The impact of ultrasound waves on changes in temperature around titanium orthopaedic implants – experimental studies

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Abstract

Introduction. Ultrasound waves were first used in medicine in 1938. Nowadays ultrasound procedures are often recommended in the treatment of many diseases. However, despite long-standing clinical experience, the literature draws our attention to discrepancies in clinically confirmed recommended therapeutic doses, and to contraindications to the use of ultrasounds. Among the commonly indicated contraindications is the presence of metal implants in the treatment region.
Objectives. The objective of this study was to assess temperature changes caused by ultrasound waves around titanium orthopaedic implants, using an experimental model.
Materials and methods. A titanium alloy located on the model of a composite bone was examined in this study as experimental model. The model was subjected to sonification in an aquatic environment. The procedures were carried

Key words:

ultrasound therapy, temperature, titanium implant, metal anastomosis

out using the continuous method and the doses 0.3 W/cm^2, 0.8 W/cm^2 and 1.2 W/cm^2. 30 procedures were conducted for each of the doses. The sonification amounted to 3 minutes. Temperature changes were measured using a professional 4 channels thermometer and type K thermocouples.

Results. Throughout the sonification procedure with a dose of 0.3 W/cm^2 the average difference between the maximum and minimum temperatures recorded by the T1 probe were equal to 0.34°C, T2 - 0.16°C, T3 - 0.01°C, T4 - 0.1°C. During the procedure with ultrasound waves at dose of 0.8 W/cm^2 and 1.2 W/cm^2 the average difference between temperatures were respectively: T1 - 0,68°C, T2 - 0,6°C, T3 - 0,15°C, T4 – 0,1°C and T1 - 2,08°C, T2 - 1,35°C, T3– 0,26°C, T4 –0,12°C.

Conclusions. 1. In the experimental conditions, the utilisation of ultrasound waves at doses of 0.3 W/cm^2 and 0.8 W/cm^2 for 3 minutes resulted in an increase in temperature in the titani-um implant region of less than 0.7°C, and at a dose of 1.2 W/cm^2 of nearly 2°C. 2. The presence of titanium orthopaedic implants in tissues does not constitute an absolute contraindication to employing sonification at small and medium doses. This, however, should be confirmed by in vivo studies.

Introduction

Many of the physical stimuli currently used in medicine have been known since ancient times. Through observation and by trial and error we have succeeded in organising and systematising our knowledge, making it repeatable, and thus more usable and effective.

At first, medicine used what nature had in store, and its resources are still being widely used today, for example in balneotherapy (mineral water, baths and drinking therapies, peloid, bathhouses and saunas). Other common sources of treatment stimuli were touch and movement, which, when appropriately matched and used, became the basis for massage and other broadly used manual techniques, as well as gymnastics and kinesiotherapy. The observation of nature also provided us with information on phenomena whose medical values were recognised and used only in the centuries to come. This was the case with electricity, which has accompanied mankind in the form of lightning, static electricity and the natural current produced by electric eels.

Ultrasound procedures have, however, a different history. In spite of different species' being able to use ultrasound waves in echolocation, such as dolphins and bats, before the nineteenth century we knew nothing about ultrasounds, as they exceeded the hearing range of the human ear, and thus could not have been captured by the senses in any way [1]. Ultrasound waves began to be researched in 1819, when Cagniard de la Tour, a Frenchman, generated ultrasounds using a special siren. In 1883 Galton determined the upper frequency of audibility of the human ear. The discovery of piezoelectricity by the brothers Jacques and Pierre Curie constituted a breakthrough in ultrasound research. This discovery was used by Paul Langevin, a physicist, who constructed in 1917 the first piezoelectric ultrasound generator [1,2].

It is assumed that ultrasound waves were first used in medicine in 1938, when Pohlman made his first attempts at using ultrasounds for medicinal purposes [1-4]. Between 1938 and 1942 Koeppen studied the impact of ultrasounds on the liver, spleen and bone marrow in dogs [6]. 1951 saw the 1^{st} Congress of Physical Medicine devoted solely to ultrasounds. During the congress, medical dosages and procedural techniques were determined. Later the scope of ultrasound utilisation in basic medical sciences, physical medicine and rehabilitation was extended [1-4,6].

