Characterisation of ultrasound-induced heating effects in the mother and fetus: a clinical perspective

Abstract

Introduction

The quantification of heating effects during exposure to ultrasound is usually based on laboratory experiments in water, and is assessed using extrapolated parameters such as the Thermal Index. In our study we have measured the temperature increase directly in a simulator of the maternal-fetal environment, the "ISUOG Phantom", using clinically relevant ultrasound machines, probes, and exposure conditions.

Methods

The study was carried out using an instrumented phantom designed to represent the pregnant maternal abdomen which enabled temperature recordings at positions in tissue mimics representing the skin surface, sub-surface, amniotic fluid and fetal bone interface. We tested 4 different probes on a commercial diagnostic scanner. The effects of scan duration, presence of a circulating fluid, pre-set and power have been observed.

Results

The highest temperature increase was always at the probe/skin interface, where temperature increases as high as 9.5 °C were observed; lower temperature rises were observed deeper in tissue and at the bone interface. Doppler modes generated the highest temperature increases. Most of the heating occurred in the first 3 minutes of exposure, with the presence of a circulating fluid having a limited effect. The power setting affected the maximum temperature increase almost linearly, with peak temperature increasing from 4.3 °C to 6.7 °C when power was increased from 63% to 100%.

Conclusions

Although this phantom provides a crude mimic of the in-vivo conditions, the overall results showed good repeatability, and agreement with previously published experiments. All studies showed that the temperature rises observed fell within the recommendations of International regulatory bodies. However, it is important that the operator should be aware of factors affecting the temperature increase.

Introduction

Progress in technology has significantly improved the quality of ultrasound images, and thus of the number of pathologies which can be detected is constantly increasing. With better resolution, diagnosis can be made earlier in pregnancy, bringing with it relevant improvements in the possibility of intervention and thus in final outcome. While there is the aim of providing clinicians with the best possible tools, it is important to ensure that available new devices and protocols are safe for the mother and the foetus. [1, 2] Although widely recognized as safe, [3-5] two main bioeffect mechanisms of ultrasound are possible. These are divided into those that are thermal and those that are mechanical in origin. [6] The potential for harm from these is shown on the scanner display by two indices known as the Thermal Index (TI) and the Mechanical Index (MI) respectively. These are related to measurements performed in water, and involve a number of approximations which do not necessarily reflect the conditions under which scanning is performed in a clinical environment.

Guidelines for obstetric scans have been produced by the British Medical Ultrasound Society (BMUS). [7] These recommendations state that a temperature increase of ≥4 °C for 4 minutes, or of ≥5 °C for 1 minute is hazardous for the fetus, and recommend that the temperature rise is well below these levels. Recent statements from the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) Bioeffects and Safety Committee underline the importance of applying the ALARA principles, namely to limit the exposure time for Doppler modes and discourage the use of ultrasound for non-medical purposes. [8, 9]

This study addresses an existing challenge in ultrasound safety from a novel perspective. It aims to characterise the temperature changes that occur in the mother and fetus when exposed to ultrasound in a clinical setting by using clinically relevant ultrasound machines, probes, and exposure parameters. The study was carried out using a simulator of the maternal-fetal environment, the "ISUOG Phantom", which enables temperature recordings from sensors in tissue mimics representing the skin surface, sub-surface, amniotic fluid and fetal bone interface. Despite the limitations of using a phantom model, it has the clear advantage of overcoming the technological (and, arguably, ethical) barriers to performing a similar *in vivo* study on pregnant women in the clinic.

Methods

The ISUOG phantom

The ISUOG Phantom is a temperature controlled, fixed geometry hollow Nylon cylinder, with an external diameter of 150 mm, an internal diameter of 120 mm and height of 130 mm. It is designed to simulate the anatomy encountered during abdominal obstetric examinations through a simplified multi-layer geometry and tissue mimicking materials which simulate the acoustic properties of skin, soft tissue, amniotic fluid and bone. A schematic of the phantom is shown in Figure 1.

