# DEVELOPMENT OF A CRANIAL MOLDING HELMET FOR INFANTS WITH FLAT HEAD SYNDROME HFS2025

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**ABSTRACT**

*The paper presents a development for cranial molding helmets tailored to infants with flat head syndrome. The helmet is built using 3D scanning of the infant's head, featuring optimized circular ventilation holes through ANSYS thermal simulation. The prototype molding shell is fabricated through 3D printing technology. By specifically analyzing stress symptoms through heart rate and blood oxygen saturation data, this paper proposes using sounds to reduce infant stress.*

**Keywords:** *Cranial molding helmet; Infant; Plagiocephaly; Sensor; 3D printing; Sound; Discomfort.*

**TÓM TẮT**

*Bài báo giới thiệu hướng phát triển mũ chỉnh hình cho trẻ sơ sinh bị bẹt đầu được thiết kế phù hợp cho từng bé. Mũ được dựng hình bằng phương pháp quét 3D phần đầu trẻ, kết hợp thiết kế lỗ tròn nhờ vào mô phỏng nhiệt trên ANSYS. Mẫu tham khảo của lớp định hình được chế tạo bằng công nghệ in 3D. Bằng việc xét riêng biểu hiện không thích ứng với mũ thông qua dữ liệu nhịp tim và nồng độ oxy trong máu, bài báo đề xuất hướng sử dụng âm thanh giúp trẻ dễ chịu khi sử dụng mũ.*

**Từ khóa:** *Mũ chỉnh hình; Trẻ sơ sinh; Bẹt đầu; Cảm biến; In 3D; Âm thanh; Không thích ứng.*

## 1. INTRODUCTION

This paper presents the treatment of flat head syndrome, a highly prevalent cranial deformity observed in infants during the early stages of development. Cranial remodeling helmets are specialized medical devices designed to correct positional plagiocephaly [1] and have been proven effective in numerous clinical studies [2, 3]. These helmets function by exerting mild, continuous pressure that gently redirects skull growth into the unoccupied regions within the helmet.

Despite their therapeutic benefits, prolonged helmet wear may lead to infant discomfort and stress. To mitigate this drawback, the present work proposes the incorporation of adaptive sound therapy as a novel approach to enhance comfort and compliance during treatment.

## 2. DESIGN

### 2.1. Design procedure

Based on the methodology presented in [4], 3D scanning of the infant's head is employed as an effective and non-disturbing initial step in the design process. The design procedure for the cranial molding helmet begins with a medical diagnosis of positional plagiocephaly. Data acquisition is performed by first securing the infant's hair with a fine mesh cap, followed by multi-angle photographic capture using photogrammetry techniques. The collected images are subsequently processed with Zephyr 3D software to generate an accurate three-dimensional model of the infant's head.

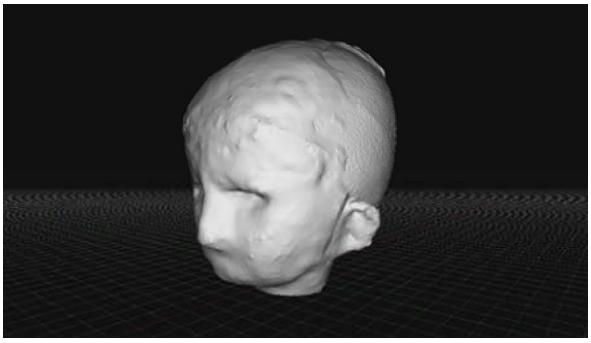

*Figure 1. 3D model generated from photogrammetry method*

### 2.2. Major design requirements

The cranial molding helmet is designed to be comfortable and pleasant for the infant. The top portion of the helmet is deliberately left open to keep the infant cool and ease because this area has almost no influence on the treatment process. The helmet is made of biomedical materials that do not cause discomfort to the infant. The sensors used in the helmet are non-invasive and non-irritating. The sound sources are arranged to avoid causing adversely affect on the infant's hearing.

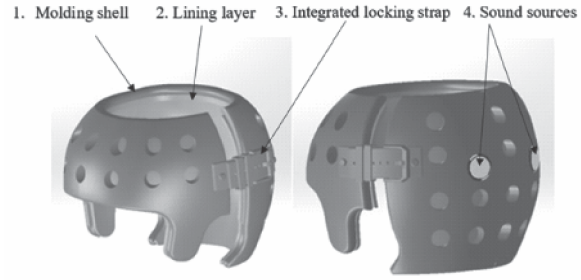


*Figure 2. Major design requirements*

### 2.3. Optimization process

Optimization was carried out using ANSYS software. Material regions that do not contribute to the corrective treatment were removed, thereby reducing the helmet weight ☞

and material consumption. Additionally, these removed areas improve ventilation, keeping the infant cooler and more comfortable.

