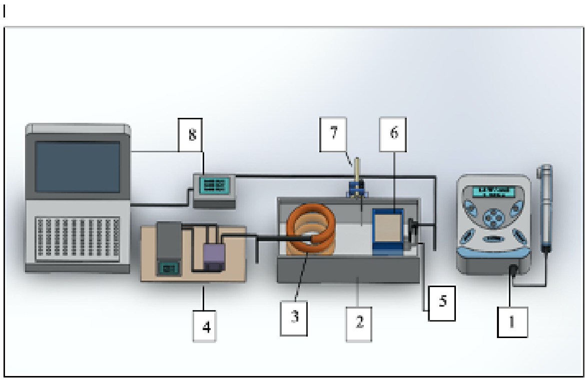
Before the measurements, it was checked whether the device to be used in the study applies the power that appears on the it's screen.. The device used was PUG, a portable ultrasonic power meter created by TÜBTAK UME Medical Metrology Laboratory. Then phantom container placed in the experimental setup.

Multi-Channel Temperature Measurement Device (Model 1, 2019) which provides its energy via USB, was connected to the computer. Data can be read and commands can be entered on the screen. The software of the Temperature Measurement Device was developed in TÜBİTAK UME Medical Metrology Laboratory, and the data can be transferred to Excel as raw data from this software interface (https://www.ume.tubitak.gov.tr/en/laboratuvarlarimiz/projects-18, accessed: 25.09.2021). They can be read instantly directly from the screen display.

To mimic human muscle tissue, the phantom must be held at 37°C (18) . A temperature system was created to bring the phantom's temperature to 37°C. The thermocouple measuring the temperature of the system working with electricity was prepared using the heating resistor that provides heating and prevents the temperature from dropping below 37°C and the screen showing the set temperature

In the measuring setup, a phantom cup containing thermocouples was mounted. The phantom was fitted with the apparatus (with the size of two times of the transducer head) prepared in accordance with the effective radiating area (ERA). With the temperature control mechanism, the phantom's temperature was raised to 37 °C. The 5 cm ultrasound head of the ultrasound device with an ERA of 4 was used (Chattanooga Intelect Mobile Ultrasound).

In line with the times calculated by the dose measurements, ultrasound was applied at a frequency of 1 MHz and in continuous mode. The application started when the value measured by the thermocouples showed 37°C. The ultrasound head was moved at a speed of about 4 centimeters per second. Degassed water was used as coupling agent. The value measured by the thermocouples was recorded by applying at a density of 1, 1.5, 2, 2.5 watt / cm^2 for different durations. Each measurement was taken three times and the average was calculated. The temperature of the phantom was expected to decrease to 37 ° C after each measurement. The therapeutic dose was described as the intensity and duration that enabled the temperature to rise above 40 ° C for 5 minutes. The parameters that will affect the results of the temperature measurements were determined and the uncertainty value of the temperature measurement results was calculated.the experimental set up is given in figure 1



1. Ultrasound Device
2. Termal Equilibrium Pool
3. Heater
4. Temperature Control System
5. Thermocouples
6. Muscle phantom
7. Thermometer
8. Temperature Record System

Figure 1. *Temperature measurement set up by the ultrasound application*

3. RESULTS

3.1. Results of Measurement of Acoustic Parameters of Muscle Phantom

The mass ratios of the materials used in phantom construction are given in Table 2. The acoustic parameters of the phantom we constructed are reported in Table 3. The acoustic properties of muscle tissue are included in the Table 3 too (19).

