Thermal analysis of the muscle-bone interface in test samples after the use of therapeutic ultrasound

Análise térmica da interface músculo-osso em corpos de prova após utilização de ultrassom terapêutico

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Date of first submission: June 28, 2023
Last received: December 16, 2023
Accepted: February 8, 2024

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Abstract

Introduction: Ultrasound used in diathermic therapies aims to achieve temperatures between 40 and 45 °C, since temperatures above 45 °C are known to cause tissue necrosis and burns. Many studies have been conducted to investigate the effect of therapeutic ultrasound in the presence of metallic implants, using phantoms (test samples) and *in vivo* and *ex vivo* animal models. In most of these studies, the ultrasound probe is fixed in one area, while in clinical practice, it is recommended that it be moved to avoid possible local overheating. **Objective:** To analyze the thermal field at the muscle-bone interface in phantoms in the presence or absence of metallic implants after the application of therapeutic ultrasound. **Methods:** Phantoms composed of layers simulating fat and muscle, and a layer of beef rib bone, with and without a titanium metallic implant, were prepared. The experiment involved different intensities (1.0, 1.5, and 2.0 W/cm^2) and exposure times (5 and 10 minutes), common in clinics, with linear scanning of the probe. **Results:** The experiments indicated that the muscle/implant interface heated less than the muscle/bone interface, especially at intensities of 1.5 and 2.0 W/cm^2, after 5 and 10 minutes of treatment. **Conclusion:** The results suggest the possibility of using therapeutic ultrasound in patients with metallic implants, encouraging future research to develop evidence-based protocols and safe recommendations in physiotherapy.

Keywords: Artificial implants. Heating. Therapeutic ultrasound.

Resumo

Introdução: *O ultrassom utilizado em terapias diatérmicas visa atingir temperaturas entre 40 e 45 °C, sabendo-se que temperaturas acima de 45 °C podem causar necrose tecidual e queimaduras. Muitas pesquisas têm sido realizadas para estudar o efeito do ultrassom terapêutico na presença de implantes metálicos, utilizando* phantoms *(corpos de prova) e animais* in vivo *e* ex vivo. *Na maioria dessas pesquisas, o cabeçote ultrassônico está fixo em uma área, enquanto que na prática clínica recomenda-se que ele seja movimentado para evitar eventuais sobreaquecimentos locais.* ***Objetivo:*** *Analisar o campo térmico na interface músculo-osso em* phantoms *na presença ou ausência de implantes metálicos após a aplicação do ultrassom terapêutico.* ***Métodos:*** *Foram elaborados* phantoms *compostos de camadas simuladoras de gordura e músculo e de uma camada de osso de costela bovina, sendo esta com e sem implante metálico de titânio. O experimento envolveu diferentes intensidades (1.0, 1.5 e 2.0 W/cm²) e tempos de exposição (5 e 10 minutos) comuns em clínica, com varredura linear do cabeçote.* ***Resultados:*** *Os experimentos indicaram que a interface músculo/implante aqueceu menos do que a interface músculo/osso, especialmente nas intensidades de 1.5 e 2.0 W/cm², após 5 e 10 minutos de tratamento.* ***Conclusão:*** *Os resultados obtidos apontam para a possibilidade de utilização do ultrassom terapêutico em pacientes com implantes metálicos, incentivando pesquisas futuras para desenvolver protocolos baseados em evidências e recomendações seguras na fisioterapia.*

Palavras-chave: *Implantes artificiais. Aquecimento. Ultrassom terapêutico.*

Introduction

Ultrasonic waves are generated from an electric current that passes through a piezoelectric ceramic, which in turn vibrates, producing mechanical waves with frequencies varying according to the thickness of the crystal.[1] When the frequency exceeds 20 kHz, this wave is classified as ultrasound.[2]

Therapeutic ultrasound (TUS) exhibits biological effects classified as thermal and non-thermal.[3,4] Thermal effects are produced by continuously vibrating mechanical waves[5] that aim to reach temperatures between 40 and 45 °C for about 5 to 10 minutes,[6] a sufficient time to produce beneficial physiological changes.[2] However, when the temperature exceeds 45 °C, hyperthermia occurs, whereby tissue necrosis and burns are inherent.[7,8] Non-thermal effects are produced by interval mechanical vibration (ultrasonic pulses), allowing for heat dispersion,[9] such that the maximum temperature induced in the tissue is below 40 °C.[10]

