Sleep Diagnosis and Therapy 2010; V5 N5, 27–29 Breus and Rubik

A Randomized, Double Blind, Placebo Controlled, Crossover Evaluation of Natural Frequency Technology™ and Sleep Natural Frequency Technology on Sleep in Normal Subjects with Un-Refreshing Sleep

Michael J. Breus, PhD and Beverly Rubik, PhD

Abstract

Background: The purpose of this study was to test the impact of the Natural Frequency Technology (NFT) found in Philip Stein™ Watches (thought to promote overall well-being) and Sleep NFT, (a combination of frequencies designed to promote sleep) on sleep parameters in normal healthy individuals who routinely experience un-refreshing sleep. NFT is a sub 8Hz combination of frequencies that are imprinted on a metal disk placed in a watch worn by the sleeper. Sleep NFT is also a combination of sub 8Hz frequencies, but different from the combination of frequencies used in NFT.
Methods: Subjects: Females (20) and males (8) with an average age of 37.7 years and average BMI of 26.5. Subjects underwent two consecutive nights in the sleep laboratory for each of the conditions (Placebo, /Placebo; NFT/Placebo; NFT/SleepNFT). There was a 5–7 day washout period between sessions. This was a double blind experiment. Subjects arrived two hours before habitual bedtime. They went to sleep at their habitual bedtime and stayed in bed until they woke the next morning (or 8 hours whichever came first). Upon awakening, subjects were asked to complete questionnaires (including Epworth, Slee p Quality Questionnaire, Clinical Global Impressions of Change) asking them about each of the following variables: Total Sleep Time, Sleep Onset Latency, Minutes Awake in the Middle of the Night, Perception of Refreshment, Epworth Sleepiness Scale, and Dream Quality . Vital signs were taken upon awakening and before sleep during all conditions.
Results: Data analysis was performed using a repeated measures ANOVA and Bonferoni t-tests for post hoc analysis. There was not a statistically significant difference noted when comparing overall response between conditions; however, 96% of the subjects responded to at least one of the variables during the NFT conditions. The results of those responders indicate: 43% of responders reported feeling more refreshed, 52% reported dreaming was more pleasant, 47% reported falling asleep faster, 39% reported sleeping more minutes, and 36% reported fewer minutes awake when using NFT than placebo. During the NFT/Sleep NFT condition the results of those responders indicate: 64% report feeling more refreshed, 61% report that dreaming was more pleasant, 43% report falling asleep faster, 43% reported sleeping more total minutes, while only 18% reported fewer minutes awake.
Conclusion: While the current overall results are not statistically significant, a substantial number of subjects demonstrated response to NFT or SleepNFT and reported improvements in the measured individual sleep parameters. Feeling more refreshed after sleep was the primary outcome measure that most clearly separated from placebo. Future studies to determine clinical effectiveness of NFT and Sleep NFT are suggested in the home environment.

Correspondence to: Michael J. Breus, PhD President Mindworks, 11445 E. Via Linda, Suite 2491, Scottsdale AZ 85259. Support for this study was provided by Philip Stein, Inc.

Introduction

Most electromagnetic fields (EMF) appear to have some effect on biologic life. In recent years several EMFs have been found to help support better health.[1] It has been hypothesized that some of the natural frequencies generated by the earth (e.g., the Schumann Resonance 7.83 Hz) have been affecting humans since the beginning of time.[3] The Schumann Resonance in particular appears to produce positive effects on humans at lower intensities.[1] Since the human body also produces frequencies, it also has been shown that these body frequency generators can be "tuned" or entrained to an external influential EMF.[2] Examples of this process have been effective therapeutic tools for decades, e.g., biofeedback leading to relaxation. The most beneficial frequencies for health appear to be extremely low frequencies (ELF), less than 100Hz. Siskin and Walker show the healing effects of several frequencies in their 1995 paper:[4]

Nerve Regeneration	2 Hz
Ligament Healing	10 Hz
Stimulation of Capillary formation	15, 20, 75Hz

The purposeful application of these frequencies to the body to develop a healing response has been named "bioelectromagnetic medicine".[5] Applications have been studied and found efficacious for Parkinson's Disease[6] and bone fractures.[7]

Sleep itself is defined by wave forms, many of which also lie at the ELF range. EEG signals recorded for sleep include delta waves (1-4 Hz), theta waves (6-10 Hz), alpha (8–12 Hz), and beta at (12-30 Hz). These EEG signals by definition are being generated by structures within the brain (Thalamus) and influencing other processes within the brain (neurotransmission). The question then becomes can the brain, and more specifically, sleep, be influenced by external ELF. Before a full pilot study for sleep was to be conducted, a preliminary study was performed to see if the ELF combinations found in Philip Stein™ watches could have an effect on the body by studying the effects of ELFs on heart rate.