Table 2 *Materials and mass ratios used in phantom construction*

Material	Composition ratios (%) – by mass
Distilled Water	81.5
Agarose	1.5
Aluminum Powder (Al_2O_3 0,3µm)	7
Glycerin	10

Table 3. *Acoustic parameter of muscle phantom and muscle tissue*

Acoustic parameter	**Result of measurement** (mean± standard deviation)	**Muscle tissue** (19)
Speed of sound (m/s)	1549.8±3.89	1547
Attenuation coefficient (dB/cm MHz)	1.14 ±0.08	1.09
Acoustic impedance (MRayl)	1.632	1.62
Density (kg/m³)	1053.5	1050

3.2. Results of Temperature Measurement with Ultrasound Application

Temperature data depending on different time and intensity after ultrasound applications are given below. In al figures T1, T2 and T3 show the temperatures measured by the thermocouples.

T1. Thermocouple in the center of the application area

T2. Thermocouple placed 2 cm away from T1

T3. Thermocouple placed 3 cm away from T1

The temperature changes caused by the application of ultrasound at 1Mhz frequency and 1 W/cm^2 intensity in the phantom depending on time are given in Figure 2.

In the 10-minute and 12-minute applications, the temperature increased to 40 °C but in only 14 minutes of application, it remained above 40 °C for 5 minutes.

Figure 3 shows the temperature changes in the phantom generated by ultrasound at 1Mhz frequency and 1.5 W/cm2 intensity as a function of time.

In 7 minutes of application, the temperature rise is approximately 2 °C. The temperature did not rise above 40 °C. In the 8-minute application, the phantom temperature rose above 40 °C after approximately 7 minutes of the application and remained above 40 °C until the 11th minute. In the

10-minute application, the phantom temperature remained above 40 °C for more than ten minutes.

Figure 4 depicts the temperature fluctuations in the phantom as a function of time caused by ultrasound at 1Mhz frequency and 2 W/cm^2 intensity.

According to the graphic data in Figure 4, the peak temperature value of the 6-minute application is 39.2 °C. With the 7-minute ultrasound application, the phantom temperature reached 40 °C in the 6th minute. When it drops below 40°C again, it is ten minutes. After 8 minutes of application, the time it stays above 40°C is more than ten minutes.

The temperature changes caused by the application of ultrasound at 1Mhz frequency and 2.5 W/cm^2 intensity in the phantom depending on time are given in Figure 5.

As seen in Figure 5, an increase of 2.45°C was achieved with a 3-minute application. In the 4-minute application, the phantom temperature remained above 40 °C for approximately four and a half minutes. In the 5-minute application, the temperature remained above 40 °C for five minutes.

