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Mimo: A Non-pharmacological Comforting Solution for Preterm Neonates

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Abstract—Preterm neonates often suffer from pain, distress and discomfort during the first weeks of their lives. While residing in special Neonatal Intensive Care Units (NICUs) that are designed for optimal care, they are subject to numerous interventions ranging from a simple diaper change to surgery. Although pharmacological pain treatment often is available, it cannot always be applied to relieve a neonate from pain or discomfort. Therefore, new non-pharmacological solutions are required to reduce the discomfort experienced by these babies during the first weeks of their lives. This paper describes a novel solution, called Mimo, that provides comfort through mediation of a parent's physiological features to the distressed neonate. We discuss the design and the implementation and pilot-evaluation of a first prototype. Results show that the concept is promising enough to pursue a full-scale clinical trial.

Index Terms—preterm neonates; comforting solution; bonding; heartbeat; pillow; user-centered design;

I. INTRODUCTION

Premature infants, born after a gestational age of less than 32 weeks are admitted to a Neonatal Intensive Care Unit (NICU), where they are nursed in an incubator and receive medical treatments. The last decades many new therapies have been introduced, resulting in a substantial improvement of survival. However, the stay of a preterm infant in the incubator is negatively influenced by stress (excessive light and noise) and painful procedures [1]. Gradually, the insight is growing that these factors are partly responsible for developmental impairments [2]. The Eindhoven University of Technology (TU/e) in the Netherlands has started collaboration on research with the Maxima Medical Centre in Veldhoven, the Netherlands. The goal of this project is to improve well being for the pregnant woman and her child before, during and after delivery [3]. Research results that have been reported from this project area, for example, a smart jacket for neonates integrated with textile sensors [4], a power supply based on contactless energy transfer [5], blood oxygen saturation monitoring for neonates using a reflectance pulse oximeter [6], neonatal temperature monitoring [7], data transmission [8], and a device to support cardiopulmonary resuscitation of neonates [9], [10]. Within this project, this paper presents the pilot-study of a novel, nonpharmacological comforting solution for preterm neonates.

A. Pain and discomfort

Premature neonates residing at Neonatal Intensive Care Units (NICUs) experience much pain and discomfort due to necessary medical interventions. These interventions include, but are not limited to: heel punctures, venepunctures and inor detubations [11]. The attachment and removal of sensors required for measuring physiological body signals can also be unpleasant, stressful and painful [12]. Although pain treatment is given in some of these cases, a large proportion (50%) [11], [13] of the interventions are performed without any form of pain treatment.

Simple procedures and environmental factors are also possible sources of pain and discomfort to preterm neonates. Nociception is the term used to refer to the neural processes of encoding and processing painful stimuli. In preterm neonates this nociceptional system is not yet fully developed. A possible consequence of this not-fully developed nociceptional system is that stimuli such as sound and light, which are normally not considered painful to a human being, may be perceived as painful by the preterm neonate [14]. Injuries, but also clinical procedures, will result in more widespread sensitivity to pain [15]. The consequences of untreated procedural pain in neonates can be both severe and long term. It is believed that exposing preterm neonates to pain negatively affects their ability to cope with pain and stress in later childhood [15], [16].

B. Signs of discomfort

Neonates show many different responses to pain and stress. These responses can be of both physiological and behavioural nature, and can be used to detect discomfort of a neonate. Physiological responses include an increased heart and respiratory rate, increased or decreased blood pressure, decreased oxygen saturation, vagal tone and skin temperature. Behavioural responses are even more varied. Examples include vocalizations like crying and whimpering, facial expressions like grimacing with eyes squeezed shut or a stretched open mouth, and body movements like finger and toe splaying and trunk arching [15], [17]. It is worth noting that a change in any of these responses does not always imply that the neonate is experiencing stress or discomfort. Several pain-scoring

systems (such as PIPP [18] and Comfort-NEO [19]) have been developed to aggregate the behavioural signs, providing a reliable and structured tool for pain measurement.

C. Comforting techniques

The past two decades have seen an increase in interest in neonatal pain treatment [16]. Pharmacological solutions remain popular and are the most used method for pain treatment. Non-pharmacological methods of providing comfort and pain relief do exist and some have proven to be effective. The most popular techniques include: non-nutritive sucking, offering a sweet solution, facilitated tucking and skin-to-skin care.