• Basis for selecting circular holes

The use of circular holes in the cranial molding helmet represents the optimal solution in terms of functionality, safety, manufacturability, and aesthetics while maintaining effective ventilation and overall structural strength. According to [5], the stress concentration factor for circular holes is only 3.0, compared to 4.0 for square holes and 5.2 for triangular holes.

Circular holes exhibit perfect symmetry, resulting in uniform stress distribution around the circumference and avoiding stress concentrations at sharp corners that can easily lead to cracking, as occurs with triangular or square holes. From a safety and comfort perspective, the smooth edges of circular holes eliminate sharp corners, minimizing the risk of skin abrasion or injury during prolonged wear. Circular holes are also easier to machine or print, increasing production speed, reducing dimensional errors, and saving time. This choice also provides a harmonious, minimalist, and modern appearance suitable for a cranial molding helmet.

• Basis for selecting hole size

Circular holes in the 3D-printed helmet were introduced to minimize material usage and enhance heat dissipation. Hole dimensions were determined through thermal simulations, prioritizing maximum heat removal while ensuring structural integrity and minimizing plastic consumption. The thermal simulation results for different hole sizes are presented in Table 1.

*Table 1. Thermal simulation results obtained using ANSYS for different circular hole diameters*

| **Diameter (mm)** | **Average Temperature (°C)** | **Highest Temperature (°C)** | **Lowest Temperature (°C)** | $\Delta_{t_{TB/max}}$ **(°C)** | $\Delta_{t_{TB/min}}$ **(°C)** | $\Delta_{TB}$ **(°C)** |
|---|---|---|---|---|---|---|
| Ø4 | 35.242 | 37.343 | 29.395 | 2.101 | 5.847 | 7.948 |
| Ø6 | 35.215 | 37.359 | 29.394 | 2.144 | 5.821 | 7.965 |
| Ø8 | 35.199 | 37.532 | 29.381 | 2.333 | 5.818 | 8.151 |
| Ø10 | 35.169 | 37.331 | 29.341 | 2.162 | 5.828 | 7.99 |
| Ø12 | 35.136 | 37.337 | 29.287 | 2.021 | 6.029 | 8.050 |
| Ø14 | 35.11 | 37.413 | 29.24 | 2.303 | 5.87 | 8.173 |
| Ø16 | 35.076 | 37.382 | 29.18 | 2.306 | 5.896 | 8.202 |
| Ø18 | 35.142 | 37.503 | 29.147 | 2.361 | 5.995 | 8.356 |
| Ø20 | 34.984 | 37.418 | 29.06 | 2.434 | 5.924 | 8.358 |

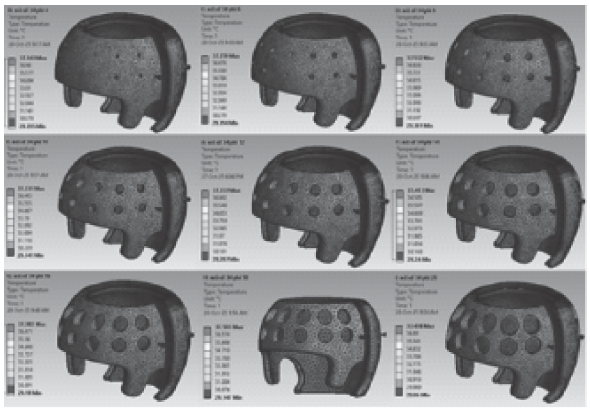

*Figure 3. Thermal optimization process performed in ANSYS R19.2.*

### 2.4. Sensors supporting the treatment of infants

#### a) Adverse effects may occur during treatment in infants

Discomfort is one of the negative factors affecting the cranial remodeling process in infants with flat head syndrome. According to [6], an infant is considered to be in a state of discomfort when blood oxygen saturation ($SpO_2$) falls below 90 % and heart rate (HR) exceeds 180 BPM (beats per minute) or drops below 100 BPM. Under these conditions, the infant tends to cry frequently and exhibits clear signs of discomfort. These physiological thresholds can therefore be used as reliable indicators to improve comfort while the helmet is worn.