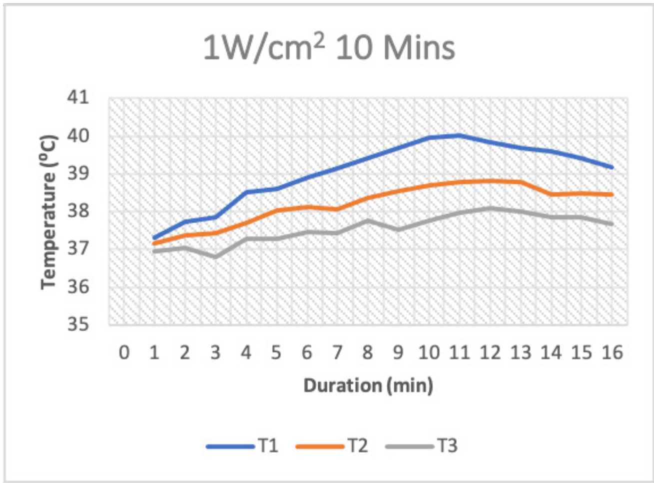


Figure 2A

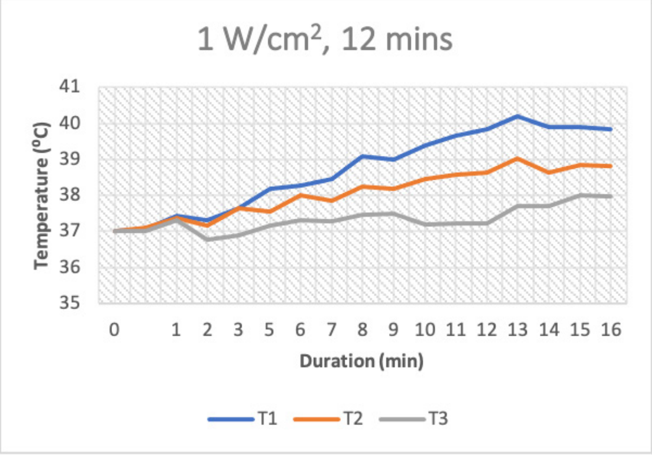


Figure 2B

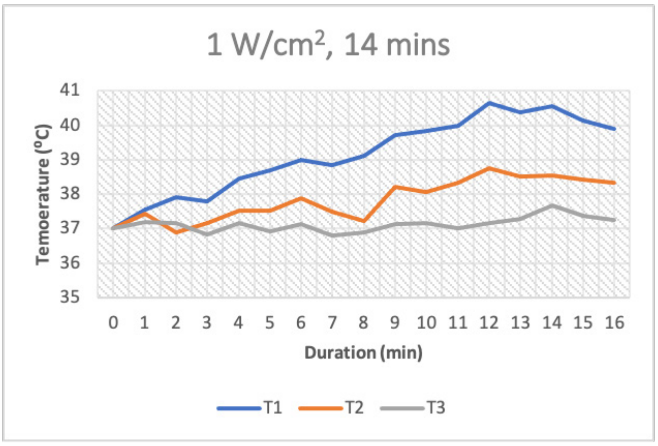


Figure 2C.

Figure 2. *Time-dependent temperature changes at a density of 1 W/cm2. A. At 10 mins application B. At 12 mins application C. At 14 mins application*

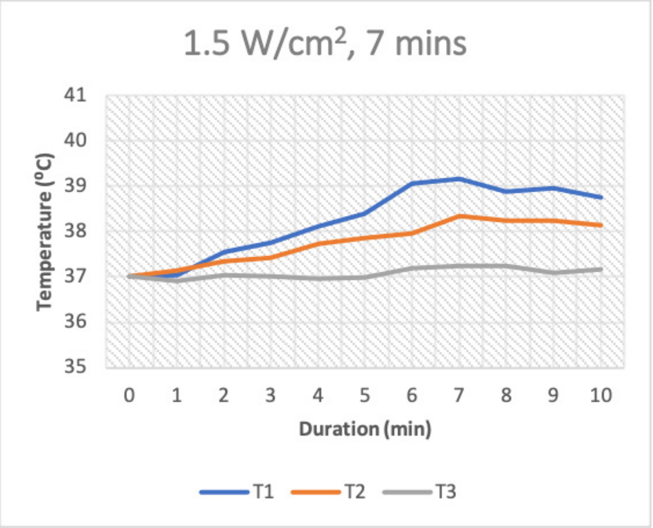


Figure 3A

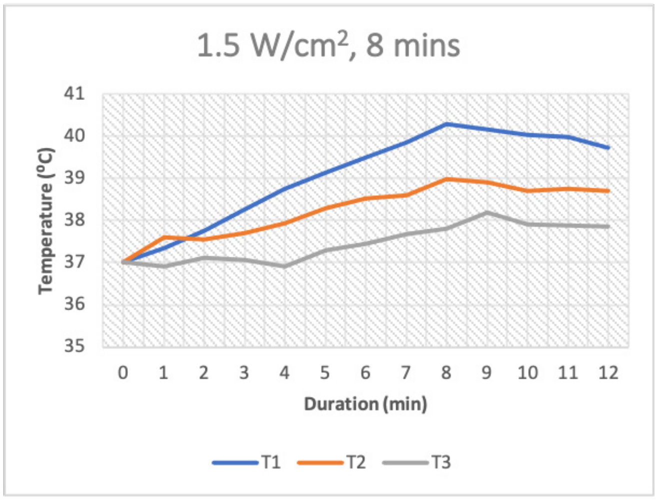


Figure 3B.

