Building and assessing anatomically relevant phantoms for neonatal transcranial ultrasound

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Abstract. This study describes the design and construction of a clinically relevant phantom to survey the temperature increase caused by ultrasound equipment, as currently used in neonatal head-scanning in the UK. The phantom is an ellipsoid of bone-mimic material, filled with brain-mimic; a circular hole in the external surface mimicks the fontanel, through which most clinically relevant scans are made. Finite-element simulations were used to identify possible hot spots and decide the most effective thermocouple positions within the phantom to investigate temperature rise during a typical scan. Novel materials were purposively designed to simulate key acoustic and thermal properties. Three Dimensional Printing (3DP) was employed for the fabrication of the skull phantom, and a specific strategy was successfully pursued to embed a thermocouple within the 3DP skull phantom during the manufacturing process. An in-process Non-Destructive Analysis (NDA) was used to assess the correct position of the deposited thermocouple inside the fabricated skull phantom. The temperature increase in the phantom for a typical trans-fontanellar scan is also presented here. The current phantom will be used in a hospital survey in the UK and, in its final design, will allow for a more reliable evaluation of ultrasound heating than is currently possible.

1. Introduction

Clinical practice is seeing an increasingly widespread use of ultrasound in neonatal units, together with the growing sophistication of ultrasound scanners and the associated potential for increased ultrasound exposure to neonates. In addition to intrauterine fetal imaging, there are other cases where ultrasonography is considered an essential, non-invasive, imaging tool. A key example is trans-cranial imaging, commonly used to diagnose congenital and acquired anomalies of the neonatal brain, particularly in premature babies and in the first weeks after birth [1]. In this context, the quasi-total absence of proper epidemiological studies, evidencing the effects of prolonged exposure to ultrasound, makes it nearly impossible to quantify the risks connected to the use of ultrasonography. This is why medical physicists and practitioners refer to guidelines on thermal indexes (related to the local increase of temperature) to reduce the risks [2]; it is also why a survey of the equipment and its use is needed.

This study is part of a larger project, funded by the UK Department of Health (DH), aimed at investigating the safe use of ultrasound for neonatal head scanning. The project proposes to design a validated, clinically relevant phantom, to be used in a hospital survey across the UK. The scope is to...
measure the temperature increase caused by ultrasound equipment currently used in neonatal head scanning, using a repeatable and traceable protocol [3]. Other activities include a paper-based survey of neonatal trans-cranial ultrasound practices, two training workshops, as well as an investigation of how to properly measure the temperature rise.

The present work marks a particular stage of the process, conducted in collaboration with Loughborough University. Following feedback from clinicians, the first generation of phantoms (PH1) – cylindrical in shape, tailored for quality assurance and characterised elsewhere [4] – was upgraded to a more anthropomorphic shape, based on an appropriate bone-mimicking material and 3D printing technology (PH2). The resulting phantom constitutes a significant step forward from the typical phantoms for testing ultrasound equipment, usually limited to standard and simple geometries.

2. Designing the phantom

While there are specific guidelines for building validated phantoms to measure exposure to ionising radiation [5], nothing similar exists for ultrasound. Moreover, for the particular ages of interest, very little data could be found in the literature [6] for the acoustical parameters of interest (i.e. speed of sound and absorption). This information was the benchmark, on which specific materials were designed and manufactured, to replicate as faithfully as possible the real neonatal head.

At the start of the process it was decided that PH2 (i.e. the phantom described in this study) would:

- model the skull of a 33 weeks pre-term neonate (i.e. a premature baby);
- be constituted by a prolate ellipsoid (i.e. the skull) filled with brain-mimic material (i.e. the brain) and covered with silicon rubber (1 mm thick);
- have a hole, with the same area and position as that of a typical fontanel at 33 weeks.

These choices fixed the dimensions of the prolate ellipsoid (figure 1), which were obtained by intersecting the reference data commonly used in UK neonatal units [7] (i.e. in the tables to assess the normal growth of a child, the 50th percentile line was used-) with those reported in [5].

2.1. From thermal modelling to phantom requirements

Finite element modelling [3] and preliminary results with PH1 phantoms [4] showed that, while the highest temperature increase is to be expected near the surface of the transducer (in correspondence to the highest change of acoustical and thermal impedance), there are other locations within the phantom that may be interesting to monitor. Figure 2 shows the temperature dependence, obtained by finite element modelling (PAFEC), for a semi-spherical skull filled with brain-mimic material (see section 2.2), and subjected to the transmission from a cylindrical transducer through a hole in the skull (the fontanel, on top in figure 2). Even if the values of the temperature rise in figure 2 are probably much higher than the ones that can observed in reality (due to the particular, “worst-case” model used for the transducer), a careful analysis shows four interesting positions to monitor: (1) just below the transducer, under the skin-mimic; (2) in the bulk of the brain; (3) between the skin and the bulk, to check the gradient; (4) in the bone opposite the fontanel, where the exciting transducer is.

