Department of Pediatrics' Groundbreaking Infant-First Research Results in Patents

Dorothea Jenkins, M.D., can recall the moment she made the connection between vagus nerve stimulation and the impact it could have on the neonates she treated. "I was attending a brain stimulation seminar lecture discussing the parameters of non-invasive transcutaneous auricular vagus nerve stimulation (taVNS) with human volunteers," says Dr. Jenkins. "As soon as I heard the details of the study, I was like 'Oh—we've got to do this in babies, and I know exactly what motor skill we can work on!'"

It was this lightbulb moment that led to Dr. Jenkins' groundbreaking, infant-first study that had a 70% success rate in at risk babies and culminated in a registered patent on both the innovative technology as well as the cranial nerve system for feeding.

The vagus nerve, a crucial part of the autonomic nervous system, plays a vital role in regulating various bodily functions, including heart rate, digestion, and even immune responses. Researchers have long recognized its potential therapeutic applications, and over the years implanted vagus nerve stimulation has been used successfully in the treatment of various medical conditions in adults, such as epilepsy and depression (initiated at MUSC by Dr. Mark George in 1998).

However, Dr. Jenkins saw a unique opportunity to harness the power of non-invasive taVNS to address the specific health challenges faced by infants born pre-term or with a brain injury. "One of the first skills that newborns have to master is feeding—the sequence of sucking and swallowing milk and then breathing. It takes more than 22 muscles, and they have to do all of that within 1-2 seconds and not aspirate, so this is a significant motor sequence to learn," says Dr. Jenkins. "Now, if you're born at term, you've got it as a reflex. But if you're born preterm or if you have a brain injury as a term baby, you may not have that reflex. We were having a large number of babies who were getting gastrostomy tubes placed because they could not learn this skill and were not able to fully feed by mouth."

Dr. Jenkins began her research journey with a simple yet profound question: Could taVNS be used to not only help these babies learn to feed, and also positively impact the neuroplasticity of their brains? Using a non-invasive device positioned on the ear branch of the infant's vagus nerve, Dr. Jenkins and her team would stimulate the baby during the sucking and swallowing phase of feeding. The results were nothing short of miraculous. When used once a day,

Dr. Jenkins' care team and a young patient

"TaVNS seems to provide a rocket boost to the infant's natural neuroplasticity, to their current sensorimotor skills and, we hope, future development."


An infant receives taVNS therapy while feeding

babies were able to get to full feeds in two weeks, and when the device was used twice a day, babies were able to achieve full feeds in an average of 8 days.

Dr. Jenkins was also able to measure the success of the technique through extensive brain imaging. "We utilized MRI scans with modified barium swallows before and after so we could look at the mechanics of swallowing as well as what we were hoping to generate, which was neuroplasticity in the brain," she says. "What we saw (through biomedical imaging) was that the corticospinal tracts—the major motor tracks—were significantly more complex and stronger in the babies who got the full feeds."

Dr. Jenkins is currently starting a new STTR multicenter, randomized controlled trial to show the effects of the BabyStrong taVNS feeding system in infants that are poor feeders. The research and results will provide the groundwork for an FDA application.

In addition to improving immediate health outcomes, Dr. Jenkins also envisions the long-term impact taVNS can have in feeding and other areas of motor delays. "Our goal is to use taVNS to improve breastfeeding—which is different than bottle feeding—and I think that would be a huge game changer for a lot of infants and their mothers who get discouraged when babies aren't learning to breastfeed," she says. "It's very expensive to keep babies in the hospital to teach them to feed, so I think the ability to hasten that and get them home is good for family bonding and their development."

Dr. Jenkins has also collaborated with MUSC pediatric occupational and physical therapists to conduct pilot trials with older infants with motor delays and greater weakness of one arm and hand, a marker of early cerebral palsy. "We paired the taVNS with Constraint-Induced Movement Therapy (CIMT) in which the good hand is wrapped or put in a soft mitt, and the weaker hand and arm are used in intensive play therapy," she says. "Those infants typically had minimal use before treatment but saw significant improvement with the combined intervention, and much better improvement than we would have expected from CIMT alone."

As the research expands into larger clinical trials, Dr. Jenkins envisions a future where taVNS becomes a standard supportive therapy for infants who face high risks of developmental challenges. "We're excited about the possibilities of taVNS paired with motor or behavioral interventions for infants after brain injury to stimulate and strengthen brain circuits and get them on a more normal developmental track," she says. "TaVNS seems to provide a rocket boost to the infant's natural neuroplasticity, to their current sensorimotor skills and, we hope, future development."