The currently known biological activities of ultrasounds include influencing the processes of oxidation and reduction, catalytic activity, mechanical interaction in the form of alternating the densification and dilution of the medium in which the waves are propagated, resulting in the increased permeability of cell membranes, or, more importantly, the thermal effect [4,5]. In some cases, raising the temperature of tissues within the treatment region can yield measurable benefits and desirable effects, such as improved microcirculation, increased collagen fibre extensibility and decreased muscle tone. Furthermore, as a result of mast cell degranulation, histamine is released, which causes the dilation of blood vessels [2,7,8,9,10,11]. Despite the complex mechanism of the action of ultrasounds, they are considered the most important procedures with a deep thermal effect.

Due to the extensive scope of their biological activity, ultrasound procedures are often recommended in the treatment of many diseases [12,14,15]. However, despite long-standing clinical experience, the literature draws our attention to a small number of well-documented studies and discrepancies in clinically confirmed recommended therapeutic doses, and to contraindications to the use of ultrasounds [12,13,16,17,18,19]. Among the commonly indicated contraindications is the presence of metal implants in the treatment region, which, according to some authors, rule out the use of ultrasound waves [4,8,20,21,22]. For these authors, the main argument is the increase in temperature around metal bodies, which can have a destructive effect on the surrounding tissues. It is worth highlighting that until recently, and certainly during the time of conducting the majority of the quoted studies, whose results point to metal fixation as a contraindication to sonotherapy, austenitic steel has been a widely used biomaterial. Currently, due to their better biological and physicochemical properties, titanium and its alloys are being used more frequently to manufacture metal implants. This is due to their biocompatibility, corrosion resistance in the body-fluid environment, high strength parameters, non-ferromagnetic proprieties and low thermal conductivity (3.5 to 5x lower than steel) [23]. A more detailed determination of temperature changes in the area of metal fixation caused by ultrasound waves would make it possible to more precisely programme treatment procedures that use ultrasounds.

The objective of this study was to assess temperature changes caused by ultrasound waves around titanium orthopaedic implants, using an experimental model.

Materials and methods

A titanium alloy (TiAl6Nb7) commonly used in orthopaedics for bone fixation was examined in this study. The material was delivered free of charge by ChM sp.o. (Lewickie, PL). The fixation model was a rectangular plate, with the dimensions of 21x2 cm, located on the model of a composite bone (Promedicus, PL). The model was placed in a 35x24x13 cm plastic container, which, in turn, was located in a bigger 74x44x17 cm container. Both these containers were filled with normal saline. In the bigger container the liquid temperature was maintained at a constant level similar to human body temperature (36.6°C), using a kit consisting of an aquarium heater, an RT-2C regulator by ZUH TOMAR (PL), and a FAN FILTER Professional water pump by Aquael (PL).

The model located in the smaller container was subjected to sonification in an aquatic environment, using a Sonicator 715 (Technomex, Gliwice, PL) device and a head with a diameter of 5 cm, generating waves with a frequency of 1 MHz. The procedures were carried out using the continuous method and the doses 0.3 W/cm^2, 0.8 W/cm^2 and 1.2 W/cm^2. 30 procedures were conducted for each of the doses. The sonification time was comparable to the real time of the procedure used in humans, and each and every time amounted to 3 minutes.

Temperature changes were measured using a professional 4 channels DT–8891 E (CEM Warszawa, PL) thermometer and type K thermocouples (NiCr–NiAl), with a temperature measurement range of –200°C to +1200°C, and a sensitivity of 41 μV/°C. While taking the measurements thermocouples were covered with plastic sheaths and placed in the middle of the model's length. The T1 thermocouple was placed immediately next to the metal plate, T2 at a distance of 1cm from the plate, and T3 at a distance of 2 cm from the plate. The T4 (reference) thermocouple was placed at a distance of 15 cm from the model. The temperature changes were recorded constantly using dedicated software installed on PC-class computer. Temperature changes were recorded every 1 second for 6 minutes, i.e. throughout the sonification (3 min) and cooling periods (subsequent 3 minutes) (fig. 1).