The top window is an acoustically transparent membrane (12 µm Mylar, Goodfellow Cambridge Ltd., UK) which protects the internal layers.

The first (top) layer is 1.5 mm thick silicone rubber (SILEX Ltd, UK) which simulates the skin. To mimic soft tissues, an agar-based gel was selected and produced in house. This is based on the recipe described by Brewin et al. [10] It is the standard formulation suggested by regulatory bodies (IEC60601-2-37 Annex DD) [11] for performing temperature tests on diagnostic probes. A gel block

25 mm thick was in contact with the silicone rubber layer. Behind a fluid gap, two further gel blocks of thicknesses 5 mm and 25 mm sandwiched a 5 mm thick high-density polyethylene disk designed to mimic a soft tissue-bone interface. The phantom was filled with a solution of deionised water and 11.9% w/w of Glycerol to preserve the agar-based gel and simulate the amniotic fluid.

The attenuation coefficient α and speed of sound (SoS) of the tissue mimicking materials at the relevant frequencies are shown in Table 1 and were measured at the National Physical Laboratory using the setup described by Rajagopal et al. [12] These values are comparable to those of real tissues listed in the 2018 version of the IT'IS foundation database for tissue properties. [13]

An 8 W resistive heater (Silicon Heater Mat, RS Components, UK) was placed at the bottom of the phantom. The internal temperature was kept stable using a custom-made controller which drove the heater and a peristaltic pump. With the circulation pump off, the phantom mimicked the conditions of the embryonic period prior to establishment of the utero-placental circulation.

Four 75 μm fine wire K-type insulated thermocouples (5SRTC-TT-KI-40-1 M, Omega Engineering, UK) were embedded in the phantom at the proximal skin surface, distal skin surface, at the back of the first block of soft tissue mimicking material and at the soft tissue-bone interface. The thermocouples are smaller than half of the wavelength at the highest frequency under examination.

A fifth thermocouple was placed outside the acoustic field to control the temperature of the circulating solution. The temperature data from all thermocouples were recorded using a TC08 datalogger (PicoTech, UK) connected to a computer. The sampling period was 1 s as in the previous study by Miloro et al. [14]

Experimental setup

A standard commercially available ultrasound equipment was tested. It was equipped with four different probes: two convex probes with centre frequencies of 4 and 6 MHz, a 4D probe with centre frequency 7 MHz and a linear probe with centre frequency 9 MHz.

Before each test, the internal temperature of the phantom was allowed to stabilise to a physiological temperature (between 35 °C and 37 °C). Ultrasound coupling gel was applied to the top surface of the phantom to ensure good acoustic coupling. The temperature at the surface was in the range 27 °C to 29 °C in all the experiments.

The probes were clamped to a rigid base and aligned with the axis of the phantom using the thermocouples as reference points. A photograph of the setup is shown in Figure 2.

Experimental protocols

Five different sets of experiments were carried out to assess the effects of the probe, the pre-set, the exposure duration, the power setting and the circulatory flow.

1. Exposure duration: the 9 MHz probe was used in a 1st trimester pre-set mode. Simulated skin, and foetal bone interface temperature changes were recorded for 30 minutes in B-mode and Power Spectral (PW) Doppler modes, and were repeated 3 times.

2. Fluid circulation: the 9 MHz probe in 1st trimester pre-set mode was used. Simulated skin and foetal bone interface temperature changes were recorded for 30 minutes in B-mode and PW Doppler exposure with amniotic fluid mimic flow either on or off. Measurements were repeated 3 times.

3. Probe studies: Surface temperature changes were recorded over 3-minute exposures for B-mode, Colour Doppler and PW Doppler exposures using the four probes described above. The ultrasound equipment was operated in 1st trimester pre-set mode.

4. Pre-set studies: the 9 MHz probe was used with: 1st trimester, 2nd trimester and Fetal Echo pre-sets. Surface temperature changes were recorded over 3-minute exposures for B-mode, Colour Doppler and PW Doppler exposures and were repeated 3 times.