Non-nutritive sucking was one of the first nonpharmacological comforting techniques to be studied and refers to offering a pacifier for the neonate to suck on [20]. A sucrose solution can be provided as an extra means of comfort during more painful procedures. A syringe is used to gently squeeze some sucrose on the inside of the neonate's cheek. A pacifier is offered after the delivery of the sucrose, distracting the infant with something sweet to suck on [21].

During facilitated tucking, the caregiver holds one hand on the baby's head and another one on the feet or body, depending on what is feasible at that moment [22]. Similar techniques are containment and swaddling [23]. The aim of all these techniques is to restrict the movement space for the neonate and to maintain it in a position similar to in-utero.

One of the most successful comforting techniques is skinto-skin care (SSC), otherwise known as kangaroo care [24]. During SSC the mother and infant are wrapped in cloth together, with the infant held to the bare chest of the mother. One downside of this comforting technique is that the neonate needs to be taken out of the incubator, which can be stressful to the child. Some neonates are unable to receive this particular kind of care, because their medical condition does not allow them to be taken out of the incubator.

Other comforting techniques include presenting the neonate with an audible heartbeat [25] or music [26] and aromatherapy [27]. If possible, breastfeeding can also be used as a non-pharmacological comforting technique, although its effect was demonstrated on term neonates [28].

The majority of these comforting techniques have in common that a parent or nurse needs to be present to provide the desired care. Although the sole presence of its parents might be comforting to a neonate, most parents are unable to be with their child continuously. The same holds for nurses, as they often have multiple neonates to care for. A comforting solution that does not require the continued presence of a parent or nurse is thus a design path worth exploring.

This paper presents a new concept for comforting preterm neonates. This concept aims at comforting preterm neonates by mimicking selected features of the baby's mother or father and making them available to the baby when the parents cannot be present themselves. The following sections will describe the concept in more detail, and discuss the implementation and evaluation of a prototype based on this concept. Finally, the implications of the proposed concept are discussed and future directions are outlined.

II. CONCEPT

The concept for the proposed comforting solution was not based on findings from literature alone. To understand the field better user studies were performed, the NICU environment was observed and current comforting techiques were further investigated. The results of these observations are described below, followed by an explanation of the concept proposed.

A. User studies

An essential first step in the development of a new, nonpharmacological pain treatment is the recognition and evaluation of the status-quo. In User Centered Design (UCD) the end-user is constantly involved in the design process. This becomes problematic when designing solutions for neonates, simply because it is impossible to communicate with these 'users'. In this case, medical staff and parents can be valuable sources of information, in effect becoming the voice of the neonates. Interviews with medical staff and observations at a NICU facility have been performed in order to gain better insight on the conditions and treatments given at a NICU. The following paragraphs discuss these findings and their implications for the concept that is explained in detail in the last paragraph of this section.

B. NICU environment

NICU wards commonly house several incubators which are often shielded from light entering. These incubators provide a controlled environment, where amongst others temperature and moisture levels are kept at an appropriate level. The neonates constantly have their physiological signs monitored and are therefore attached to many sensors. Small bean-bag pillows are used to provide both comfort and support to neonates, and can be used by nurses to stabilize the neonates in a position that allows treatment. Small plush toys are also often present in the incubator, allowing parents to share something more personal with their child. The fact that some objects (such as the bean-bag and plush toys) are already present within an incubator gives rise to the opportunity to design a new comforting solution that can be integrated with these objects.

C. Comforting neonates

Neonates can be comforted in two ways: by providing an active comforting treatment, or by taking away sources of discomfort. Some hospitals (e.g., the Maternity District Hospital "Helena Venizelou" (GR)) have a very strict policy that focuses on the latter. The fragile neonates are taken out of the incubator only for medical treatments. The care policy focuses on limiting external stimuli to the neonates as much as possible. Noise and light levels are reduced to absolute minimum and parents can visit their babies during fixed visiting hours.

Other hospitals (e.g., MMC in Veldhoven (NL) and the Maastricht University Medical Centre (NL)) are less strict and

emphasize on the value of parent-child bonding as a source of active comfort, therefore they allow parents to visit their baby in the NICU at any given time. These hospitals also encourage the parents to take part in their child's care, by changing diapers or bottle feeding. This kind of involvement also helps the parents who often feel that they cannot help their fragile baby during the stay at the NICU. These hospitals encourage kangaroo care as a means of comfort and bonding. Nurses and parents from these hospitals stated that infants are the most relaxed during kangaroo care.