It was then decided to provide the phantom with at least 4 thermocouples, one of which is to be embedded in the portion of skull opposite the fontanel. The challenging task of embedding the thermocouple in the skull will be described in section 3.2.

2.2. Brain mimic material

According to [6], at 1 MHz the brain of a 28 weeks old neonate has a speed of sound of 1528 ± 5 m/s and an absorption coefficient of 0.16 – 0.3 dB/cm. Considering the large range of frequencies used in neonatal trans-cranial ultrasound (contemporary scanners offer frequency as an adjustable parameter), the value at one single frequency is not sufficient to characterise the material. Assuming a power dependence on frequency, an exponent of 1.05 can be obtained by the data in [6].

The materials were acoustically characterized at NPL in the range 2-20 MHz and the values at 1 MHz were obtained by interpolation (i.e. a power fit). Comparing the results with the target data from literature (table 1) the TMM with 0.91 g/l was chosen to represent the brain in our phantom.
2.3. Skull mimic material

A procedure similar to that in section 2.2. was used to select the best candidate for the skull phantom, starting from data in [6]. The base material was the ceramic powder normally used in 3D printing (see section 3.), and infiltration with different fluids was used to change its acoustic properties.

Since it is particularly important to fill the porous ceramic uniformly and to avoid undesired air bubbles. For this reason, the infiltration was performed by immersion, under vacuum conditions (-95 kPa), in a dedicated chamber. The test samples were left to cure for 72 hours at 25 °C.

In this study, three fluids were chosen: epoxy resin (Clear Coat™ by System Three Resins Inc.), polyester resin (Crystic® 2-414PA by Scott Bader Ltd.) and wax (Paraplast™ X-TRA by McCormick Scientific™). Preliminary tests for these materials showed a penetration of the infiltrant inside the ceramic up to a few millimeters (perfect for a thickness of the skull of 2 mm), so their acoustical characteristics in the range 2-20 MHz were measured using disks of 2, 3 and 5 mm. The use of disks with different thicknesses reduced the uncertainty on the measured parameters.

A comparison with the target value from the literature (table 2) identified the ceramic infiltrated with epoxy resin as the best candidate to mimic neonatal cranial bone.

Table 1. Acoustical characteristics of different candidate brain mimics and target values from the literature [6]. The brain mimics share a similar formulation, but differ in the concentration of Al₂O₃.

| Al₂O₃ (g/l) | Speed @ 1 MHz (m/s) | Absorption @ 1 MHz (dB/cm) | Power dependence of absorption with frequency |
|------------|---------------------|-----------------------------|---------------------------------------------|
| 0.91       | 1528                | 0.264                       | 1.06                                        |
| 1.82       | 1531                | 0.437                       | 1.02                                        |
| 2.73       | 1537                | 0.571                       | 1.00                                        |
| Target     | 1528 @28 weeks      | 0.16 to 0.3                 | 1.05                                        |

3. Building the skull

The efficiency of rapid prototyping (RP) technologies for medical applications has been widely documented and different authors have already pioneered the adoption of RP for the manufacturing of phantoms for ultrasound tests [9]. In particular, 3DP (Three-Dimensional Printing) developed by ZCorporation® (Burlington, USA) is an increasingly popular additive manufacturing process. Some key attributes of 3DP, like the relative low cost of building material, the speed of manufacturing and its level of accuracy [10], make this technique suitable for several precision applications, including the building of anatomical models for surgical planning, education or training [11].
Particularly important for this study is the fact that the porous structure of the ceramic powder used in 3DP allows post-processing treatments, such as infiltration with liquid substances. With this technique, the physical properties of the final material can be adjusted over a wide range [12].

A further reason to choose 3DP as prototyping technology for this work comes from the great accessibility to the building chamber during the printing process. This peculiarity of 3DP allowed a Fine-Wire Thermocouple (FWT) to be embedded in the phantom skull during printing, in a position opposite to the fontanel (i.e. position 4 of figure 2), as required in section 2.1.