5. Power studies: the 4 MHz and the 9 MHz probes were used. The surface temperature changes were recorded for 30 minutes at the power level of the 1st trimester pre-set in B-mode (63% and 79% for the 4 MHz and the 9 MHz probe respectively) and for 100% power.

A summary of the protocols is shown in Table 2.

Results

All results are presented as mean and standard deviation where appropriate. Two-tailed paired student t-tests were used to determine statistical significance between groups.

Thermal indices

Two different values of the thermal index, indicating the potential thermal hazard in soft tissue (TIS) and at the tissue/bone interface (TIB), were recorded. International standards do not require the TI to be displayed when it is less than 0.4, so in some cases these values were not available. [15]

Thermal indices displayed for the configurations used in the work are reported in Table 3.

The guidelines from BMUS [7] restrict the exposure time when TI>0.7. These times, shown for clarity in Table 4, are valid for both TIS and TIB and for 1st and 2nd trimester.

Exposure duration studies

A representative example of the temperature changes measured by the four thermocouples is shown in Figure 3.

The maximum temperature increase is at the probe/skin interface. A slower temperature increase is observed for the thermocouple positioned under the skin. No changes can be observed for the sensor positioned in the deeper soft tissue mimicking material, while measurable variations can be observed at the tissue/bone interface, probably due to the higher absorption coefficient of the bone mimic.

The example in Figure 3 is representative of the different experiments performed during this work. The complete dataset is provided as additional material to this paper. However, for clarity, the following discussion will focus on the results of the probe/skin mimic interface and on the tissue/bone interface when relevant.

An analysis of the maximum temperature rises at the probe-skin mimicking interface (surface) and at the bone/tissue interface are shown in Figure 4 and reported in Table 5. Results refer to B Mode and PW Doppler. Results shown are an average of 3 independent tests.

At the skin interface 35 to 44% of the mean 30-minute surface temperature rise was observed after 1 minute, and 56 to 64% after 3 minutes. At the bone/tissue interface 34% of the mean 30-minute temperature rise was observed after 1 minute, and 42% after 3 minutes.

Effect of amniotic fluid mimic flow

The results of the study of the effects of circulation flow, designed to mimic the embryonic and fetal stages of the pregnancy, are shown in Figure 5 for B-mode and Power Spectral Doppler. Statistical analysis showed no significant variation between the two conditions ($p>0.13$ in all cases). The maximum temperature increase at the soft tissue/bone interface was 0.1 °C for both modes and, for clarity, these have been omitted in the figure.

Probe studies

The results for 3-minute exposures using the four different probes are shown in Figure 6 and summarised in Table 6.

The lowest temperature increase for the three modes is always for the transvaginal (TV) probe. The 9 MHz probe gave the highest temperature increase.

Pre-set study

Three different pre-sets were tested for the 9 MHz probe: 1st trimester, 2nd trimester and Foetal echo, as these are commonly used in clinical practice. [16] Results are shown in Figure 7. In the B-Mode setting, the greatest difference in temperature was seen between the 2nd trimester and Fetal Echo pre-sets, the difference being 0.6°C (P=0.03). The differences were not significantly different between the 1st trimester and Fetal Echo pre-sets in Colour Doppler, (difference 0.4°C, P=0.40) and between the 2nd trimester and Fetal Echo pre-sets in Spectral Doppler, (difference 0.1°C, P=0.93).

Table 7 summarises the results for the three pre-sets.

Power studies

Finally, the effect of power settings was analysed for the 1st trimester pre-set. The results for the probe-skin mimic interface are shown in Figure 8. For the 4 MHz probe a change in power output setting from 63% to 100% showed a significant increase in heating effect. The mean temperature increase rose from 4.3 °C to 6.7°C (p=0.0015). This maximum temperature appears to be linear with power, as a rise of 6.8◦°C was expected if a linear interpolation is applied to the value of the temperature increase at 63% power.

Similar results are obtained for the 9 MHz probe, with a change from 79% to 100% causing an increase in temperature from 7.1 °C to 9.6°C (p=0.0213).

No statistically significant changes in temperature was observed at the bone interface for any of these cases.