Preliminary Pilot Study

In a preliminary pilot study with ten subjects conducted by Dr. Beverly Rubik at an independent laboratory,[8] the effect of

ELFs (including a 7.83 Hz imprinted into the Philip Stein™ watch) on heart rate variability (HRV) was measured. HRV refers to the variable time between heartbeats. Higher levels of HRV indicate greater resilience and adaptability to stress. Lower values are associated with reduced adaptability to stress and change. Typically HRV also decreases with age. In this study the measurements were taken in a laboratory setting for each subject in individual sessions under three conditions, during which they were seated and resting comfortably: *(1) before wearing the watch, (2) five minutes afterward, and (3) one hour later*. Nine out of ten subjects showed positive changes in HRV. HRV increased 32.6% for all subjects at one hour, from 42.6 to 56.6 milliseconds, on average. The increase at five minutes was not as strong, 7.4% for all subjects, from 42.6 to 45.8 milliseconds, on average, so it appears that length of time of exposure to the ELF may be a factor. These positive results on HRV with associated improvements in autonomic nervous system balance suggest increased relaxation is associated with exposure to the Natural Frequency Technology in the Philip Stein watch™.

Preliminary Pilot Study Conclusions

Exposure to the ELF appears to produce an increase in HRV after one hour.

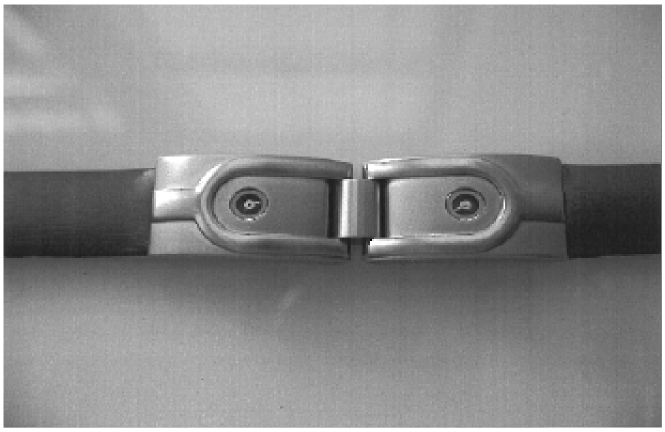
Based on the results of the preliminary pilot study of the effect of ELF on HRV, it was proposed that the ELFs in the Philip Stein™ watch should have some effect on sleep, due to the apparent effect observed on the autonomic nervous system. With an increase in HRV, there was a noted decrease in stress. Since stress has been shown to induce poor sleep, an exploratory study was designed to determine if the positive effect of ELF on stress would have also have an effect on sleep.

The Sleep Study

The purpose of this study was to test the impact of the Natural Frequency Technology (NFT)™ found in Philip Stein™ watches and the NFT Technology (comprised of different ELFs) (Sleep NFT) found in a separate "Sleep Bracelet" on sleep parameters in normal, healthy individuals who routinely experience un-refreshing sleep.

The Devices

Participants received two identical bracelets with polished stainless steel cases. There were two available active bracelets and one placebo bracelet. Within the NFT active bracelet cases were two NFT™ stainless steel disks with embedded frequencies;, within the Sleep NFT active bracelet cases were two Sleep NFT stainless steel disks (with a different combination of frequencies). The frequencies ranged from slightly above 0 Hz to no more than 8Hz. One of the key frequencies was 7.83 (The Schumann Resonant Frequency). The placebo bracelet had the same disks without any embedded frequencies.



Methods

Prospective participants were screened at Visit 1 where vital signs were collected with a urine drug screen. If they met none of the exclusion criteria they returned for Visit 2 approximately five days later. Visits 2 , 3 and 4 each consisted of one visit to the office (in the morning) and two overnight stays at the sleep lab. At each visit, the subjects went to the office the morning of the first overnight stay to be dispensed a bracelet (placebo or NFT determined by randomized counterbalanced schedule) by an un-blinded staff member. The un-blinded staff member did not perform any procedures on subjects. The subjects returned to the office that evening for an overnight stay at the sleep lab. The subjects were required to wear the bracelet given to them that morning for a minimum of ten hours prior to lights out. Lights out occurred plus/minus one hour from the subject's habitual bedtime. Upon arrival for the overnight stay, a urine drug screen and breathalyzer was performed. Vital signs (heart rate, blood pressure and pulse) were collected. The subject was then issued a second bracelet (placebo or NFT Sleep) in a counterbalanced random order. Total time in bed was equal to eight hours. After eight hours in bed the subject was awakened, if not already awake. Thirty minutes after awakening a Sleep Quality Questionnaire (SQQ) was completed by the subject. Vital signs were collected each morning. The bracelet issued the night before was removed, and the subject was reminded to continue wearing the bracelet issued at the prior morning's visit all day and to arrive at the sleep lab in the evening for the second night. When the subject arrived for the second night, the same procedures as the previous night were conducted and the subject was re-issued the same second bracelet as the previous night. The morning after the second night, the subject completed the SQQ, the Epworth Sleepiness Scale, vitals were collected and the study staff completed the Clinical Global Impression of Change Questionnaire. The subjects then had both of the bracelets removed, and returned for the third visit between five and seven days later (washout period), Visit 3 repeated the same two day procedure as described for Visit 2 in a counterbalanced manner. Visit 4 was scheduled between five and seven days after Visit 3 (washout period), and again repeated the same two procedure as described for Visit 2. The protocol underwent full review and approval by an IRB.