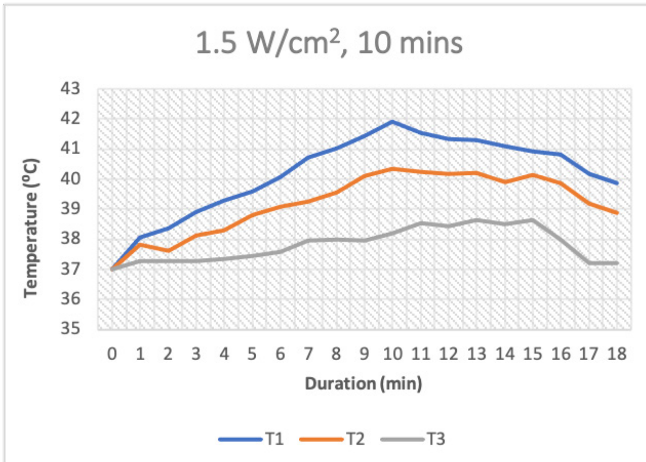


Figure 3C.

Figure 3. *Time-dependent temperature changes at a density of 1,5 W/cm2 A. At 7 mins application B. At 8 mins application C. At 10 mins application*

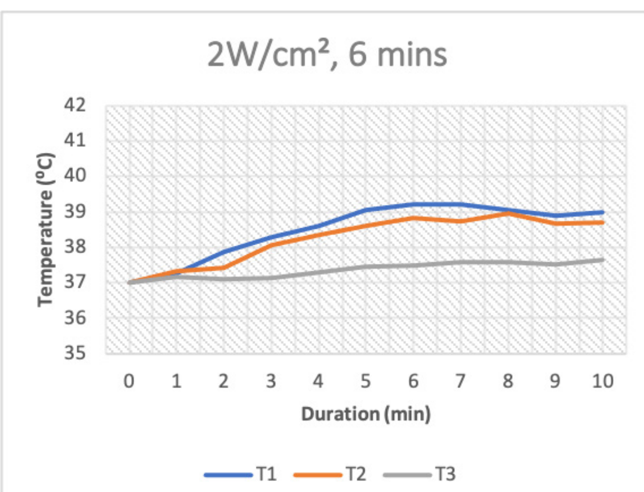


Figure 4A.

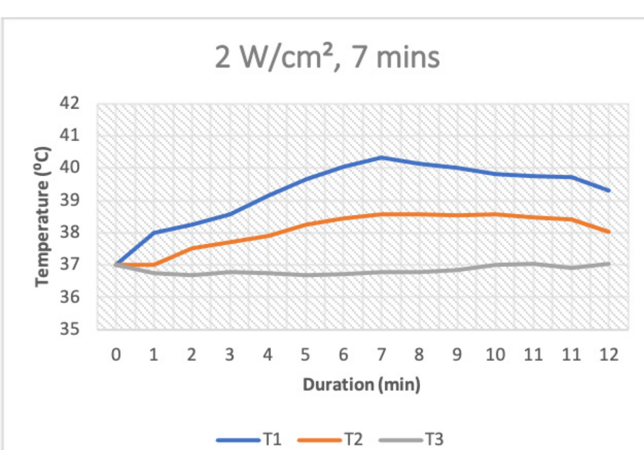


Figure 4B.

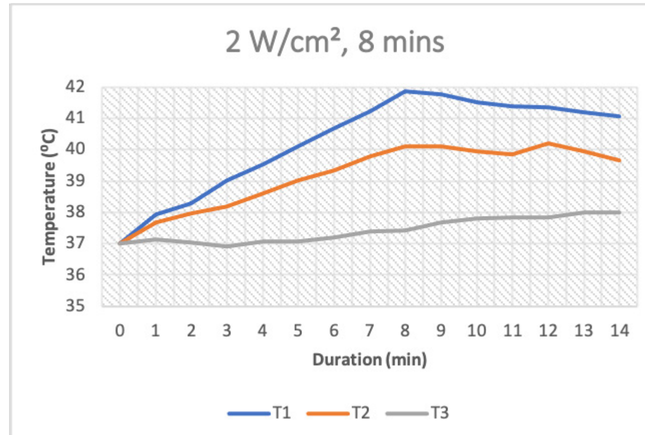


Figure 4C.