Discussion

As previously reported [14] the maximum temperature increase is seen at the ultrasound probe/skin interface and is likely to be due to transducer self-heating. [17] It is important to note that this effect is not considered in calculation of the Thermal Index. The temperature at the tissue/bone interface increases more slowly, suggesting a more important contribution from acoustic absorption than from direct heating. In agreement with previous studies, Doppler modes showed the highest temperature increase.

In none of the experiments described here, did the temperature measured at the tissue-bone interface and within the soft tissue mimic approach the safety limits reported in the most recent guidelines, [7] as all the measured values were below 1 °C, which is the lowest level for which time limits are suggested. On the other hand, significant temperature increases are recorded at the skin interface. However, it is important to note that the starting temperature for the sensors at the interface was significantly lower than for that within the phantom (on average 28 °C against 36 °C); we were of course measuring temperature rise rather than absolute temperature.

Under these conditions, all the probes and all the tests undertaken were compliant with the relevant standard. [11] Unsurprisingly, endocavitary probes have the most stringent requirements. This is reflected in the lower temperature increase shown by the transvaginal probe. One of the probes displayed a TIB higher than that recommended by the guidelines, namely with PW Doppler mode in 1st trimester settings. Such a setting should never be used in clinical practice.

The results for long exposures show that most of the heating happens within 3 minutes, which is a typical scanning time, even for an experienced clinician. [18]

The results from experiments with and without use of the water circulation pump suggest that the establishment of utero-placental circulation has only a small influence on the temperature rise induced by ultrasound. There was a marginally greater heating effect in the simulated embryonic period than in the fetal period, but this was not statistically significant. The implication, assuming the model holds, is that ultrasound has an equivalent thermal effect in the embryonic and fetal periods – however, it must be remembered that up to eight weeks after conception, organogenesis is taking place in the embryo and in this period cell damage might lead to fetal anomalies or subtle developmental changes. [7]

Large temperature differences were seen between different probes in all modes of operation. In particular, the differences between the 7 MHz transvaginal probe and the 9 MHz abdominal probe (lowest and highest temperature increase respectively) were 2.6°C, 2.4°C and 2.0°C for B-mode, Colour Doppler and Power Spectral Doppler respectively. While these differences where expected, it is worth noticing that the Thermal Indices in Table 2 did not correlate with the final temperature increases seen when different probes are used.

With regards to the choice of pre-set, it is of little consequence whether 1st or 2nd trimester is chosen. The fetal echocardiogram pre-set resulted in a small but statistically significantly greater heating effect. Also, in this case, there is a limited correlation between the displayed TI and the actual temperature increase.

The power setting is important for reducing the temperature increase without compromising the image quality. [19] For the two probes examined (4 MHz and 9 MHz) the temperature increase was proportional to the power setting. Settings such as gain, focal zone, and tissue harmonic, also affect the quality of the image. Alteration of these settings should be preferred to increasing the acoustic power in order to improve the quality of image.

Several factors could affect the translation of the results reported in this manuscript to clinical situations. Measurement artifacts have been minimised by accurate identification of the thermocouple. Positioning of the probe and alignment of the thermocouples were verified by B-mode image. The measurement conditions are considered conservative compared to patient measurements, as the probe was held in a stationary fixed position, which is not the case in diagnostic scans. Furthermore, perfusion is not present in the phantom.

In conclusion, although the ISUOG phantom provides a crude mimic of the *in-vivo* conditions, the overall results showed good repeatability, and agreement with previously published experiments.

Although all measurements fell within the recommendations of the International regulatory bodies, it is important that any operator should be aware of factors affecting the temperature increase.

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Figures

Figure 1: Schematic diagram of maternal-foetal ISUOG Phantom, the position of the thermocouples is indicated by the white dots.

Figure 2: Photograph of maternal-foetal Phantom ISUOG setup.

Figure 3: Temperature changes during a 30 minutes exposure for the four thermocouples using the 9 MHz probe in Power Spectral Doppler mode.

