The Future of Neonatal Skull Suture Detection

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Instrumental birth is common practice, but without properly determining the position of the fetus prior to placement, trauma to both mother and baby can occur. Currently, internal vaginal examination is the easiest method to determine fetus position, but is challenging as it requires tactile feedback to determine anatomical landmarks. To assist clinicians with this task, we have designed a novel sensor glove that can detect changes in the surface that indicate anatomical structures of the neonatal head, thus allowing the user to determine the position of the fetus. However, we still need to determine the utility and usability of this device. In this work in progress, we present the pilot study and explore improvements based on the findings from the study to refine both general and ecological validity aspects of the study.

CCS Concepts: • **Human-centered computing → Usability testing**.

Additional Key Words and Phrases: instrumental birth, fetal position, ecological validity, sensor gloves, usability testing

1 INTRODUCTION

Instrumental birth (ventouse/forceps) is common, with up to 30% of first-time mothers having an instrumental birth [1] and around 20% of women having a caesarean section [8]. In approximately one-third of instrumental births, instrument placement is incorrect due to inaccurate determination of the fetus position, which can lead to trauma to the mother and baby [9]. It can also fail, which leads to a woman having a caesarean section when she is fully dilated. Furthermore, caesarean section at full dilatation can lead to preterm birth in future pregnancies, around 15% [4]: a leading cause of neonatal morbidity and mortality [10]. Between 2012-2013, preterm delivery cost the public sector £3.4 billion [7]. An ultrasound scan (the gold standard) can accurately diagnose fetal position [3], but is not always available in an emergency situation as the machine is large, has a long setup period, and is operator dependent. Therefore, current normal practice is via a digital vaginal examination (VE), relying on haptic feedback to identify anatomical features on the fetal head, which is challenging due to the swelling over the baby's head, overlapping of the skull bones in some cases, and not being able to directly visualise what is being examined

To improve clinicians' ability to ascertain the position of the fetus during a VE at full dilation, we have developed a novel low-cost sensor glove to assist during examination [5]. The sensor glove has a specialised sensor on the tip of the index finger of a clinical glove that can detect subtle changes in surface area, see Figure 1. Preliminary tests show that the device can accurately detect the sutures (landmarks used to determine fetal position) on a physical simulation of a fetal head, known as a phantom fetal head [5].

The aim of this study is two-fold; to ascertain whether the device can accurately and repeatedly determine fetal position when used on a phantom of a fetal head; and, to better understand what is required of users when using the device, how it will fit into their current clinical practice, and determine design guidelines for future iterations.

In this work in progress, we present the setup and preliminary findings from our pilot study and highlight modifications we have made to the study to improve ecological validity [2] for future studies, as doing so will provide better insights into work in practice.

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Fig. 1. The sensor glove, used to detect sutures

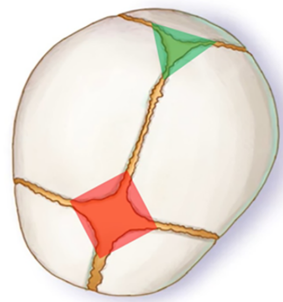

Fig. 2. Schematic representation of the fontanelles and sutures of a fetal head

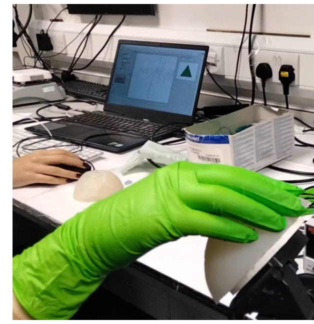

Fig. 3. Pilot study setup, with the participant using the sensor glove on the phantom fetal head

2 BACKGROUND

Digital vaginal examination is a technique where the clinician will insert their fingers into the mother's vagina to identify the position of the fetus based on anatomical landmarks on the fetal head during the second stage of labour [6]. The sutures are the joints between the five main skull bones of the baby's head. At the intersection of the sutures are fontanelles, with the anterior fontanelle at the front of the head having four sutures adjoining it and a posterior fontanelle at the back of the head having three sutures [6], see Figure 2. Haptically a clinician is able to detect the suture lines, from which they can locate the fontanelles and determine the anterior and posterior fontanelles, thus identifying the position of the fetus, which consists of occipito-anterior (head down), occipito-posterior (back to back), and occipito-transverse (on their side).

3 PILOT STUDY

To evaluate the glove's utility and usability we initiated a multidisciplinary study that incorporated the expertise of the clinical, engineering, and human factors teams. Moulds representing the fetal head were 3D printed from which a silicone-based phantom fetal head was created and validated by an obstetrician [5]. This phantom included all essential anatomical features, including bone segments and suture lines, and was mounted to a tripod to enable easy repositioning of the phantom. Using this method, two phantom fetal heads were developed, (1) a 'normal' phantom with easily identifiable sutures, and (2) a phantom with 'moulding', which is when the skull bones and compressed during labour due to maternal soft tissues and pelvic structures causing a reduction in the size of sutures and a change in the shape of the fetal head. Additionally, during labour, swelling called caput can develop over the fetal head, which affects the clinician's ability to detect and determine sutures. To replicate this, an additional silicone membrane was moulded to cover the existing phantom mould.