The statistical analysis of the obtained data was conducted using the Statistica 10.0 software (StatSoft Polska). The normality of the distribution was verified using the Kolmogorov–Smirnov test, with the Lilliefors correction, and the Shapiro–Wilk test. The values of the analysed measurable parameters were characterised using the arithmetic mean and standard deviation. The assumed statistical significance indicator (p) was set at the level of 5% ($p<0.05$).

Results

Throughout the sonification procedure with a dose of 0.3 W/cm^2 the average difference between the maximum and minimum temperatures recorded by the T1 probe were equal to 0.34°C (Z=1.98, p=0.079). In the case of the T2 probe, this difference was 0.16°C (Z=0.51, p=0.14), for the T3 probe it was 0.01°C (Z=0.41, p=0.97), and for the T4 probe – 0.1°C (Z=0.49, p=0.81). No statistically significant differences were found between the values measured by the individual probes (T1-T4) ($p>0.05$). After finishing the sonification, e.g. in the 3-minute cooling phase, the average drops in temperature recorded equalled 0.22°C (Z=1.9, p=0.08), 0.05°C (Z=0.47, p=0.83), 0.09°C (Z=0.58, p=0.92), and 0.1°C (Z=0.56, p=0.79) for the T1–T4 probes respectively. The differences between individual probes (thermocouples) were not statistically significant ($p>0.05$) (Table 1).

During the three-minute application of ultrasound waves with the intensity of 0.8 W/cm^2 the average rise of temperature values recorded by the probe

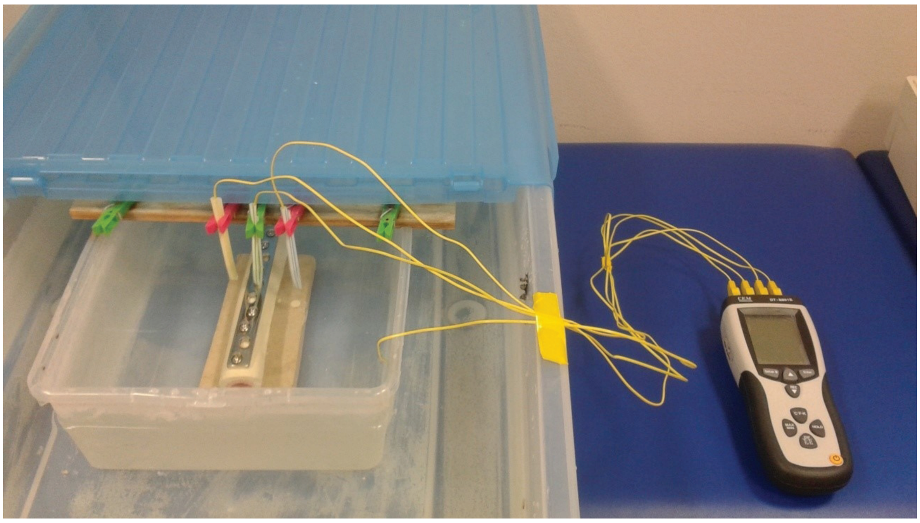

Fig. 1.
An overview of the experimental model

Table 1.
The changes in temperature recorded by the T1-T4 probes during ultrasound wave propagation at a dose of 0.3 W/cm2 (mean ± standard deviation; n=30).

Probe	Increase in temperature [°C] in the sonification phase (t=3 min.)		Z	p	Difference between groups	Decrease in temperature [°C] in the cooling phase (t= 3 min.)		Z	p	Difference between groups
	Mean	SD				Mean	SD			
T1	0.34	0.12	1.98	0.079	-	0.22	0.09	1.9	0.08	-
T2	0.16	0.04	0.51	0.14	-	0.10	0.05	0.47	0.83	-
T3	0.01	0.06	0.41	0.97	-	0.09	0.04	0.58	0.92	-
T4	0.10	0.10	0.49	0.81	-	0.10	0.10	0.56	0.79	-