Figure 4: Results of the study of effect of exposure duration on maximum temperature achieved at the skin surface, and at the bone/soft tissue interface for the different modes.

Figure 5: The effect of flow on the temperature rise at the ISUOG phantom surface (n=3) following exposure to B Mode (left) and PW Doppler (right) for different exposure times. The values for the tissue/bone interface have been omitted for B-mode.

Figure 6: Temperature changes at the phantom surface (n=3) for three different trans-abdominal (TA) probes and one transvaginal (TV) probe.

Figure 7: The effect of different pre-sets on the US-induced temperature rise at the probe-skin interface (n=3).

Figure 8: The effect of power on the US-induced temperature rise at the ISUOG phantom probe-skin mimic interface (n=3) for the 4 MHz (left) and 9 MHz probes (right).

Tables

	4 MHz		6 MHz		7 MHz		9 MHz	
	α (dB/cm)	SoS (m/s)	α (dB/cm)	SoS (m/s)	α (dB/cm)	SoS (m/s)	α (dB/cm)	SoS (m/s)
Skin mimic	9.7	1009	24.8	1010	33.2	1011	49.1	1013
Soft tissue mimic	2.46	1541	3.55	1542	4.12	1542	5.30	1542
Bone mimic	18.2	2476	31.1	2490	38.2	2496	50.9	2502
Amniotic fluid mimic	0.04	1535	0.08	1535	0.11	1535	0.2	1535

Table 1 – Speed of sound (SoS) and attenuation (α) of the materials for the ISUOG phantom. Uncertainties in SoS and attenuation are 1% and 10% respectively. Measurements were carried out at 20 °C

Test ID	Probe	Mode	Pre-set	Duration
Duration	9 MHz	B-mode and Power Spectral Doppler	1st trimester	1 to 30 minutes
Circulation	9 MHz	B-mode and Power Spectral Doppler	1st trimester	30 minutes
Probe	All	B-Mode, Colour Flow and Power Spectral Doppler	1st trimester	3 minutes
Pre-set	9 MHz	B-Mode, Colour Flow and Power Spectral Doppler	1st Trimester, 2nd Trimester and Fetal echocardiogram	3 minutes
Power	4 MHz and 9 MHz	B-Mode	1st trimester	30 minutes

Table 2 – Summary of the scanner settings and probes used

	TIS			TIB		
Probe mode	B-mode	Colour Doppler	PW Doppler	B-mode	Colour Doppler	PW Doppler
4 MHz 1st trimester	-	0.7	0.6	-	0.7	3
6 MHz 1st trimester	-	1.2	1.1	-	1.2	3.4
7 MHz 1st trimester	-	0.6	0.7	-	0.6	2.4
9 MHz 1st trimester	-	1.1	1.4	-	1.1	2.9
9 MHz 2nd trimester	-	1.1	1.4	-	1.1	2.9
9 MHz Foetal echo	-	1.1	1.4	-	1.1	3

Table 3 –Thermal indices displayed for the configurations used in the study

TI range	Maximum recommended exposure time
<0.7	No restrictions
0.7<TI<1.0	60 minutes
1.0<TI<1.5	30 minutes
1.5<TI<2.0	15 minutes
2.0<TI<2.5	4 minutes
2.5<TI<3.0	1 minute
>3.0	Not recommended

Table 4 Recommended exposure times in 1st & 2nd trimester, for different displayed Thermal indices [7]

Time (mins)	Surface temperature rise (°C) – mean (s.d.)		Bone temperature rise (°C) – mean (s.d.)	
	B-Mode	PW Doppler	B-Mode	PW Doppler
1	2.5 (1.0)	3.3 (0.3)	0.0 (0.1)	0.2 (0.1)
3	4.0 (1.0)	4.7 (0.4)	0.0 (0.1)	0.3 (0.1)
10	5.9 (1.0)	6.2 (0.5)	0.0 (0.1)	0.4 (0.2)
30	7.1 (0.8)	7.3 (0.8)	0.1 (0.3)	0.7 (0.5)