The participant for the pilot study was an obstetrician with 6 years' experience who had no prior experience with the sensor glove. After reading the participation information sheet and signing the consent form, they proceeded to put on a sensor glove followed by another glove over the top, to ensure a sanitary working environment. The sensor glove was then connected to a computer for the engineer to read the signals from the glove and record observations. The participant was then asked to sit down and one of the two phantoms was placed next to them ready for exploration. The participant was asked to explore the phantom with their hand using the sensor glove to determine the orientation of the phantom without looking at the model while using the think-aloud method to verbalise their thought processes, as can be seen in Figure 3. Once the participant was confident in their decision regarding the orientation of the phantom, they were asked to use the sensor glove to traverse around the fontanelle while the engineer captured the readings from the glove. Using this method we were able to capture (i) the true position of the phantom by the way it was placed, (ii) the participant's opinion of the phantom's position, and (iii) the sensor glove's estimation of the phantom's position. The study was repeated ten times with the participant, with the position and type of phantom being used changing between each examination. For two of the recordings, the caput was also included to cover the phantom.

Once all of the examinations were complete, the participant was asked to use the sensor glove while observing the output monitor. The current user interface (UI), see Figure 4, consists of two parts: a line graph showing the peaks and troughs of when a suture is detected and a display image highlighting either a green triangle representing the posterior fontanelle or a red diamond representing the anterior fontanelle. In this evaluation, while continuing to use the think-aloud method, we were able to identify how the participant interpreted the data from the sensor glove.

At the conclusion of the examination and exploration with the sensor glove, a semi-structured interview was conducted with the participant. The focus of the interview was to determine their thoughts on using the glove and how it affected their tactile feedback, how it could be adopted into clinical practice and any barriers that it may face, and their opinion on the current interface. Additionally, we also explored the ecological validity of the study design, with a focus on the setup and the fidelity of the phantom fetal heads. A System Usability Study (SUS) questionnaire was also used, for the participant to evaluate the usability of the sensor glove overall.

4 IMPROVEMENTS FOR FUTURE STUDIES

From the pilot study we were able to identify a number of key elements that need further refinement for both general and ecological validity of the study; (1) a screen to hide the fetal head, (2) means to restrict hand movements, (3) a higher fidelity phantom fetal head, (4) easier method to switch and rotate phantoms, and (5) changing the colours of the fontanelle indicators on the UI.

During the pilot study the participant stated "*You haven't got always the full range of movement or the full feel of the full fetal head. But to make it more realistic, it should be for me a sort of tube that you put your hand into... and then assess it in a tight spot*". To improve this for future studies we designed a rig that is attached to a camera stand, consisting of a shield with a 90cm hole cut in the centre, see Figures 5 & 6. This shield represents the mother's pelvis and the hole is cut to the average size

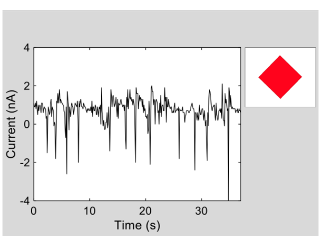

Fig. 4. Current user interface for the sensor glove

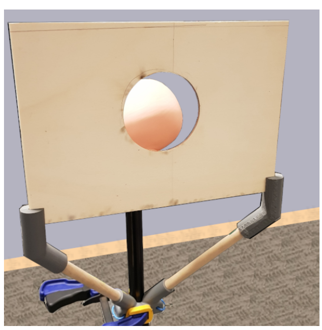

Fig. 5. Front of the new setup with a shield to fetal head

Fig. 6. Rear of the new setup showing restriction to fetal head

of a woman's vagina at full dilation. The shield hides the fetal head from direct observation and restricts the hand movements while still allowing us to observe participants' techniques.

The phantom fetal head used during the pilot study, although well received, is still not a high enough fidelity to evaluate the glove. Therefore, a 3D model of a scanned fetal head will be used to print a new high-fidelity phantom that can be mounted to the camera stand for quick insertion and removal. Additionally, a better camera stand was acquired that allowed for easier rotation of the phantom to the various required positions.

Lastly, during the semi-structured interview, the pilot participant remarked that "*[the fontanelle colours] may be alarming to have one that's green and one that's red. I think if they were... more neutral like blue and yellow, then maybe that would be less confusing than green and red*". Therefore, to reduce triggering a negative reaction to the UI, the colours of the fontanelle indicators were changed to blue and yellow.

ACKNOWLEDGMENTS

This work is partially supported by the Wellcome/EPSRC Centre for Interventional and Surgical Sciences (WEISS) (203145Z/16/Z), the NICEDROPS project supported by the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme under grant agreement no. 714712 and la Caixa foundation fellowship (LCF/BQ/EU19/11710055) for CSF. MKT also acknowledges the Royal Society Wolfson Fellowship. DS and ALD are part funded by the NIHR University College London Hospitals Biomedical Research Centre. The Wellcome Trust were not involved in the study.

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