IMPROVED TREATMENT OF PLAGIOCEPHALY

Clients:

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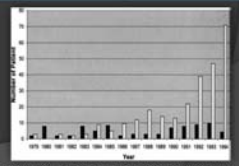
Background

- Asymmetrical molding of the head caused by external forces
- Infants ages 4 to 18 months undergo corrective helmet treatment
- Currently, there is no quantitative means of measuring the forces an orthotic helmet applies to the skull

Mid-1970's
First orthotic helmet developed

1992
Back to Sleep Campaign for SIDS

1996
Fivefold increase in plagiocephaly found in 1992 - 1994

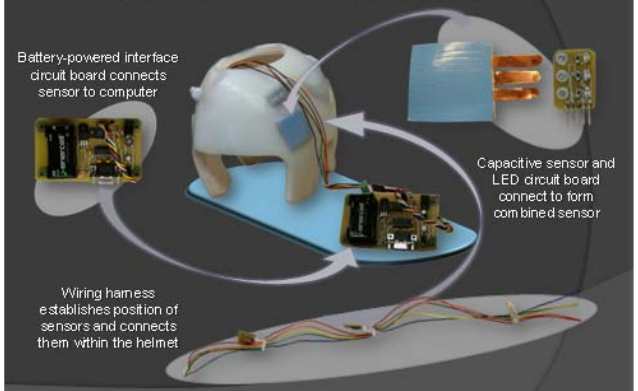


Kane AA, Mitchell LE, Craven KP, et al. Observations on a recent increase in plagiocephaly without synostosis. Pediatrics 1996; 97:877-885.

Objectives, Specifications, Constraints & Risks

- **OBJECTIVES**
  - To produce a method of measuring contact forces applied by orthotic helmet on the skull
  - To achieve a better, faster, and more complete treatment for plagiocephaly
- **SPECIFICATIONS**
  - Battery-powered
  - Sensors <1" in thickness
  - Aliplast foam is material in contact with head
  - Device in helmet is undetectable to patient
  - Maximum detectable force is 9.21 lb-force
  - Minimum detectable force is 0.385 lb-force
  - Noise is <0.385 lb-force
  - Sensors must conform to 3D surface
- **CONSTRAINTS**
  - Materials should be:
    - Non-toxic
    - Currently used in orthotic helmets
    - Readily available
    - Low cost
- **RISKS**
  - Sensors may be destroyed in the process of building the helmet
  - Sensors may be detectable if they are not small enough
  - Sensors may not be sensitive to relevant force range

Device Illustration

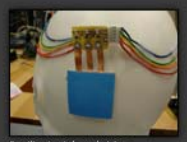


Production Methods

Building sensors: alternating layers of foam and copper

Soldering components to create LED circuitboards and interface circuit board

Attaching sensors to circuit boards

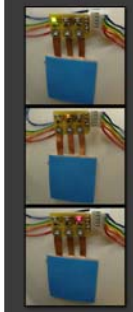


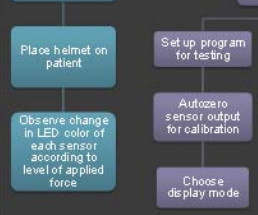
Positioning integrated force measuring system on head mold

Testing sensors using a force transducer

Adding a layer of plastic to create helmet

Operation Block Diagram



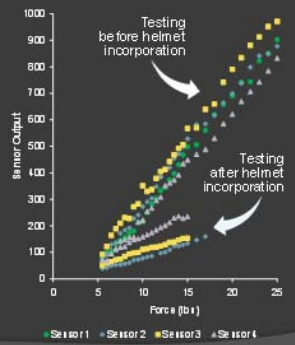


LED MODE: Used to light LEDs up, with colors and flashing rates corresponding to nine levels of applied force

COMPUTER OUTPUT MODE: Used to calibrate sensors, choose display mode, and read quantitative outputs

Results:

Force / Sensor Output Relationship



- Highly linear relationship between sensor output and force
- Sensor sensitivity decreased after incorporation into helmet
- Linearity was unaffected by incorporation into helmet (R^2 = 0.99 for each sensor)
- Connection of sensor 1 was weakened during helmet incorporation

Specifications vs. Actual Performance

Specification	Specified	Actual Performance	Test Method
Battery-powered	Has battery	Has battery	N/A
Thickness	< 1" (25.4 mm)	4 mm	N/A
Foam in contact with head	Aliplast foam	Aliplast foam	N/A
Patient comfort	Should not be able to detect device in helmet	Could not detect device in helmet	Have consultant try on helmet
Maximum force	9.21 lb-force	≥ 15 lb-force	Apply load with mechanical force transducer
Minimum force	0.385 lb-force	0.128 lb-force	Calculate sensitivity from output-force calibration curve
Noise	< 0.385 lb-force	0.193 lb-force	Record output for one minute after system has been at rest for a substantial period

Conclusions, Recommendations, & Acknowledgements

- **CONCLUSIONS**
  - Incorporated force-measuring system into orthotic helmet
  - Designed a system that gives output corresponding to applied force
    - However, sensitivity of system was reduced following incorporation into helmet
  - Strategically designed system so that LEDs are visible through the helmet casing
  - 3D surface did not adversely affect capacitance measurement
    - This is a result of designing and building the sensors on a 3D surface
- **RECOMMENDATIONS**
  - Perform clinical studies using helmets with force-measuring system on patients
  - Add more layers to sensors to increase capacitance so that sensitivity will be less affected by system incorporation into helmet
  - When building the system into the helmet, pull the last layer of foam and cut a window for the LED sensors after setting the sensors

ACKNOWLEDGEMENTS

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