located directly by the metal implant (T1) was 0.68°C (Z=4.02, p=0.0023). For the thermocouple located at a distance of 1cm from the implant (T2) the increase in temperature was 0.6°C (Z=2.98, p=0.0097), for the T3 thermocouple this value was 0.15°C (Z=0.57, p=0.12), and for the T4 thermocouple, it was 0.1°C (Z=0.51, p=0.72). Statistically significant (p<0.05) differences were found between the T1 and T3, T1 and T4, T2 and T3, and T2 and T4 probes (thermocouples). A significantly higher increase in temperature was observed on the thermocouples located closer to the titanium implant (T1 and T2), than on those located at distances of 2 cm (T3) and 15 cm (T4) from the implant. No statistically significant differences were observed between the results obtained using the other thermocouples T1-T2 and T3-T4 (p>0.05). Within the three-minute observation window after the procedure, the average value of temperature drop for the T1, T2, T3 and T4 probes amounted to 0.4 °C (Z=2.53, p=0.031), 0.28°C (Z=1.90, p=0.08), 0.1°C (Z=0.40, p=0.73) and 0.1°C (Z=0.55, p=0.78) respectively. Statistically significant differences (p<0.05) between the measurements taken by the T1 and T3, and T1 and T4 probes were found. No significant differences were observed between reading obtained from the other thermocouples T1-T2, T2-T3 and T3-T4 (p>0.05) (Table 2).

During the sonification procedure with a dose of 1.2 W/cm^2 the average difference between temperatures recorded by the T1 thermocouple was 2.08°C (Z=4.12, p=0.001). The increase in temperature for the T2 probe, located at a distance of 1 cm from the implant, was 1.35°C (Z=3.99, p=0.007), while for the T3 it was 0.2°C (Z=0.58, p=0.1), and in the case of the T4 probe 0.12°C (Z=0.39, p=0.8). A statistically significant differences (p<0.05) between the measurements taken by the T1-T2, T1-T3, T1-T4 and T2-T3, as well as the T2-T4 probes were found. A statistically significantly higher increase in temperatures was observed on the thermocouple located close to the titanium implant (T1), than on those located at distances of 1 cm (T1), 2 cm (T3), and 15 cm (T4) from the implant (p<0.05)(Table 3).

In the cooling phase, which lasted for three minutes, the average decrease in temperature recorded by thermocouple placed next to the titanium implant (T1) was 1.35°C (Z=3.76, p=0.008). The average decrease in temperature values recorded by the T2 probe was 0.78°C (Z=2.83, p=0.012), for the T3 probe was 0.18°C (Z=0.56, p=0.19), and for the T4 probe – 0.15°C (Z=0.57, p=0.16). Statistically significant differences between the measurements taken by the T1-T2, T1-T3, T1-T4 and T2-T3, as well as the T2-T4 probes (p<0.05) were observed. The average temperature drop in the cooling phase observed on the T1 probe was statistically significantly higher than in the case of the temperature drops on the T2, T3 and T4 (p<0.05) thermocouple probes. The Z figure for T1-T4 was between 1.56-4.78 (Table 3).

During the procedure with ultrasound waves at a 0.3 W/cm^2 dose, the average maximum increase in temperature recorded by the probe located

Table 2.
The changes in temperature recorded by the T1-T4 probes during ultrasound wave propagation at a dose of 0.8 W/cm2 (mean standard deviation; n=30).

Probe	Increase in temperature [°C] in the sonification phase (t=3 min.)		Z	p	Difference between groups	Decrease in temperature [°C] in the cooling phase (t= 3 min.)		Z	p	Difference between groups
	Mean	SD				Mean	SD			
T1	0.68	0.38	4.02	0.0023	T1-T3, T1-T4	0.40	0.31	2.53	0.031	T1-T3, T1-T4
T2	0.60	0.50	2.98	0.0097	T2-T3, T2-T4	0.28	0.24	1.90	0.08	-
T3	0.15	0.11	0.57	0.12	-	0.10	0.03	0.40	0.73	-
T4	0.10	0.10	0.51	0.72	-	0.10	0.10	0.55	0.78	-

Probe	Increase in temperature [°C] in the sonification phase (t=3 min.)		Z	p	Difference between groups	Decrease in temperature [°C] in the cooling phase (t= 3 min.)		Z	p	Difference between groups
	Mean	SD				Mean	SD			
T1	2.08	0.65	4.12	0.001	T1-T2, T1-T3, T1-T4	1.35	0.69	3.76	0.008	T1-T2, T1-T3, T1-T4
T2	1.35	0.79	3.99	0.007	T2-T3, T2-T4	0.78	0.65	2.83	0.012	T2-T3 i T2-T4
T3	0.26	0.15	0.58	0.1	-	0.18	0.17	0.56	0.19	-
T4	0.12	0.13	0.39	0.8	-	0.15	0.22	0.57	0.16	-