Figure 4. *Time-dependent temperature changes at a density of 2 W/cm2 A. At 6 mins application B. At 7 mins application C. At 7 mins application*

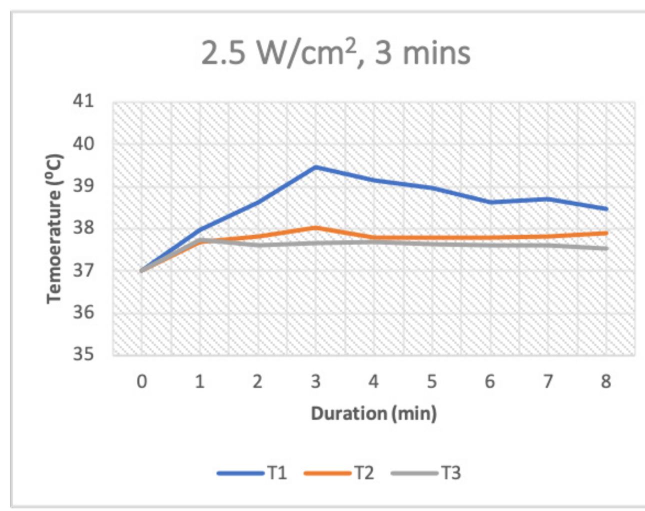


Figure 5A.

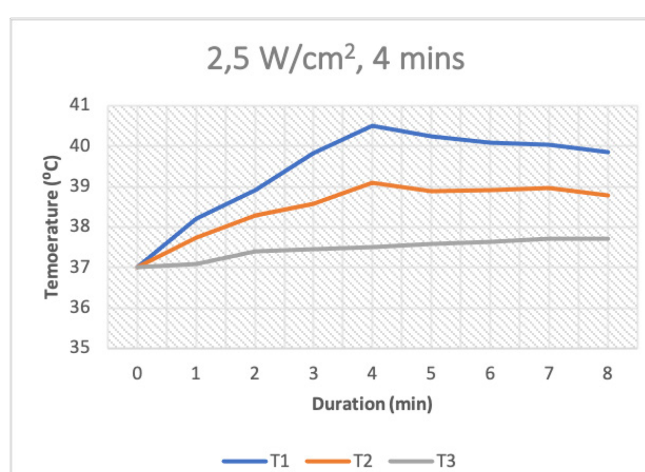


Figure 5B.

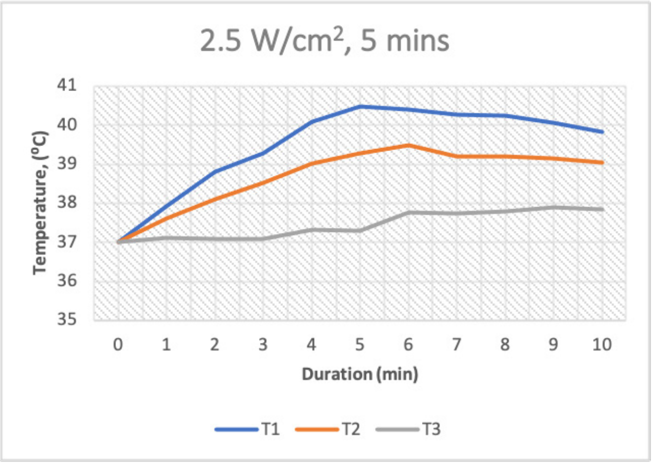


Figure 5C.