Although it is clear that parents can play an important role in the comfort of their child, they cannot be present at all times to provide this comfort. In all hospitals, some more than others, there are situations in which alternative means of comforting are required. Therefore, it seems appropriate that a new comforting solution would focus on providing a neonate with the same feeling of comfort that parents would provide, even when the parents cannot be physically present.

D. Concept

Based on the literature review, the aforementioned user studies and a brainstorm with the design team, several concepts for a novel solution for comforting preterm neonates were proposed. After a few elimination rounds, one concept was selected. This concept, called Mimo, is a comforting solution that provides neonates with an experience similar to being held by their parents.

As already noted, neonates show less stress signs when they are in contact with their parents and held to their chest. This seems to be one of the most pleasant experiences for a preterm neonate. However, neonates cannot receive this kind of comforting at all times; parents cannot always be present at the NICU and in many occasions neonates are in a condition that does not allow them to be taken out of the incubator.

Mimo, aims at providing a comforting solution with qualities similar to those of being held to a parent's chest, available especially when the parent cannot provide the comfort himor herself. This concept might not only increase the general comfort level, but it can also contribute to the bonding between parent and infant. Mimo gives parents the chance to record their personal features such as heartbeat, smell and temperature, which can be mediated to the child when it is in need of comfort. When the concept is fully realized, the child might experience a feeling as the parents were close to them, even when the parents are not there in a physical sense.

One of Mimo's basic characteristics is its ease of use, which enables parents to record their physiological features without guidance or in a special environment.

III. PROTOTYPE

The original concept for Mimo includes mediation of several physiological features, such as smell, heartbeat and respiration. However, building a prototype that would mediate all these features would make it more difficult to identify the most beneficial attributes of the concept. Therefore, the initial prototype of Mimo was designed to only mediate the parent's heartbeat by means of vibrations, much like a pulse.

One of the basic characteristics of the concept is that Mimo should be easy to set up and use, so that parents could record their physiological data on their own, without the guidance of a nurse for example. Then, the nurse needs only to switch on and activate Mimo when comforting is needed. Moreover, the Mimo prototype features a pillow-like device to convey the heartbeat, which can replace the regular pillows that are used in incubators, thus sustaining the neonate's environment and avoiding extra special equipment that would load the incubator. This prototype was designed to be comfortable and ergonomic for a premature neonate, but also washable and clinically safe to meet hospital standards.

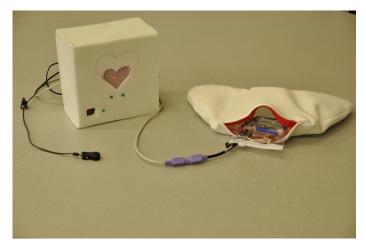


Fig. 1. Prototype with the Mimo Recorder on the left and the Mimo Pillow on the right.

The Mimo prototype (see Figure 1) consists of two distinct parts:

- 1) A recording unit (*Mimo Recorder*), for registration of the parent's heartbeat
- 2) A pillow-like object (*Mimo Pillow*), for transmitting the parent's heartbeat to the neonate

A. Mimo Recorder

The Mimo Recorder is a white, cubical box that allows parents of preterm neonates to make a recording of their heartbeat. A heartbeat sensor (photoplethysmograph), as well as a connection cable are attached to the side of the box. The front of the box features a number of LEDs displaying the status of the recording process and a button to initiate the recording process.

1) Sensor: The heartbeat sensor that is used in the prototype is a photoplethysmograph, which is an optical sensor that measures a person's pulse. An infra-red LED on one side of the sensor shines through the finger onto a photosensitive sensor at the other side of the finger. The amount of blood that flows through the finger influences the amount of light that reaches the sensor, hence providing information about the person's pulse. Although there are other ways to record a heartbeat (such as electrocardiogram sensors), the photoplethysmograph provides a quick and easy way to record a heartbeat. The ease of use of this method outweighs the slightly lower accuracy compared to other methods.