Table 2.
The changes in temperature recorded by the T1-T4 probes during ultrasound wave propagation at a dose of 1.2 W/cm2 (mean standard deviation; n=30).

immediately next to the titanium implant (T1) was 0.34°C. Increasing the intensity to 0.8W/cm^2 resulted in an increase in temperature on the T1 probe by 0.68°C on average (fig. 2). On the other hand, the use of a 1.2 W/cm^2 dose resulted in an increase in temperature of 2.08°C. The temperature differences observed on the T1 probe between 0.3 W/cm^2, 0.8 W/cm^2 and 1.2 W/cm^2 intensities were statistically significant ($p<0.05$). The average difference between the extreme temperatures recorded by the probe located at a distance of 1 cm from the implant (T2) was 0.16°C at a dose of 0.3 W/cm^2. When a dose of 0.8 W/cm^2 was applied, the increase in temperature was 0.68°C, and with the intensity of 1.2 W/cm^2 – 1.35°C. The temperature differences observed on the T2 probe between the intensities 0.3 W/cm^2, 0.8 W/cm^2 and 1.2 W/cm^2 were statistically significant ($p<0.05$). The increase in temperatures recorded by the T3 and T4 probes (located at distances of 2 and 15 cm from the implant, respectively) was similar in all intensities used: 0.01–0.26°C. No statistically significant difference in temperature increase on the T3 and T4 probes was recorded ($p>0.05$) (Fig. 2).

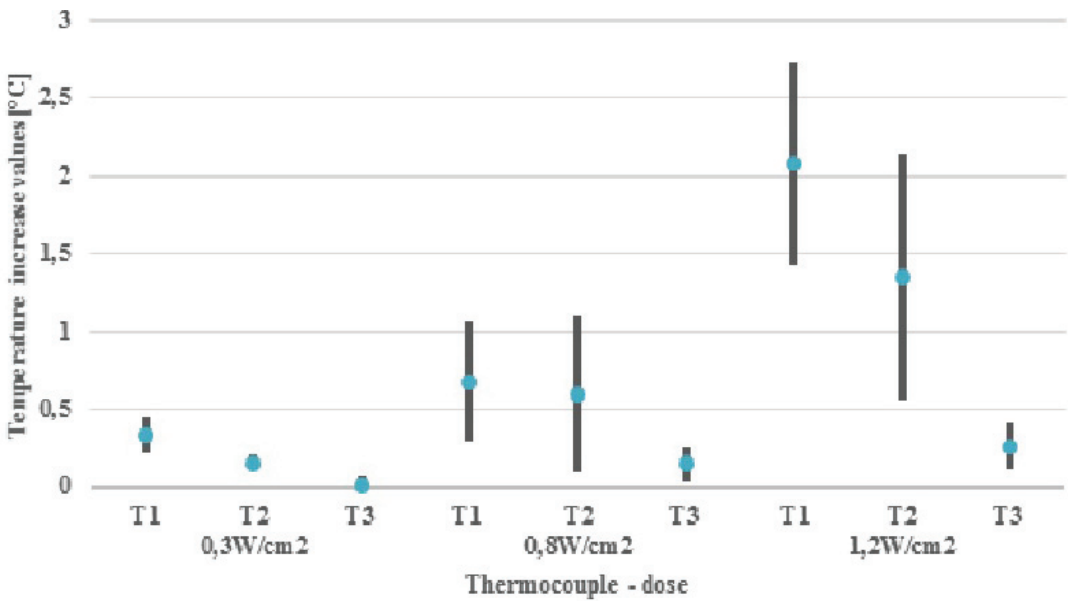

Fig. 2.
A cumulative temperature increase graph in °C depending on the ultrasound wave doses: 0.3, 0.8 and 1.2 W/cm^2 for the T1-T3 thermocouples (mean ± SD). For visualization reasons the readings from T4 reference probe were excluded.