The effects of TUS on biological tissues can be reversible or not. Thus, knowledge about the indications and contraindications of this therapy is crucial.[6] However, there is still considerable controversy regarding its indications and contraindications for use on mammary glands, bone epiphyses, and metallic implants.[5]

In the specific case of irradiation with TUS in tissues containing metallic implants, the most relevant point is to identify whether the heating produced by TUS at the muscle/implant and implant/bone interfaces is greater than at the muscle/bone interface, which is known to heat more than the rest of the irradiated tissue.[11]

Infrared thermography has recently been used as a tool to evaluate temperature variations in phantoms and/or *ex vivo* biological tissue.[11,12] It provides some advantages over other thermometry instruments, such as higher sensitivity, advanced software and cameras,[11,13] as well as a thermal resolution of 0.1 °C,[14] allowing analysis not only of specific points but also of the entire image. It has been widely used in the non-invasive study of TUS-induced heating.[12]

Phantoms are test samples that mimic the properties of biological tissuess.[15] Their use in research avoids unnecessary risks to animals and humans, eliminating excessive exposure to living beings. Additionally, they have the advantage of being more easily controlled. As such the aim of this research was to analyze the thermal field at the muscle-bone interface in tissue-mimicking test samples (ultrasonic phantoms) with and without the presence of a metallic implant after TUS application.

Methods

A phantom was constructed to mimic the layer of fat and another the layer of muscle with acoustic and thermal properties closest to those of biological tissues,16 both with dimensions of 13 x 8 x 2 cm in the shape of a parallelepiped. For the muscle phantom, initially, 3% graphite powder was added to a beaker containing

110 ml of PVC (polyvinyl chloride), and the mixture was then placed in a Pyrex dish with dimensions of 13 x 8 x 5 cm. Next, the dish was placed in a microwave oven for 30 seconds with the power adjusted to 50%. This heating procedure was repeated seven times, always stirring the liquid manually between intervals in order to homogenize the temperature, preventing the mixture from exceeding 160 °C.[17] For the fat layer, a phantom was made using the same process, but without adding graphite powder. The phantoms were not placed in a vacuum chamber to remove air bubbles. It is important to note that the acoustic parameters of the phantoms were measured, being compatible with human muscle and fat layers.

The beef rib bone was obtained from a butcher, cleaned to remove any attached tissues, and then washed with a neutral detergent. Two samples of the rib, measuring approximately 13 x 4 cm, were selected, one of which had a titanium alloy plate implanted with two screws fixed at the ends. The metallic plate and screws were donated by the surgical center of the Hospital das Clínicas, Rio Branco, Acre state.

The experimental setup was arranged with the samples in the following sequence: fat, muscle, and bone (Figure 1A), with or without the metallic implant. This assembly was supported by a copper frame (Figure 1B) and secured with a latex cord on the sides. To achieve the human body temperature range (36.5 to 37.0 °C), an ultrathermostat cryostat water bath (521/D; Nova Ética, Vargem Grande Paulista, Brazil) was used. The samples were immersed and maintained in the water bath until reaching the thermal equilibrium of the temperature set on the device.

The therapeutic ultrasound (TUS) equipment used in this study was the SONOMED V model (Carci, São Paulo, Brazil), previously evaluated with a radiation force balance (UPM-DT-1AV; Ohmic Instruments, Easton, MD, USA). Thermal images were captured using an E6 thermal camera (Flir Systems Inc., Wilconville, USA), with the camera lens positioned 30 cm from the upper surface of the phantom or bone to be thermographed. The region assessed was the lower surface of the fat and muscle phantom and upper surface of the bone. It is important to note that images were recorded both before and after TUS application, and the experimental apparatus was the same for all protocols. The application of TUS followed specific nominal parameters commonly used in clinical practice: a fre-quency of 1 MHz for all applications, intensities of 1.0, 1.5, and 2.0 W/cm², for 5 and 10 minutes at each inten-sity, with linear scanning of the applicator probe in all protocols.