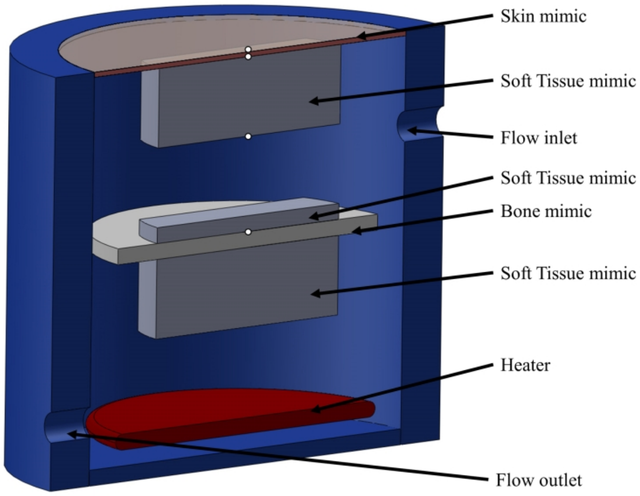
Table 5 Temperature rise at different times for the 9 MHz probe

Scanning mode	Surface temperature rise (°C) – mean (s.d.)			
	Probe 1 - 9MHz	Probe 2 - 6MHz	Probe 3 - 4MHz	Probe 4 - 7MHz
B-Mode	3.9 (0.4)	2.3 (0.5)	2.0 (0.3)	1.4 (0.2)
Colour Doppler	5.2 (0.5)	3.8 (0.9)	3.8 (0.6)	2.9 (0.5)
PW Doppler	5.7 (0.8)	4.4 (1.0)	4.0 (0.5)	3.7 (0.6)

Table 6 Temperature rise at the skin interface for the four different probes

Scanning mode	Surface temperature rise (°C) – mean (s.d.)		
	1st Trimester	2nd Trimester	Fetal Echo
B-Mode	3.9 (0.4)	3.8 (0.2)	4.3 (0.3)
Colour Doppler	5.2 (0.5)	5.5 (0.5)	5.6 (0.4)
Spectral Doppler	5.7 (0.8)	5.8 (0.7)	5.7 (0.3)

Table 7 Temperature rise at the skin interface for the three different pre-sets

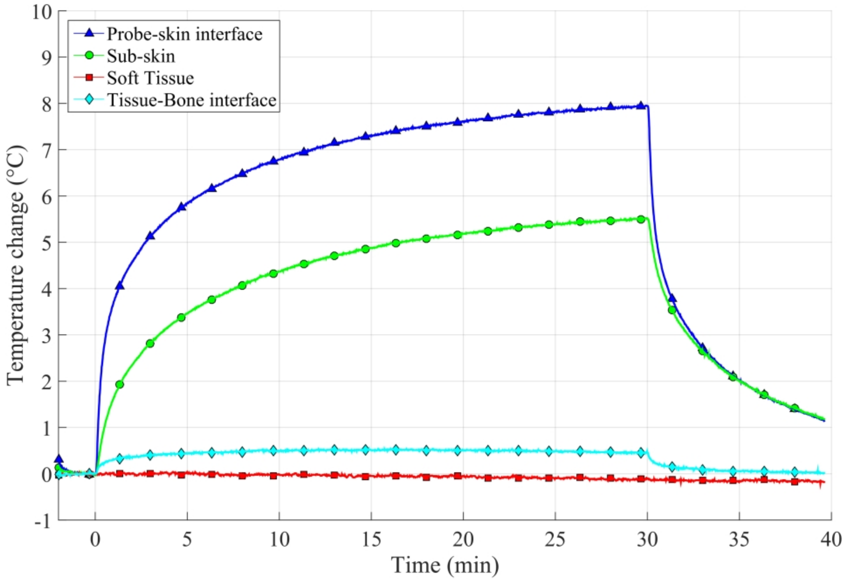


Schematic diagram of maternal-foetal ISUOG Phantom, the position of the thermocouples is indicated by the white dots.

