3D-Printed Ear Splint for Congenital Ear Deformity

An estimated 5-10% of the four million children born each year in the United States have congenital ear deformities. These deformities can draw negative attention to a child and have lifelong physical and psychological effects. Existing treatments include surgical intervention at age five or six, or non-surgical approaches that are expensive, difficult to use, and cumbersome to wear.

The Solution

University of Michigan researcher, David Zopf, M.D., Assistant Professor, Department of Otolaryngology — Head and Neck Surgery, has created FerroForm, a non-surgical, customizable 3D-printed device that offers affordable, effective, and easy-to-use treatment for ear deformities.

FerroForm addresses the limitations and drawbacks of current ear malformation treatment alternatives. Made from medical grade silicone with embedded magnets, the device shapes the ear and allows for growth of the newborn during the time period that the splint is worn.

FerroForm could have a significant regional, national, and worldwide impact by helping parents and clinicians manage ear deformities, and allowing pediatricians to provide treatment earlier in a patient’s life (when treatment will be quickest, best tolerated, and unlikely to cause further damage).
Ferroform is a magnetic, 3D printed ear splint that treats congenital ear deformity in children

**Significant Need**
Existing treatments include surgical intervention that runs the risks of general anesthesia and surgery, and non-surgical methods that are expensive, difficult to use, and require continuous wear of a cumbersome device for up to several months.

**Compelling Science**
Rather than adhesives, FerroForm uses an anchoring design within the ear canal that ergonomically wraps around the ear and is secured in place using magnets. It shapes the ear and can adjust for a child as they grow.

**Competitive Advantage**
FerroForm is a sizeable device that molds to an individual infant’s ear deformities and can be easily applied, removed, and replaced. This can lead to shorter treatment times because progress can be assessed in real time rather than waiting for follow-up medical appointments. Also, the use of magnets rather than adhesives minimizes the potential for skin irritation and increases patient comfort and compliance.

MTRAC funding will allow us to complete a clinical trial examining the feasibility of using 3D printing technology to produce FerroForm, and help us further refine the device’s design, establish a scalable manufacturing process, and gather clinical safety and efficacy data. We also hope it helps raise awareness for patients and families with congenital anomalies.

**MTRAC Project Key Milestones**
- Refine design based on clinician and patient feedback
- Explore means for in-office individualization (customizable moldable silicone)
- Select one design from three options for clinical trial
- Determine scalable manufacturing process
- Validate FDA Class 1 (PMA exempt) status with regulatory consent

**Overall Commercialization**
- **Intellectual Property**
  - A provisional patent, 62/395, 451, has been filed with a recent submission for full patent
- **Commercialization Strategy**
  - Attract strategic investors to help launch a start-up company
- **Regulatory Pathway**
  - Class 1 medical device
- **Product Launch Strategy**
  - TBD

David Zopf, M.D.