Discussion

Ultrasound therapy is one of currently mostly used physical therapy procedures [24]. The effect of such physical stimuli on a living organism is associated with mechanical action and conversion of the delivered energy to heat, and thus with increasing the temperature of tissues in the treatment region. In addition to the undeniable therapeutic benefits, this is, however, associated with a risk of thermal damage to the tissues in the case of using a too-intensive stimuli.

Mika, Kasprzak and Kochański [3,7,26], consider that metal elements located inside tissues constitute a contraindication to ultrasound procedures. On the other hand, authors such as Robertson Ward, Low & Reed [25] indicate that metal implants could not be contraindications to employing ultrasound stimulus. They justify this by the fact that metal elements reflect ultrasound waves at the interface, which leads to increased energy absorption around the implant without a significant increase in its temperature. Even if the metal is heated, the heat is distributed to the surrounding tissues by conduction. Kocaoglu, Cabukoglu, Ozeras, Seyhan, Karahan & Yalcin [27] also state that internal bone fixation does not constitute a contraindication to administering ultrasound therapy. They support their statement with the results of experiments on animals with intramedullary placed metal implants and temperature sensors. Regions with implants were subjected to sonfication using a head with a diameter of 5 cm, emitting waves with a frequency of 1MHz, at a dose of 1W/cm^2, once a day for 5 minutes over the course of 27 days. The sonification did not result in a temperature rise or local tissue necrosis. When it comes to the negative effects of heat on tissues, Robertson [25] states that irreversible effects in the organism, i.e. the disintegration of proteins, cells and tissues, take place after exceeding local temperature of 45°C. He also states that changes in core temperature to be obtained from the therapeutic procedures are limited to 5-6°C above or below the core temperature. According to Mika [26], the safe limit for tissue temperature increase is 1°C. Presented discrepancies are considerable. However, it is worth highlighting that they might result from the aforementioned differences in the material of the implant. It appears more justified to compare the results of our research to Robertson's researches basing on similarity of materials than to rely on Mika's arguments, which refer to stainless steel that is used rarely now.

Taking into account only the impact of temperature on tissues, our research proves that small, medium and large doses alike (0.3, 0.8 and 1.2 W/cm^2), with a continuous wave and a frequency of 1 MHz, are safe for the patient. An average increase in temperature with the dose of 0.3 W/cm^2 was to 0.3°C close to the implant and 0.1°C at a distance of 1cm and 2 cm from the implant. In the case of a sonification medium dose (0.8 W/cm^2) an increase in temperature close to implant amounted to nearly 0.7°C, at a distance of 1 cm to 0.6°C, and at a distance of 2 cm to 0.2°C. The results of our research recorded during sonification with a large dose (1.2 W/cm^2) also fell within the ranges proposed by Robertson [25]. The rise of temperature in the region close to titanium implant were 2,0°C, at a distance of 1cm it was 1.4°C, and at a distance of 2 cm was only 0.3°C.

We should also draw special attention to the fact that our research was conducted in laboratory conditions, using an individually created model that did not take into account hormonal or vascular reactions, or segmental reflexes. The occurrence of such autonomic reactions undoubtedly influences heat distribution, both in the procedure phase itself and during cooling. In addition, it should be pointed out that our research was conducted using a titanium model which has different physicochemical properties from the once-used austenitic steel products. Perhaps the contraindications to the use of ultrasound in the case of metal implants present inside tissues were based on the utilisation of a biomaterial other than titanium. Taking into account the present state of the art in bio-engineering and the advanced level of materials it utilises, as well as the results of the own research, it appears justified to verify and update the safety principles for physical procedures employing ultrasound waves.

As in the literature there are few researches on this topic, it is necessary to carry out further experiments in the field of using ultrasound therapy on people with metal implants. Our own research by no means solves the issue in question and requires further exploration in *in vivo* studies.

Conclusions

1. In the experimental conditions, the utilisation of ultrasound waves at doses of 0.3 W/cm^2 and 0.8 W/cm^2 for 3 minutes resulted in an increase in temperature in the titanium implant region of less than 0.7°C, and at a dose of 1.2 W/cm^2 of nearly 2°C.
2. The presence of titanium orthopaedic implants in tissues does not constitute an absolute contraindication to employing sonification at small and medium doses. This, however, should be confirmed by *in vivo* studies.

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