#### b) Devices supporting the measurement of adaptation level in infants when using cranial molding helmets

In the medical field, particularly in neonatal care, various devices are employed to monitor and evaluate the degree of helmet acceptance in each infant. Table 2 lists some commonly used medical devices for measuring physiological parameters in newborns.

*Table 2. Selection of devices for measuring physiological parameters in infants*

| Device | Placement location | Measured parameters | Principle of operation | Advantages | Ref. |
|---|---|---|---|---|---|
| MAX30100 sensor | Glabella (Forehead) | - HR<br>- $SpO_2$ | PPG based on light reflection/absorption through blood vessels | Compact, low-cost, non-invasive, helmet-integrable | [7] |
| Empatica E3 wearable | Wrist | - HRV, BVP<br>- EDA<br>- Skin temperature | Variation of heart rate and skin electrical resistance | Real-time physiological index measurement | [8] |

According to [7], the MAX30100 sensor provides highly stable heart rate measurement and $SpO_2$ accuracy of up to 99.4 %. To monitor the infant's adaptation level during helmet use, the MAX30102 sensor is proposed for integration owing to its non-invasive nature and focus on heart rate and blood oxygen saturation. This device was selected for its high accuracy and because it is an improved version of the MAX30100.

Based on the measured physiological parameters, the infant's comfort threshold can be easily determined using the previously mentioned heart rate and $SpO_2$ limits. This enables appropriate interventions to enhance comfort while wearing the helmet. One such solution is presented in the following section.

☞

### 2.5. Integration of sound into the treatment

In our study [9], the integration of a sound system into the cranial molding helmet was proposed to improve infant comfort during prolonged helmet use, based on continuous monitoring of heart rate and blood oxygen saturation.

The study by Kobus et al. [10] employed the sansula musical instrument together with simple, gentle and sustained vibrating melodies in order to synchronize the infant's heart rate and reduce it. Table 3 presents the results of a parental survey describing the infant's condition before and after the application of music therapy.

*Table 3. Survey of infant condition before and after the application of music therapy.*

| **Infant's condition** | Calm | Tense | Excited | Comfortable | Fidgety | Cramped | Relaxed |
|---|---|---|---|---|---|---|---|
| **During the music therapy** | 94% | 3% | 3% | 88% | 6% | 0% | 91% |
| **After the music therapy** | 75% | 6% | 3% | 78% | 6% | 0% | 88% |

Based on recommendations for safe sound environments in newborns [11], the sound intensity produced by the helmet is limited to 50 dB – the level recommended for both indoor and outdoor daily activities – to ensure auditory safety and prevent discomfort.

Other studies have also demonstrated that various types of sounds can significantly increase comfort in young children. To offer greater flexibility in helmet use, a sound system is proposed that automatically adapts to both environmental context and the infant's physiological state. This context- and physiology-aware system operates according to two main principles, summarized in Table 4 below.

*Table 4. Operating principles of the adaptive sound system.*

| **Criteria** | **Context-based mode** | **Physiology-based mode** |
|---|---|---|
| Operating regime | Manually adjusted by parents | Automatic activation by the system |
| Activation timing | According to parents' pre-set or real-time decision | Immediately upon detection of abnormal signs |
| Activation condition | "Indoor" mode selected during rest or when staying indoors. "Outdoor" mode selected when parents wish to take the infant outside | - Heart rate more than180 BPM or less than 100 BPM<br>- $SpO_2$ under 90% |
| Primary objective | Create an environment suitable for the context, helping the infant relax and become familiar with the outside world | Quickly intervene and stabilize the infant's physiological state |
| Sound termination timing | Parents manually switch mode or turn off | Automatically stops when physiological parameters return to normal (stable heart rate and $SpO_2$) |

Table 5 lists several types of sounds proven effective in increasing infant comfort for indoor and outdoor situations.