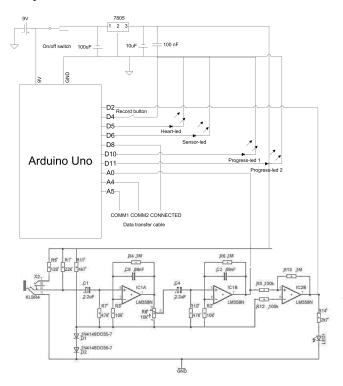


Fig. 2. Circuit diagram of the electronics in the Mimo Recorder.

2) Electronics: An overview of the circuitry inside the Mimo Recorder can be found in Figure 2. The heart of the Mimo Recorder is an Arduino Uno [29] microcomputer, powered by a 9V battery. The Arduino handles almost the complete recording process, ranging from sensing and storage to transmission of the heartbeat to the Mimo Pillow. A filter module ensures the quality of the heartbeat signal that the Arduino records. It was deliberately chosen to use a battery rather than a fixed power supply, to provide maximum flexibility to parents in their choice of a recording location.

3) User Interface: The user interface of the Mimo Recorder was designed to be as simple as possible, such that parents could perform the complete recording process themselves. Four LEDs provide feedback to the parents about the status of the heartbeat recording. One light shows whether the device is switched on, another light indicates whether the sensor is properly attached and the two remaining lights indicate whether the recording has not started yet (lights off), is currently in progress (lights blinking) or has finished (lights on). In order to record their heartbeat, parents first need to attach the sensor to their finger or earlobe. Once the sensor indicator confirms that the sensor has been properly attached, the parent can press the recording button and wait for the status lights to light steady. Then, the Mimo Pillow can be connected to the recording unit and the heartbeat will be transferred to the pillow.

B. Mimo Pillow

The Mimo Pillow is the part of the prototype that stays with the neonate. It is a boomerang-shaped pillow that is filled with polymer beads and contains a pouch that accommodates the electronics. The polymer beads that are used for the filling ensure both softness for the neonate, and stability that allows the pillow to be shaped around the neonate's body and act as support.

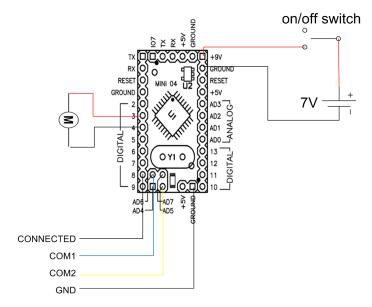


Fig. 3. Circuit diagram of the electronics in the Mimo Pillow.

1) Electronics: Much like the Mimo Recorder, the Mimo Pillow is controlled by an Arduino Mini microcomputer. This Arduino version is much smaller and flatter than the one used in the Mimo Recorder, such that it is hardly felt on the outside of the pillow. Other efforts to ensure that electronics are not felt by the neonate have been made by using a specialized flat model racing battery as power supply, a tiny vibration motor to mediate the heartbeat vibrations, and by using a tiny control to switch on or off the electronics. A detailed overview of the electronic circuit is provided in Figure 3.

2) User Interface: The heartbeat data that has been recorded with the Mimo Recorder can be transferred to the Mimo Pillow by connecting the connection cables of both devices. Once the heartbeat data has been transferred to the pillow, it is immediately ready for use. The recorded heartbeat data is stored in the microcomputer in the Mimo Pillow and is played back continuously, as long as the device is switched on.

IV. PILOT STUDY

To test the viability of the concept, a pilot study was performed with the Mimo prototype. While a pilot-study is not directly suitable for generating results on the effectiveness of the prototype, it is a good starting point to test the initial response of the neonates, nursing staff and parents to the device proposed. The study was conducted with four preterm neonates; three of them residing at the Medium Care Unit and the other one at the Neonatal Intensive Care Unit of the Máxima Medical Center in Veldhoven (NL).

A. Method

First, the heartbeats of the neonates' mothers were recorded with the Mimo Recorder. Then the pillow was presented to the neonates directly after uncomfortable procedures such as diaper changing or bathing. The pillow was presented both in a switched-on state, as well as a switched-off state. The neonates were observed before, during and after the uncomfortable procedures. Since this was a pilot study it was impossible to change the routines of the nurses present during the evaluation. This in turn caused that sometimes additional care was provided to the neonates next to the Mimo Pillow. For example, the preterm neonate who was tested in the NICU was also offered a sucrose solution in combination with the Mimo Pillow.