Table 2. Comparison between the target values from [6] and the candidate materials for skull bone.

| Infiltrant | Absorption @ 1 MHz (dB/cm) | Power dependence of absorption with frequency |
|------------|-----------------------------|---------------------------------------------|
| Epoxy      | 6.8                         | 1.5                                         |
| Polyester  | 64.9                        | 1.37                                        |
| Wax        | 23.6                        | 0.97                                        |
| Target value | 5 to 7 for neonates         | 1.2 to 2.1                                  |

3.1. Production process

A Z510 Spectrum 3D printer (24-bit color models at a resolution of 650 × 540 dpi) was employed for the manufacturing process and set so that, with each printing layer in the XY plane, the phantom grew in thickness steps of 0.1 mm in the z direction. During the printing process, a FWT was embedded at the top of each semi-ellipsoid composing the skull (figure 2), positioned in the XY plane at 0.5 mm from the inner surface of the skull. After completion, the parts were then placed into an air-circulating oven at 80°C for 2 hours, and at 120°C for 1 hour. This guaranteed the full curing of the water-based binder within the parts and the elimination of excess moisture, which could impede infiltration. Infiltration with epoxy resin followed soon afterwards, as described in section 2.3.

3.2. Thermocouple embedding on 3DP parts

Preliminary trials showed that only very fine objects could be embedded in a 3DP prototype. The strength of the prototype, in fact, mainly relies on the quality of the bond created between the deposited layers. The presence of an external body (e.g. a thin-film thermocouple) within the jetted layers might compromise the bonding between the printed planes, and, consequently, it could affect the integrity of the final structure. Fine-wire thermocouples (FWT) with a diameter of 0.005 in. (0.127 mm) proved to be the most effective, while still offering a reasonable resistance to handling.

The printing process could be monitored thanks to a novel Non-Destructive Analysis (NDA) technique, specially developed for 3D printing at Loughborough [12]. In particular, the image of each jetted layer, constituting the final object, was acquired in real time using a modified CMOS camera (Trust® WB-6250, 1240 x 1024 pixels), with a resolution of 876 ppi. An automatic acquisition program (designed using RoboRealm®) allowed the operator to follow the embedding of the selected FWT on a monitor, greatly improving the accuracy in positioning the thermocouple (figure 3).

After reaching the desired height, the 3D printer was paused and the FWT was positioned over the un-bound powder layer (layer A in figure 3). The FWT was deposited along the roller movement direction, thus avoiding the obstruction of the powder distribution on the next spreading phase. After the working conditions (i.e. 38 °C) were restored in the printing area, the job was resumed. The next layers were additionally built over the deposited FWT, which was embedded inside the phantom.
Figure 3. A series of subsequent printed layers, showing how the FWT is embedded. Calibration was needed to fix the coordinate system in the following frames.

Figure 4. Temperature rise at fixed distances for transfontanellar 15 minutes scans with PH2, using two transducers (different for shape and working frequency). Values of the absorption coefficient in the two materials have been reported, for comparison.

4. Temperature increase in the PH2 phantom
The phantom was tested using a HP 77020A scanner and two transducers, different in shape, power and operating frequency: HP21200B (2.5 MHz) and HP21211B (5 MHz). Emitted powers were measured using an acoustic balance before the tests, while the temperature rise was measured using a profile thermocouple by Omega (containing 3 thermocouples spaced 2 mm), which was aligned along the transducer axis (figure 4). The scanning conditions chosen represent a “worst case scenario” for a trans-fontanellar scan: the transducer is placed on the fontanel for 15 minutes (the average duration of a scan in hospital practice [3]) and aligned along the thermocouple probe, in absence of a thermal dissipation mechanism mimicking perfusion. This considered, it might not be surprising that values as large as 2.5 °C were measured. On the other hand, it is worth noticing that powers as high as 150 mW
might be currently in use in UK hospitals. Figure 4 also highlights a possible effect of the shape of the transducer; a more comprehensive picture will be obtained during the final part of the project.

5. Conclusions
This paper described the process of building an anatomically relevant phantom (PH2), designed to assess the temperature increase in the neonatal head during transfontanellar scans, and the first measurements with it. A careful choice of tissue mimicking materials was crucial for the reliability of the final phantom and, to the authors’ knowledge, this is the first time that the skull of a neonate is reproduced with such an accuracy (at least from the ultrasonic point of view). This study also highlighted the advantages offered by rapid prototyping (and in particular by 3D printing) in the development of phantoms for medical ultrasound. The innovative techniques developed at Loughborough to embed thermocouples in 3DP prototypes and to monitor the printing process were paramount for this achievement. Further developments will include an even more anatomically relevant phantom, based on the feedback received so far from clinicians. Last but not least, the (high) temperature increases measured with PH2 confirm the need for a hospital survey, to test equipment as it is used in neonatal units. Such a study will represent the completion of the DH funded project.

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