The copper support with the bone sample, with or without the metallic implant attached to it, was submerged for 15 minutes in a water bath. The fat and muscle phantoms were added immediately, and another 15 minutes was required for the entire system to reach the pre-selected temperature (thermal equilibrium). After 30 minutes, one of the samples was removed from the water bath, and the temperature on the sample's surface was measured using an infrared camera.

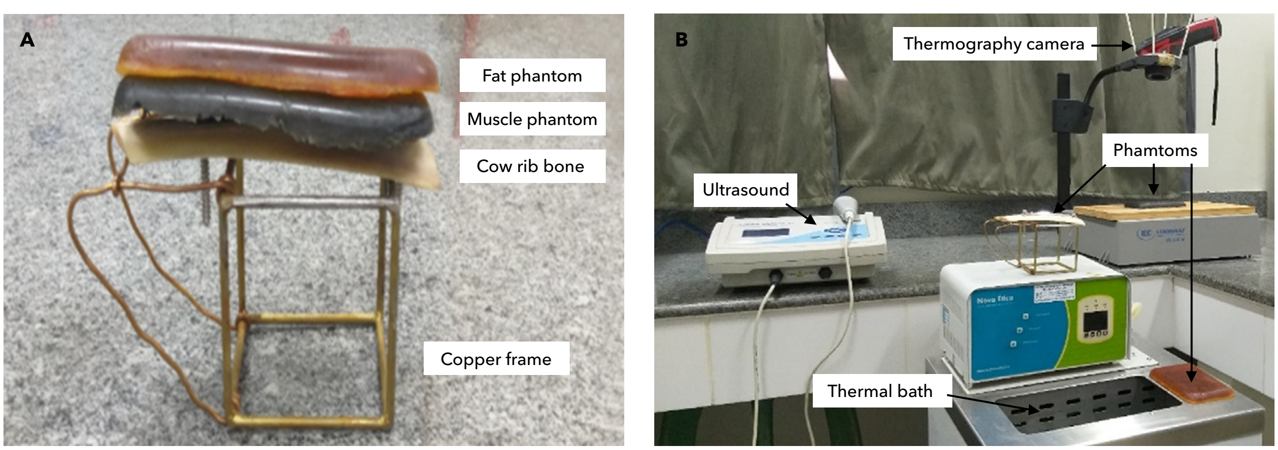

Figure 1 - Illustration of the arrangement of fat and muscle phantoms and the bone on a copper support (A) and experimental setup (B).

The same procedure was performed before starting each protocol. After the first temperature recording of the samples, they were repositioned on the copper support, submerged again in the water bath, and therapeutic ultrasound was applied with the predetermined parameters in each protocol. Finally, the second thermal image was recorded immediately after the application. Measurements and protocols were repeated on the experimental apparatus with and without the metallic implant five times for each protocol. For purposes of data analysis simplification, the temperature variation in the first layer (fat) was not considered.

Statistical analysis was performed using SPSS20 (JAVA®), with a significance level of 0.05. The Shapiro-Wilk normality test was used, and the paired t-test was applied to compare the temperature means recorded before and after ultrasound application in each sample.

Results

For data analysis purposes, temperature variations between 3.0 and 8.0 °C were considered capable of generating a therapeutic effect through heat. Temperature variations above 8 °C were considered damaging to muscle and bone tissue. The analyses were conducted at the muscle/bone interface, with the surface of the muscle considered the underside in contact with bone and/or metallic implant, and for the bone, the upper surface was analyzed.

The variation in spatial average temperature was calculated from the difference between the average temperature of the selected area after and before TSU application. Five repetitions were performed for each parameter. After thermal images were transferred to the Flir® Tools program, the arithmetic mean of the five temperatures obtained was calculated.