*Table 5. Selection of comforting sounds for infants in indoor and outdoor environments*

| Sound type | | Effect | Technical characteristics | Ref. |
|---|---|---|---|---|
| Indoor | Sansula | Synchronizes and reduces heart rate, helps the infant stabilize | 30-50 dB | [10] |
| | Lullaby | Stabilizes heart rate, increases oxytocin, reduces heart rate by 5-10 BPM, deepens sleep | Heart rate 50-70 bpm, sound level approximately 60 dB | |
| | Mother's womb sounds | Makes the infant feel safe, comfortable, and sleepy | 70-90 dB. Recommended use within 50-65 dB | [12] |
| Outdoor | Rain, ocean waves, river, birdsong, wind, etc. | Reduces discomfort, masks outdoor noise, helps the infant cope with rain, stimulates natural environmental perception in newborns | 25-50 dB | [13] |

Based on the aforementioned studies, the sounds from [10] are recommended for indoor use, while the natural environmental sounds from [13] are proposed for the therapeutic solution.

However, according to the American Academy of Pediatrics (AAP) [14], daily sound exposure should not exceed 8 hours to prevent potential hearing damage in infants. Therefore, parents are advised to refer to the recommended usage durations and timings presented in Table 6 below.

*Table 6. Recommended duration and timing of sound therapy during the day.*

| Location | Recommended time | Recommended sounds |
|---|---|---|
| Indoor | Before lunch break and before bedtime | Sansula, lullabies, heartbeat, womb sounds… |
| Outdoor | Before 10:00 a.m. and after 4:00 p.m. | Birds chirping, running water, falling rain… |

### 2.6. Prototype manufacturing procedure of the molding shell

According to [15], 3D printing is one of the most advanced manufacturing technologies currently available and is particularly suitable for producing cranial molding helmets. The additive manufacturing process considerably simplifies the fabrication of complex-geometry components; therefore, it was selected for producing the reference prototype of the molding shell. Thermoplastic Polyurethane (TPU) was chosen as the printing material due to its moderate cost, excellent durability, and non-toxic characteristics.

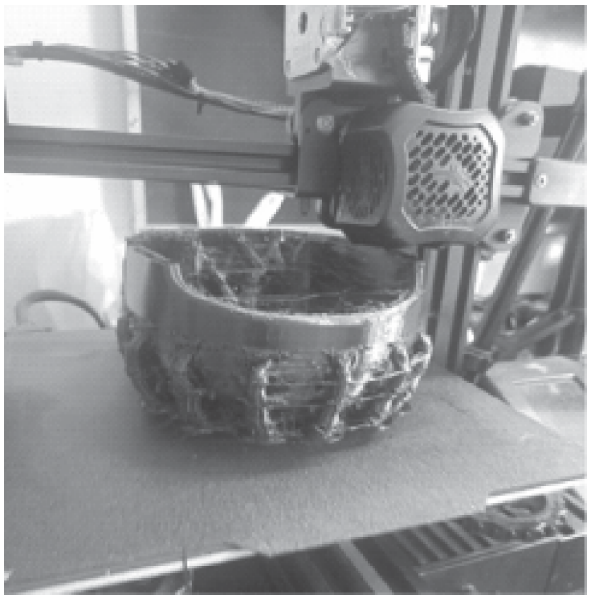

*Figure 4. 3D printing process of the molding shell prototype.*

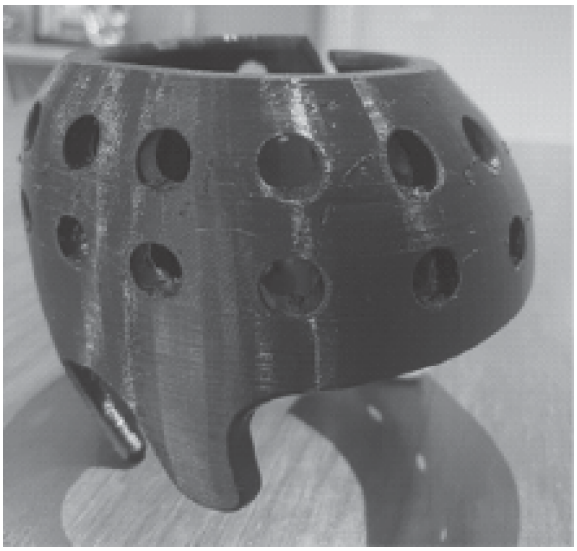

*Figure 5. 3D-printed molding shell prototype of the cranial helmet.*

## 3. CONCLUSION

In this paper, a development direction for a cranial molding helmet for infants with flat head syndrome has been proposed. A fully personalized design procedure based on 3D scanning of the infant's head and thermal optimization of ventilation holes using ANSYS simulation has been presented. In addition, the integration of adaptive sound therapy has been introduced to alleviate discomfort and unwanted physiological responses while wearing the cranial molding helmet.❖

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