B. Results

1) Neonates: None of the neonates showed signs of increased stress due to the pillow's presence. In addition, some neonates showed positive responses to the pillow's presence. For example, one neonate was in severe distress after he had been bathed and was crying continuously. The crying baby was put back in the bed and the switched-on pillow was put next to him. Immediately after putting the pillow next to him, he stopped crying and showed no further signs of distress. However, when the pillow was taken away from him after a short while, he immediately started crying again. Other neonates fell asleep while lying against a pulsating Mimo pillow, further indicating that it may have a comforting effect.

2) Parents & hospital staff: Although it had not been the primary intention of the concept, it turned out that the prototype had a positive effect on the neonates' parents. During the pilot study parents made many spontaneous, positive remarks on Mimo and enjoyed the interaction with it. Hospital staff were also interested in Mimo and positive about its potential comforting effects on preterm neonates. Some of them also suggested that a full-scale study on the effectiveness of Mimo should be performed, based on the results of the pilot study.

V. DISCUSSION

This paper presented the design, implementation and evaluation of a new, non-pharmacological comforting solution for preterm neonates. The concept (named Mimo) aims at comforting a neonate by providing it with a feeling similar to that of being close to a parent. Most neonates seem to experience a strong sense of comfort when being held by their mother or father.

The Mimo concept consists of two parts: a recording unit and a technologically enhanced pillow. The recording unit is used to record physiological data (such as heartbeat, breathing rhythm, parental smell and body temperature) from a parent. This data can then be transferred to the pillow, which includes technology that enables it to 'replay' the recorded data to the neonate. A prototype for Mimo has been designed and evaluated in a pilot study. The prototype is a limited implementation of the original concept, as it focuses only on the recording and playback of a parent's heartbeat. The pilot study performed with this prototype has shown that Mimo has no negative influence on the comfort of neonates. Furthermore, there are strong indications that Mimo might have a positive effect on the comfort of neonates.

As already mentioned before, because of the limitations that apply to a pilot study, it is difficult to make definite conclusions based on the data gathered. More neonates would be required for testing, all of whom would have to go through more trials. Also, the trials would have to be even more structured and controlled than in the current study. Due to the limitations of performing a pilot study, these issues could currently not be addressed.

Performing studies on preterm neonates is a difficult process in which it is hard to collect useful data and attribute that data to the experience the neonate is having. Much thought had gone into the evaluation plan during the design phase of this study. Due to the imposed limitations, this evaluation was stripped from many of its features. A full clinical study should include a blind evaluation of close-up video recordings of the neonates during procedures. Nurses who have experience with the ComfortNeo scale could then view video excerpts and provide scores on the comfort level of the neonate. In a future study, the physiological data of the neonates could also be logged for the purpose of statistical analysis. Such data collection was not possible during this pilot study and conclusions based on this data would also lack any statistical significance. Acquiring more accurate behavioral and physiological data for analysis of more neonates in better controlled conditions would be key to a future study.

In the current pilot study, most of the participating neonates resided in the medium care ward. Babies in the medium care ward are already much more stable than neonates staying in the NICU. This also means that these babies are exposed to less painful medical procedures, which also means they are less exposed to comforting techniques than neonates in the NICU.

Most of the trials in the current study occurred during diaper changes. The neonates that participated in this study were usually fed directly after a diaper change. It is not unreasonable to assume that neonates that remained fussy after a diaper change were actually expecting to be fed. In such a situation, the Mimo would most likely not render the desired effect.

In the current study, neonates received an artificial heartbeat reconstructed from a physiological recording of their mothers heartbeat. It can be argued that the neonate is not able to detect the difference in heart beats of different persons. Although untested, this argument is moot from the design point of view. Not only should the Mimo provide care to the neonate, it also contributes in empowering the parents during a stressful time. A random heartbeat would take this empowerment away from parents, and would not contribute to parent-child bonding either.

VI. CONCLUSION

We designed a new non-pharmacological comforting solution for premature newborn infants based on the transfer of maternal heart beat into a pillow that is equipped with a "pulsator". In a small pilot study we found that the response of the infant was positive. Finally, parents and hospital staff who interacted with Mimo during the pilot study, regarded Mimo as a very promising concept that would possibly not only comfort premature neonates, but also help parents bond with their infant. A full-scale clinical follow-up study is currently being conducted to confirm these indications.

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