Figure 5. *Time-dependent temperature changes at a density of 2,5 W/cm2 A. At 3 mins application B. At 4 mins application C. At 5 mins application*

Depending on the applied density, the times required for the therapeutic effect at 1 MHz frequency are given in the Table 4

Table 4. *Intensity and time at which the therapeutic effect occurs*

Intensity (W/cm^2)	Time (min)
1	14
1,5	8
2	6-7
2,5	4-5

3.4. Temperature Measurements' Uncertainty

The sources of standard uncertainty and the resulting combined standard uncertainty of temperature measurements during ultrasound application are listed in Table 5.

Table 5. *Uncertainty Budget for Temperature Measurements*

Sources of uncertainty	Error%	Probability Distribution	Divisor	Uncertainty%
Error of measurement system (Thermocouple system)	0.02	Normal	2	0.01
Environment temperature change and fluctation	0.05	Rectangular	1.73	0,03
Probe positioning error	0.08	Rectangular	1.73	0.05
Water temperature change	0.02	Rectangular	1.73	0.01
Thermocouple positioning	0.09	Rectangular	1.73	0.05
Distance change between probe-thermocouple	0.08	Rectangular	1.73	0.05
Repeatibility	0.09	Rectangular	1.73	0.05
Reproducebility	0.10	Rectangular	1.73	0.06
Loss of phantom's properperties	0.10	Rectangular	1.73	0.06
Combined Uncertainty				**0.13**
Expanded Uncertainty= U (k=2)				**0.26**

4. DISCUSSION

In light of the principles of metrology, the study intends to investigate the standardized, traceable dose quantities that will produce the required therapeutic physiological change in the tissue while avoiding the danger of tissue harm. For this purpose, phantom simulating muscle tissue was created and its acoustic properties were measured. Then, 1, 1.5, 2, 2.5 Watt/cm^2 intensity ultrasound was applied to this phantom at a frequency of 1 MHz and the time to create a therapeutic effect was determined.

Phantom construction is guided by Gutierez et al. (20). They have used graphite powder as a scatter agent in their work but we used aluminum powder. The scattering ratio used was changed until the phantom best reflected the acoustic properties of the muscle tissue. Phantom's speed of sound, attenuation coefficient was measured ten times and averaged. Mast's data were used as a basis for our research (19). The speed of sound was 1549.8±3.8 m/s (U=6.7), which was consistent with the Mast's data, 1547 m/s. According to Mast , the attenuation coefficient of muscle tissue is 1.09 dB / cm MHz, while various values such as 1.1 dB /cm MHz have been reported in the literature (21). These figures are similar to the attenuation coefficient we measured at the end of the investigation, 1.14±0.8 dB / cm MHz (U =0.55). The acoustic impedance and density of muscle tissue, according to Mast, are 1630 MRayl and 1050 kg/m3, respectively. The muscle phantom's acoustic impedance (1.632 MRayl) and density (1053,5 kg/m^3) values were computed extremely near to the reference values. The table does not include the standard deviation in acoustic impedance and density calculations because it is so small. this phantom is appropriate for use in ultrasonic measurements.

1 MHz and 3 MHz frequencies are used in therapeutic ultrasound applications. Since the muscle tissue is located deeper, 1 MHz frequency application, which penetrates deeper, is preferred. There are different data on the amount of depth 1MHz penetrates. Watson states that 1 Mhz penetrates to an average of 4 cm depth, since tissue densities are different in humans (22). Cisowska-Adamiak et al showed that 1 MHz, has a half-depth penetration in the muscle of approximately 1.2 cm (23) As a result of the experiments in which we evaluated the temperature increase at different depths before starting the this study, we noted that the maximum temperature increase was 3 cm. Therefore tissue temperatures were measured at 3 thermocouple locations at 3 cm depths from the phantom surface.