253x142mm (300 x 300 DPI)

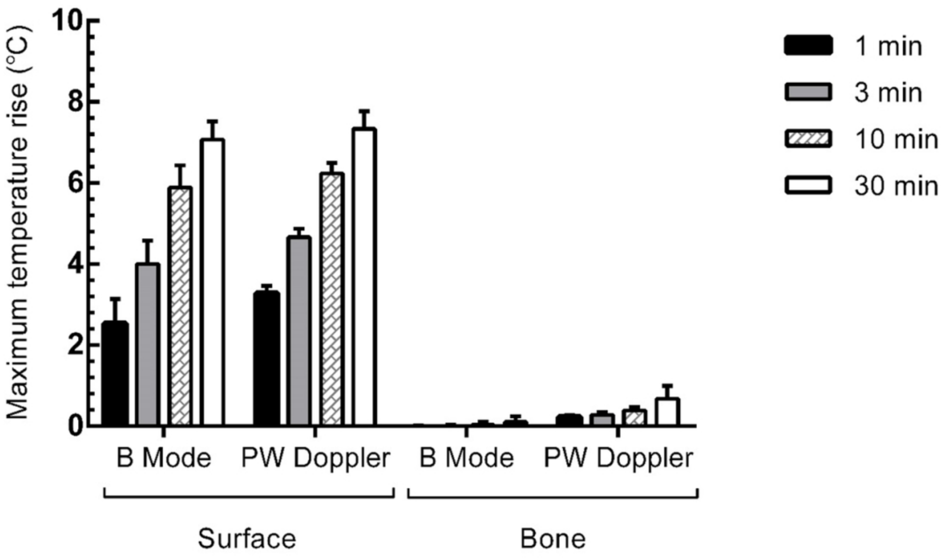
Photograph of maternal-foetal Phantom ISUOG setup.

30x17mm (300 x 300 DPI)



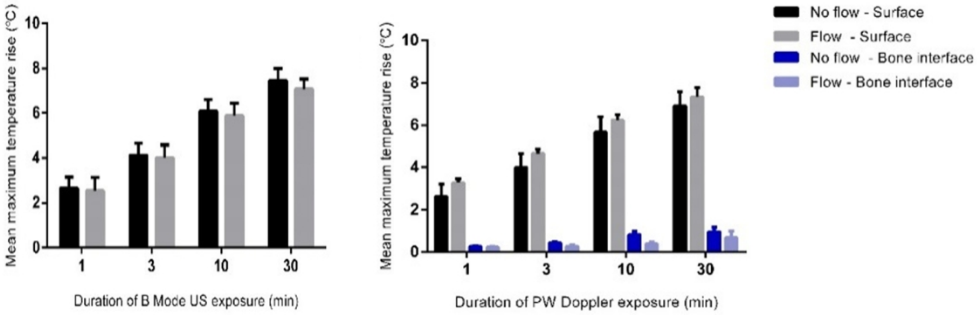
Temperature changes during a 30 minutes exposure for the four thermocouples using the 9 MHz probe in Power Spectral Doppler mode.

355x222mm (300 x 300 DPI)



Results of the study of effect of exposure duration on maximum temperature achieved at the skin surface, and at the bone/soft tissue interface for the different modes.

117x72mm (300 x 300 DPI)



The effect of flow on the temperature rise at the ISUOG phantom surface (n=3) following exposure to B Mode (left) and PW Doppler (right) for different exposure times. The values for the tissue/bone interface have been omitted for B-mode.