The results are displayed in Table 1. After the images were analyzed using the Flir® Tools program, in the phantom experiment without and with metallic implant, using parameters of 1 W/cm², 1.5 W/cm², and 2 W/cm², at 5 and 10-minute intervals, it was found that the temperature required to generate a therapeutic effect at the muscle/bone interface (inferior muscle and superior bone) was not reached. The protocol that raised the temperature closest to the range recommended in the literature was the nominal intensity of 1.5 W/cm², with an application time of 10 minutes in the muscle region without an implant, resulting in a temperature variation in the muscle of 1.78 ± 1.30 °C.

Table 1 - Difference in spatial average temperature at the muscle/bone interface

Application time	Intensity (W/cm²)	Muscle			Bone		
		Without implant	With implant	p-value	Without implant	With implant	p-value
5 minutes	1.0	0.58 ± 0.36	0.96 ± 0.73	0.456	0.42 ± 0.26	0.60 ± 0.56	0.494
	1.5	1.30 ± 0.57	1.18 ± 0.58	0.637	0.98 ± 0.57	0.84 ± 0.85	0.732
	2.0	1.72 ± 0.58	1.10 ± 0.46	0.052	1.04 ± 0.80	0.64 ± 0.51	0.116
10 minutes	1.0	0.98 ± 0.24	1.70 ± 1.47	0.289	0.66 ± 0.32	0.94 ± 1.16	0.562
	1.5	1.78 ± 1.30	1.44 ± 0.99	0.175	0.74 ± 0.36	0.78 ± 0.97	0.902
	2.0	1.78 ± 0.55	1.52 ± 0.51	0.354	0.84 ± 0.42	0.64 ± 0.75	0.686

Note: paired t-test, significant difference for < 0.05.

According to Table 1, the muscle phantom experienced greater heating than the bone with and without metallic implants in all parameters analyzed. In general, comparing the temperature in the muscle phantom when the bone was without and with an implant makes it possible to observe that the temperature elevation was higher in the absence of the implant; however, the temperature difference was not statistically significant in any of the cases. The bone without a metallic implant irradiated for 10 minutes at intensities of 1.5 W/cm² and 2.0 W/cm² heated less than expected when compared to those irradiated for 5 minutes. This outcome may have occurred due to the device sometimes indicating "overheating" and not irradiation until the temperature normalized. As used in clinical practice, the operator continued performing linear scanning movements with the probe, and the device continued the countdown of the application time, which may have led to cooling of the samples. It is suggested that further studies use ultrasound equipment that maintains irradiation for the entire adjusted period. Another hypothesis is the possible presence of tiny air bubbles, since the phantoms could not be subjected to a vacuum chamber for their removal, which may reduce the propagation of the mechanical wave in the material.

In addition, the greater the irradiation intensity and time, the higher the temperature levels reached. However, in the bone with metallic implants, the temperatures decreased with an intensity increase for 10 min.; once again, this may have been caused by the previously mentioned factor. For normality analysis using the Shapiro-Wilk test, the distributions were normal for all variables in the experiment.

Discussion

When comparing the two subgroups of the experiment, it was observed that in the protocols using intensities of 1.0 W/cm^2 and 1.5 W/cm^2 and application times of 5 and 10 minutes, the bone with a metallic implant heated more than that without an implant. By contrast, for the protocol related to the nominal intensity of 2.0 W/cm^2 and application times of 5 and 10 minutes, the implant-free bone heated more than its counterpart with an implant. The use of protocols in continuous mode and with the three nominal intensities, with and without the metallic implant, did not generate a therapeutic effect. This is believed to be due to several factors, including application time, irradiated area, and linear scanning movement.

Application time is usually obtained by dividing the area to be treated by the effective radiation area (ERA) of the TSU probe.[6] In the present study, the area of the irradiated phantom was approximately 100 cm^2, and the ERA of the ultrasound beam used was 7 cm^2; thus, the time should have been 14 minutes. However, application times of 5 and 10 minutes were used in the protocol used. This may have impacted the average temperature at the interface, which did not reach the 40 to 45 °C range required for the expected therapeutic effect.