One of the reasons for the use of continuous ultrasound is to increase the temperature that will create a biological effect in the tissue. Contrary to its name, thermal dose is time dependent (16) Therefore, the formula suggested by Hougton was used. The application time to meet the amount of energy required for effective treatment was calculated by placing the density and area of the device head into the formula. Ultrasound was applied to the phantom at times below and above the value found as a result of the calculations and temperature changes were observed.

The temperature measurement system has a measurement error of ±0.2 °C. The system takes a measurement every two seconds. The graphs show changes on a minute basis. The deviations seen in the graphs are thought to be caused by these factors. The application head movement was made to be approximately 4 cm/sec. No timer was used since the head movement speed had no effect on the temperature increase and all applications were made by the same person (24). Again, since the coupling agent used during the application did not affect the temperature change, water, which did not cause deterioration on the phantom surface, was used instead of gel (25).

It has been observed that the time required to exceed 40 °C at the end of 1W/cm^2 application should be 10 minutes and the application time should be 14 minutes for the therapeutic effect to ocur, in this study. Myrer et al. placed a thermocouple in the posterior calf and applied 1 W/cm^2 ultrasound for 10 minutes and showed that the temperature increased by about 6 °C (26). Draper et al. recorded a temperature increase of 3.5 °C in the medial triceps surae muscle at the same dose (27). In our study, an increase of 3.03 °C (U=0.26) was achieved after 10 minutes of application. This difference is thought to be caused by skin and adipose tissue in vivo studies.

As a result of our experiments, the time required for a therapeutic effect in 1.5 W/cm^2 applications was found to be approximately 8 minutes. It has been shown in previous studies that ultrasound is not effective in lower duration applications (28) Ebadi et al in which they investigated the effectiveness of ultrasound in patients with frozen shoulder, they applıed to the patients ultrasound for 6 minutes at an intensity of 1.5 W/cm^2. They showed that ultrasound did not have any effect on pain, range of motion and function (7). Yıldırım et al. compared the results of 4 and 8 minutes of application and concluded that 8 minutes of application was more effective in reducing pain and increasing the ability to carry out activities of daily living in patient with knee osteoarthritis. (29). These data support the results of our study, although it shows that the application times in the previous studies should be reviewed.

Test results from this study show that the time required for the application of 2 W/cm^2 is approximately 7 minutes. In the application of 2 W/cm^2, the rate of temperature increase in the tissue is 0.38 per minute (30). When we look at the graphic data given in the figure, it is seen that this speed is 0.43 in our study. This difference is considered by our study made from a single-layer pantom. But measurement uncertainty must also be taken into account.

Although it was stated that therapeutic ultrasound applications were performed at an intensity of 0.2-3 W/cm^2, it was seen that the intensity of 2.5 was not preferred in the study. If this application is to be preferred, according to the results of our data, it is thought that the application of 4 minutes at this intensity is more reliable and the applications performed over a period of time may cause tissue damage.

Since ultrasound applications are used in musculoskeletal problems, muscle phantom was preferred. Although the acoustic values of the muscle phantom meet the values given in the literature for soft tissue (including skin, fat, fascia, muscle), it would be more appropriate to use multi-layered phantoms in order to be more precise and simulate the human body in the best way (19). In this respect, the use of a single-layered phantom is seen as a limitation of our study. In this respect, the use of a single-coil phantom is seen as a limitation of our study.

5. CONCLUSION

In this study, the doses required to reach the temperatures that will reveal the therapeutic effect in ultrasound applications were investigated. This study is experimental study and it was made in accordance with metrology principles in terms of determining the factors affecting the measurement results and giving the uncertainty value. Therefore, the results can be considered as reliable. In order to achieve the therapeutic effect, the ultrasound doses used in studies should be checked.

Phantoms are more used in high intensity focused ultrasound applications. In this regard, they can be used also in measuring the effıcıency of the physiotherapy devices as well as for dosing in physiotherapy**.** Measurements in multi-layer phantoms would be useful in future research.

Conflict of interest: The research is not financed, and the authors have no conflicts of interest to report.

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