Subject Inclusion Criteria

general good health, must self report un-refreshing sleep for at least the past 3 months, and no current sleep disorder. Un-refreshing sleep was defined as a nightly total sleep time of <6 hours, a sleep onset latency of >30 min, a WASO of >30 minutes, and an Epworth Sleepiness Scale Score of >10.

Subject Demographics

Twenty females and eight males completed the study. Average age was 37.7 years and average Body Mass Index (BMI) was 25.4 for females and 27.5 for males.

Results

Data analysis was performed using a repeated measures ANOVA and Bonferoni t-tests for post hoc analysis. For each subject, data for the two night stay in the laboratory was combined and averaged. There were no statistically significant differences noted when comparing the conditions. The conditions (placebo/NFT; placebo/SleepNFT; NFT/SleepNFT). However, 96% of all subjects responded to at least one variable, and the results of those responders indicate:

- 43% of responders reported feeling more refreshed when using the NFT than using placebo
  - 64% reported feeling more refreshed when wearing both the NFT and Sleep NFT than placebo.
- 52% reported dreaming was more pleasant when using the NFT than placebo
  - 61% reported dreaming was more pleasant when using both the NFT and Sleep NFT than placebo.
- 47% reported falling asleep faster when using the NFT than placebo
  - 43% reported falling asleep faster when using both the NFT and SleepNFT than placebo.
  - The largest reduction was an improvement of 32 minutes.
- 39% reported sleeping more total minutes when using the NFT than placebo.
  - 43% reported sleeping more total minutes when using both the NFT and SleepNFT than placebo.
  - The largest improvement was an increase of 65 minutes.
- 36% reported fewer minutes awake when using the NFT than placebo.
  - 18% reported fewer minutes awake when using both the NFT and SleepNFT than placebo.
  - The largest improvement was a decrease of 22 minutes.

Conclusion

While the current overall results are not statistically significant, a substantial number of subjects demonstrated improvements in the measured individual sleep parameters. Feeling more refreshed after sleep was the primary outcome measure that most clearly separated from placebo. There was not a clear indication that the combination of devices was better than the single device alone condition across all of the sleep parameters. A direct comparison of devices was not conducted in this study. Factors effecting the overall statistical significance of these results could have been environmental (a first night effect), subject inclusion or exclusion criteria, or a placebo effect. Results of this pilot study suggest future studies to determine clinical effectiveness of NFT and SleepNFT should be conducted.

References

1. Crasson, M (2003) 50–60Hz electric and magnetic field effects on cognitive function in humans: a review. Radiat Prot Dosimetry. 106 (4): 333–40.
2. Cherry, NJ. Human Intelligence: the brain, an electromagnetic system synchronized by the Schumann Resonance signal. Med Hypotheses, (2003), Jun 60 (6): 843–844.
3. Polk, C; Postow, E. eds. CRC Handbook of Biological Effects of Electromagnetic Fields. Boca Raton, FL; CRC Press, (1986).
4. Siskin, BF, Walker J. Theraputic aspects of electromagnetic fields for soft-tissue healing. In Blank M ed. Electromagnetic fields: Biological interactions and Mechanisms. Advances in Chemistry Series 250. Washington, DC: American Chemical Society, (1995): 277–285.
5. Rubik, B. Bioelectromagnetic medicine. Admin Radiol J (1997a); XVI: 38–46.
6. Sandyk, R, Derpapas K. Further observations on the unique efficacy of picoTesla range magnetic magnetic fields in Parkinson's Disease. Int J Neuroscience, (1993); 69, 167–183.
7. Sharrard, WJW. A double blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg (Br) (1990); 72B; 347–355.
8. Rubik, B. (2009) Exploratory Study on the Beneficial Effects of Wearing Philip Stein Frequency Timepieces. (Unpublished manuscript). Institute for Frontier Science; Oakland, CA 94611.