Grey[18] conducted research to compare the exposure time of tissues irradiated by TSU, using mathematically constructed scanning patterns and manual application patterns by therapists, as it is unknown whether the total treatment time or the planned average local exposure time really represent local exposure. During his study, the author found a significant difference in how ultrasound was applied, and in the manual application by 22 therapists, the average exposure time was shorter than imagined. Thus, the linear scanning application pattern used in the present experiment may have also influenced local exposure, resulting in the ideal temperature not being achieved.

De Sá[6] conducted three ultrasound application protocols, one static, one with circular scanning, and another with linear scanning, to determine which could generate an optimal heating pattern. The author found that the best heating for a frequency of 1 MHz, intensity of 2 W/cm^2, and time of 10 minutes was obtained with circular scanning in an area 3.77 times larger than the ERA, using a speed of 2 cm/s. The author also stated that the heating level is entirely dependent on the parameters used, suggesting inadequate heating in clinical treatments. This leads us to suppose that another factor that may have influenced the temperatures reached in the present study was the linear scanning used in the protocols. However, what influenced the outcome obtained by De Sá[6] was not only the type of movement but also the speed, time as a function of area, and device parameters. In the present study, an attempt was made to use a speed of 2 cm/s by counting the time with an analog clock.

Reis et al.[11] assessed the thermal distribution area and peak temperature in muscle phantoms and bone with metallic implants using a protocol with a fixed probe and circular movement, and an application time of 2 minutes, nominal intensity of 1 W/cm^2, and frequency of 1 and 3 MHz. One of their conclusions was that there was greater heating in the muscle than in the bone with an implant. Thus, the present study corroborates the data found by the authors, given that what they concluded was also observed in experiments with and without a metallic implant, differing in the type of scanning and parameters used (closer to clinical practice).

The aforementioned study also stated that applying TSU over regions with metallic implants proved to be safe.[11] In this experimental research, it was found that although the bone with a metallic implant heated more than that without an implant in most protocols, it still did not reach a temperature that could cause damage. This information corroborates several authors, such as Garavello et al.,[3] Sun et al.,[19] and Cameron.[20]

It was observed that applying TSU on the fat and muscle phantoms and bone without the metallic implant resulted in greater heating compared to application in the presence of the implant. It is believed that because the metallic implant is a good heat conductor, it may have dissipated the heat to the water in which the experimental apparatus was immersed, since the bone with an implant also generally heated less than that without an implant.

Thus, two observations were made when comparing the application of protocols using continuous mode in the presence of bone with and without a metallic implant: that the muscle heats up more than the bone in the absence of the metallic implant, and that in the presence of the implant, the muscle heats up less than without the implant. This indicates that the heat generated is quickly dissipated by the metallic plate, and may have also been transferred to the water where the experimental apparatus was immersed. Reis et al.[11] also reported that the implant is responsible for the rapid heat dissipation into the environment during the thermal imaging process.

As can be observed in Table 1, with the increase in irradiation intensity and application time, the trend is to an increase in the temperature of the muscle/bone interface. This occurs because the higher the intensity, the greater the energy irradiated, causing an increase in phantom and bone temperatures.

Conclusion

In the experiments with phantoms, there was a lower increase in muscle temperature in the presence of a metallic implant compared to without the implant. This is a good indication that diathermy treatment with therapeutic ultrasound (TUS) in patients with metallic implants does not damage biological tissue, at least at doses where there was no overheating of the probe and with the metallic plate model used in this study.

Future studies could consider the use of different-sized plates, other types of scanning with the probe and equipment that do not turn off due to overheating. It is suggested that when repeating the experiment with phantoms, the exact moments of overheating should be monitored to confirm whether this influences the final temperature of the region irradiated by TSU.

Authors' contributions

CKBFN was responsible for setting up the experiment and data collection; LMBB for tabulating, statistically analyzing the data, and creating tables; KAC for conducting the experiments and interpreting the results; VLS for writing the text and standardizing the norms according to the journal; WCAP for revising the text and adding significant parts; and LEM for developing the research project, reviewing the text, and analyzing and interpreting the data. All authors approved the final version.

References

1. Kitchen S. Eletroterapia: prática baseada em evidências. 11 ed. São Paulo: Manole; 2003.

2. Oliveira DP. Estudo do campo térmico do ultrassom terapeutico em phantom do terço medio do braço com e sem implantes metalicos [dissertação]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2013. 89 p.

