TapAlign: A Novel Device for Improving Neonatal Lumbar Puncture Success Rates

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Need

Lumbar punctures are the **gold standard** for diagnosing bacterial meningitis, which is a life-threatening infection of the brain and spinal cord.
With treatment, the mortality rate for bacterial meningitis in newborns is 5–20%. Without treatment, the mortality rate is **close to 100%.**
50% of infants between 4-28 days old may receive a lumbar puncture, and there is a **31% first attempt failure rate** of lumbar punctures for infants less than 3 months old.

Objective

Design an **adjustable horizontal stabilization** device for infants (0–6 months) that maintains spinal curvature, ensures airway safety, and keeps the infant securely immobilized during lumbar punctures.

Existing Solutions

Smöltap:

- Smöltap only accommodates infants 0-2 months old. Ours accommodates infants up to 6 months.
- Our device allows for horizontal positioning (Smöltap is vertical) which is a clinician preference.

Ultrasound:

- Not used on infants in clinical studies.
- Does not provide physical stabilization.

Design Inputs

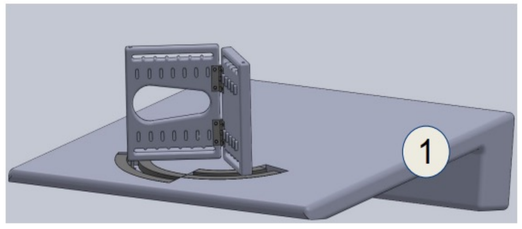
Constraints

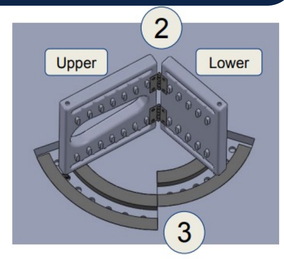
- **Time:** 3 terms, nine-months total
- **Budget:** Limit of $600 per DrExcel Health and NBME
- **Resources:** BME and DrExcel Health advisors will provide expertise for project
- **Policy:** Follow FDA guidance manual for pediatric medical devices

Requirements

- Provides necessary spine curvature (≤140°) and adequate intervertebral space without compromising airway
- Keeps infant immobilized during procedure ~30 minutes
- Adjustable for infants aged 0-6 months
- Simple and quick to set up ≤1 min

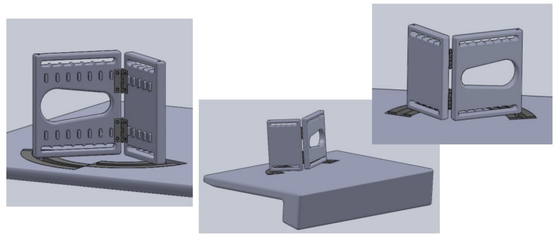
Prototype





1. Angled and padded base
2. Infant support pieces; upper and lower
3. Railings

Alternate views



Intended Use

Product characteristics

- Frontal, angled support allows easy intervertebral access
- Hole in the front for breathing.
- Lockable railing and straps maximize safety.
- Outer neoprene material for comfort, polycarbonate inside for support.
- Small and lightweight design allows quick setup and breakdown

Verification/Validation

- **Achieved Curvature Test:** Ensure the device can adjust from 0 to 140 to achieve maximum intervertebral space in infant's lumbar space.
- **Strap Stability Test:** Confirm that the device can withstand the force of the average-sized infant of up to 6 months of age.
- **Set Up and Removal Test:** Ensure that an infant can be quickly removed from the device in the event of an emergency.
- **Dimensions Test:** Ensure the device (150cm x 120cm x 20cm) is smaller than and can fit on a standard operating table.
- **Device Length Adjustability:** Verify device compatibility with infant heights from 5th to 95th percentile for 6 months of age (46.8-71.1cm).

Conclusion and Impact

- Developed an easy-to-use, adjustable, portable supportive device for infant lumbar puncture procedures that can **increase neonatal lumbar puncture success.**
- Physicians can easily and rapidly set up the device so that patients suspected of neonatal meningitis can be **tested and treated as quickly as possible.**
- The device can comfortably and quickly accommodate **infants of all sizes from 0-6 months of age.**
- This **easily adjustable device** allows for physicians to perform the procedure at the angle that works best for both the patient and the physician, and with the patient in the **horizontal position** that aligns with procedural training.
- The U.S. spends over **$3 billion annually** on neonatal care, with **$700 million each year** going towards lumbar puncture procedures.
- Each day that a neonatal patient spends in the hospital without a successful lumbar puncture **adds tens of thousands of dollars** to the cost of their care. The ability to cut down on unsuccessful lumbar punctures and have neonatal patients treated as quickly as possible could greatly reduce these costs and help thousands of infants.

Acknowledgements:
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