



Mechanical Dermal Stimulation to Modulate the Interoceptive Network in Sleep-disordered Populations

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Gina Sensale is a Research Assistant at Feelmore Labs, Inc.

She received a B.S. degree in Psychology, from the University of Connecticut in 2018. Her B.S. research track was concentrated in behavioral neuroscience, including lab work in physiological psychology and drugs and behavior. She has since worked in neuromodulation research, studying noninvasive therapeutic techniques such as transcranial magnetic and mechanical neurostimulation, through various forms of neuroimaging, signal processing, and cognitive testing. She is currently researching therapeutic applications of mechanical dermal stimulation technology.



Introduction: Interoception



Interoception is the perception of sensations originating in the body. Most are preconscious but some somatic interoceptive signals, especially those related to emotion are often perceived consciously.



The conscious perception of the internal bodily state can be broken into three domains: overall awareness, sensitivity to interoceptive changes, and accuracy in assessing interoceptive signals



Interoception can become dysregulated. Awareness may lapse, sensitivity to change can become blunted or magnified and/or assessments become inaccurate. Interoceptive dysregulation has emerged as a significant component of stress and many affective disorders



Introduction: Interoception system

C-Tactile Afferent Neurons (CTAs) and Affective Touch

Mammals, including humans, are hard-wired for receiving and processing affective (slow, light) touch via specialized mechanoreceptors, CTAs, found in all hairy skin.

Affective touch, in turn, is associated with feelings of calm, relaxation and social connectedness, all related to improved interoceptive regulation.



Introduction: Interoception and Sleep

- In the last decade, an estimated 83 million adults in the United States reported suffering from insufficient sleep; however, few non-drug therapeutic interventions exist that are both low-side effect and effective in treating sleep-related disorders. ^[7]
- Research studies have found that interoceptive sensitivity and awareness may in fact disrupt several processes during sleep initiation and sleep. ^{[2][3][4]}
- Dysregulated interoception may be an underlying mechanism for sleep-related disorders, as with affective disorders, making that system a potential therapeutic target.

Interoceptive Therapeutics: Mechanical neurostimulation

- We studied changes in brain activity pre and post mechanical dermal stimulation, in-lab, for over 2 years, testing different variables such as frequency, intensity, and duration of stimulation.
- We found evidence in support of CTA mechanoreceptors' known response characteristics of touch, mainly low intensity and low frequency (~10 Hz) stimulation.
- We developed a novel mechanical stimulation device, targeting the affective touch pathway, designed to improve interoceptive regulation
- Once developed, a pilot trial was conducted to assess the potential of this intervention in sleep.

- A simple headband with small piezoelectric actuators at the distal ends.
- It delivers short bursts of very low intensity, low frequency (10 Hz) mechanical stimulation, targeting CTAs associated with the affective touch pathway.



Study Procedures

- 245 adults were screened for poor sleep via Pittsburgh Sleep Quality Index (PSQI)
- 25 adults met the study criteria (Global PSQI > 10) and were enrolled in the study
 - 14 Females, 11 Males
 - Age range: 24 60 years old (mean=35)

30-Day Study Flow



***PSQI** is a self-report measure assessing sleep quality and disturbances over a 1-month timeframe.

****Sleep Quality Rating** is a 1-item selfreport measure utilizing a scale of 1 to 5, where 1 represents little to no sleep at all, and 5 represents great sleep (no problems falling or staying asleep).

All study procedures were reviewed and approved by an ethical board (Solutions IRB, #: FWA00021831)

Results

- In the sample of 25 participants, 3 participants were excluded from analysis due to lack of compliance with the study protocol (i.e., device usage, completing the study)
- Results are reported as Mean \pm SD and will cover the following measures of sleep:

Pittsburgh Sleep Quality Index (PSQI)

- •Global PSQI score is the sum of all 7 components (0-21)
- •7 component scores representing different components of sleep (0-3)
- •A decrease in scores represent an improvement in sleep

Sleep Hours

- •Assessed via a commercial wrist Photoplethysmography (PPG) device: Garmin VivoSmart 4
- This was chosen as it was most reliable for sleep time in earlier studies

Sleep Quality Rating

- •1-Item self-report rating scale assessing sleep quality (1-5)
- •An increase in sleep quality rating score represents a perceived improvement in sleep

Pittsburgh Sleep Quality Index (PSQI)

- **86%** of compliant participants (n=22) reported an overall improvement in sleep after using the device for 30 days, indicated by a decrease in Global PSQI scores on average.
- Global PSQI scores improved by 43% on average
- (Pre: 9.8 ± 3.0 , Post: 5.2 ± 2.6).



- After 30 days of device use, there was an overall improvement across the 7 dimensions of sleep, represented by an average decrease in PSQI Component Scores
- 91% of participants reported improvement in sleep quality
- 77% reported falling asleep faster
- 68% reported a reduction in daytime drowsiness





Sleep Hours and Sleep Quality Rating

- Sleep hours increased 65 minutes on average, assessed via Garmin VivoSmart 4
- (Pre: 6.60 ± 0.29 , Post: 7.45 ± 0.45)



• (Pre: 3.71 ± 0.31 , Post: 4.25 ± 0.10)









Conclusion and Future Work

- This is the first human study to evaluate mechanical stimulation of the affective touch pathway in a sleep-disordered population.
- Although the trial is small, open-label, and used early prototypes, the results were significant.
- A confirmatory Randomized Control Trial (RCT) is underway and will be completed in late 2021.
- This trial suggest that interventions designed to improve interoceptive regulation may provide a novel new approach in treating sleep disorders.

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