Adjustable Cranial Orthosis For Treatment of Infant Deforma Brachycephaly and Plagiocephaly

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Erudite Adaptations

Introduction

There are two common times of cranial deformities

- Plagiocephaly: Presents as a flattening of one side of the posterior cranial region. Most common
- Brachycephaly: Presents as a flattening of the occipital region of the cranium.

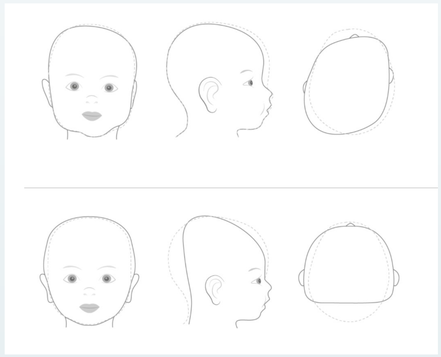


Image adopted from Hanger Clinic (1)

Long terms effects of plagiocephaly and brachycephaly can include:

- Reduction of visual field and development of visual processing
- Reduction in quality of cortical sound processing

Current treatments include helmet therapy and active repositioning

- Though repositioning is moderately helpful, helmet therapy is still the quickest method of treatment
- Cranial bands (helmets) help redirect the growth of an infant's cranium. The band holds growth in the bossed areas and promotes growth in flattened areas (2).

Problem

Cranial deformities are common among infants due to the "Back to Sleep" movement, which is an effort to reduce SIDS. Long term placement on the back causes a deformed cranium. Effects of these deformities can be cosmetic but can also cause visual field and auditory processing issues.

- Treatment involves helmet therapy. Current devices do not accommodate for infant growth effectively.

Need Statement

A new orthosis that better accommodates infant growth in treatment of cranial deformities

Market Analysis

Current devices on the market are the DOC Band and the STAR Band. The DOC Band is custom made, and STAR Band is off-the-shelf.

Image adopted from Cranial Technologies (3)

Image adopted from Orthomerica (4)

There are no adjustable cranial bands currently on the market. Selection is limited to either off the shelf or a DOC band.

Market growth is expected to continue growing due to the Back to Sleep movement, ensuring there will always be a need for these devices. The market is expected to grow by $94.49 million dollars in the next 4 years (5).

Key Global Market Share Players (5)

- Orthomerica, Ballert Orthopedic, Cranial Technologies
- Combined hold 60% of the Global Market Shares

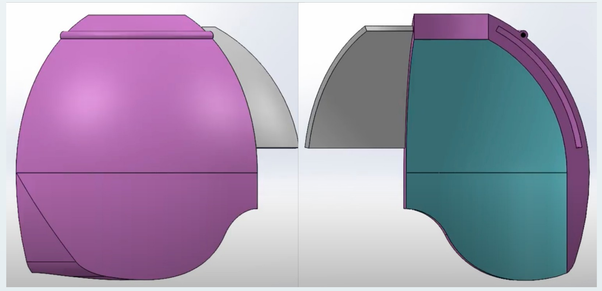
Design Concepts

Our idea is an adjustable "Cranial Belt" that contains 4 split quadrants that can be expanded to fit the infant through the entire treatment period.

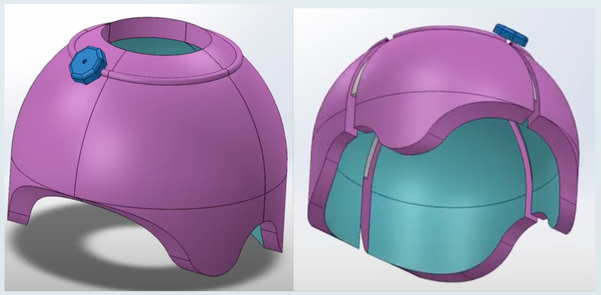
Final Design

Design Criteria and Constraints

- Create an adjustable band that will grow with the patient
- Custom fit
- Made from a hypoallergenic material
- Made of a copolymer (biomaterial)
- Comfortable for the patient
- Easy to use
- Locking mechanism that prevents removal
- Minimal parent intervention



This is a SolidWorks model showing one of the four quadrants in the helmet.



This is a SolidWorks model showing the four quadrants when the helmet is not expanded and expanded.

Materials for the different colors on the SolidWorks model

- Inner teal = aliplast foam
- Outer purple = copolymer
- Grey between quadrants = polyethylene
- Blue knob = BOA ™ shoelace system

Prototype

- The four quadrants are laced together using a BOA ™ shoelace system
- The helmet is made out of several layers including alipast foam, fiberglass, polyethylene, and copolymer
- Circular cut in the top of the helmet is a universal cut that will work to treat any type of plagiocephaly (left or right side)

Prototype Testing

Tests we've performed on our device:

- Drop test: Our device passed the drop test. When dropped from 4 feet and 5 feet onto a solid surface, the helmet remained fully in tact with no damage.
- Water resistance test: Our device passed the water resistance test. Though the helmet will never be waterproof, it is water resistant enough that basic cleaning and sweat will not damage the helmet.

Conclusion

In conclusion, a cranial helmet that has the capability to grow with a baby with plagiocephaly will allow for shorter and earlier treatment time. The design that is proposed consists of four quadrants threaded together using a BOA system, allowing it to be the exact shape needed to correct the cranial deformity. A prototype was made at Hanger Prosthetics and Orthotics under the supervision of an Orthotist/Prosthetist (O/P).

References

(1) Plagiocephaly. 2021. Hanger Clinic.
(2) Schreen G, Matarazzo CG. 2013. Plagiocephaly and brachycephaly treatment with cranial orthosis: A case report. Einstein (Sao Paulo, Brazil).
(3) How does the doc band® Plagiocephaly Baby helmet work and facts. 2020 Feb 13. Cranial Technologies.
(4) Starband. Orthomerica Products Inc.
(5) Technavio. 2021 Aug 9. Cranial orthoses market in health care equipment industry: Key drivers and market forecasts: 17000+ technavio reports. Cranial Orthoses Market in Health Care Equipment Industry.

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