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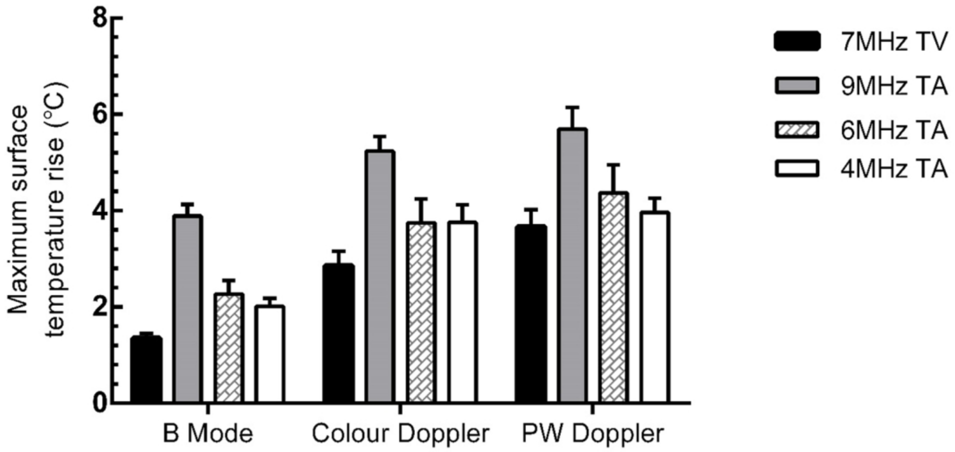
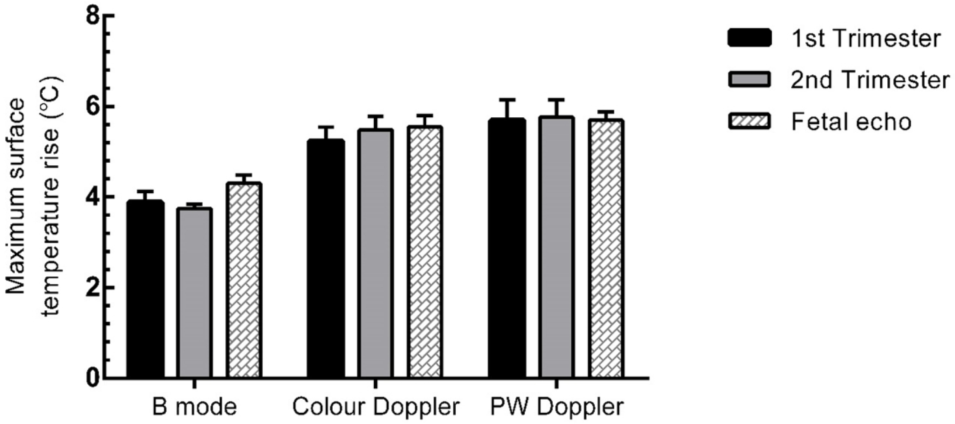


Temperature changes at the phantom surface (n=3) for three different trans-abdominal (TA) probes and one transvaginal (TV) probe.

145x74mm (300 x 300 DPI)



The effect of different pre-sets on the US-induced temperature rise at the probe-skin interface (n=3).

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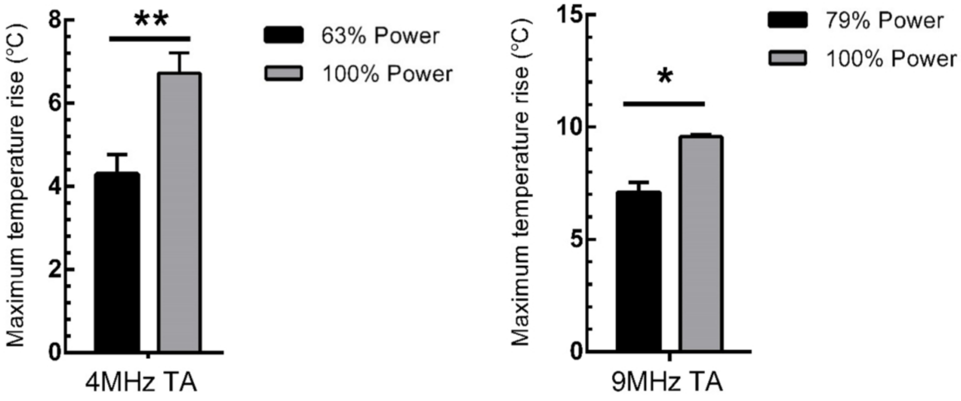

The effect of power on the US-induced temperature rise at the ISUOG phantom probe-skin mimic interface (n=3) for the 4 MHz (left) and 9 MHz probes (right).

166x74mm (300 x 300 DPI)