3. Garavello I, Mazzer N, Barbieri CH, Andrade JM. Efeitos térmicos do ultrasom terapêutico sobre os tecidos ósseo e muscular e sobre placa metálica implantada: estudo experimental térmográfico em coelhos. Rev Bras Ortop. 1997;32(6): 473-9. Full text link

4. Robertson VJ, Baker KG. A review of therapeutic ultrasound: effectiveness studies. Phys Ther. 2001;81(7):1339-50. DOI

5. Alencar I. Efeito do ultrassom terapêutico: Uma abordagem geral no aparelho e nas principais contra indicações [monografia de pós-graduação]. Goiás: Faculdade Ávila; 2004. Full text link

6. De Sá JNB. Desenvolvimento de protocolo para avaliar os padrões de aquecimento gerados por diferentes manobras terapêuticas em ultrassom de fisioterapia [dissertação]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2009. Full text link

7. Sellani G, Fernandes D, Nahari A, Oliveira MF, Valois C, Pereira WCA, et al. Assessing heating distribution by therapeutic ultrasound on bone phantoms and in vitro human samples using infrared thermography. J Ther Ultrasound. 2016;4:13. DOI

8. Zohdi TI, Krone R. Estimates for the acoustical stimulation and heating of multiphase biotissue. Biomech Model Mechanobiol. 2018;17(3):717-25. DOI

9. Agne JE. Eletrotermofototerapia teoria e prática. Rio de Janeiro: Andreoli; 2013.

10. Itakura DA, Magas V, Neves EB, Nohama P. Alteração da temperatura nos tecidos biológicos com a aplicação do ultrassom terapêutico: uma revisão. Fisioter Mov. 2012;25(4): 857-68. DOI

11. Reis LC, Costa GA, Santos TQ, Fantinati AMM, Costa Jr JFS, Fonte-Pereira AJ, et al. Estudo do aquecimento na interface músculo-osso com implante metálico em terapia por ultrassom. In: XXIII Congresso Brasileiro em Engenharia Biomedica; 2012. Full text link

12. Santos TQ, Reis LC, Costa GA, Fantinati AM, Costa Jr JFS, Pereira AJF, et al. Análise do campo térmico do ultrassom terapêutico em phantom de mama utilizando protocolos de 1 e 3 MHz. In: Congresso Brasileiro em Engenharia Biomedica; 2012. Full text link

13. Andrade Filho ACC. Teletermografia: princípios físicos, fisiológicos e fisiopatológicos da produção da imagem e suas indicações na clínica de dor e reabilitação. Acta Fisiatr. 1999;6(2):55-9. Full text link

14. Garcia DR. Validação da termografia no diagnóstico de lesões por esforços repetitivos/distúrbios osteomusculares relacionados ao trabalho [dissertação]. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2004. 124 p. Full text link

15. Oliveira DP, Santos TQ, Maggi LE, Costa-Felix RPB. Ultrasound propagation velocity and acoustic attenuation on agarose phantoms' in three different manufacture techniques. In: Pan American Health Care Exchanges (PAHCE). Brasilia; 2014, p. 1-3. Full text link

16. Maggi LE. Caracterização das propriedades acústicas de novos materiais visando a confecção de phantoms ultrassônicos [tese]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2011. 117 p. Full text link

17. Matheo LL. Mimetização da aparencia ultrassonografica dos ductos lactíferos em phantoms de mama [dissertação]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2016. 65 p. Full text link

18. Grey K. Distribution of treatment time in physiotherapeutic application of ultrasound. Physiotherapy. 2003;89(12):696-707. DOI

19. Sun MK, Shieh J, Chen CS, Chiang H, Huang CW, Chen WS. Effects of an implant on temperature distribution in tissue during ultrasound diathermy. Ultrason Sonochem. 2016;32:44-53. DOI

20. Cameron MH. Agentes físicos na reabilitação - Da pesquisa à prática. 3 ed. São Paulo: Elsevier; 2009. p. 176-206.