

SILENT NIGHTS®

Silent Night Patch Improves Qualitative and Quantitative Measures of Sleep and Enhances Quantitative Makers of Organ Function

Sherry Blake-Greenberg MA, HMD, Homer Nazeran PhD, CPEng (Biomed.)^{*}
Health Integration Therapy, Palos Verdes Estates, California 90274, USA

^{*}Electrical and Computer Engineering, University of Texas at El Paso, El Paso Texas 79968, USA

ABSTRACT

Quality sleep is essential for rejuvenation and regeneration of body systems. Many physiological and psychological factors can affect quality of sleep. One factor that influences both the quality and quantity of sleep is an over-function and under-function of the nervous system and brain activity. The level of toxicity in the vital organs is also an important factor. Stress is a main causative factor as well.

Actigraphic measurements depicting movement during sleep, Electro Interstitial Scans (EIS) of different organs reflecting physiological functional status, Leeds Sleep Evaluation Questionnaire as well as sleep diary data reflecting subjective self-evaluation of sleep were collected from 20 volunteers [5 males and 15 females, 20-79 (55 ± 12) years of age, 105-235 lbs (158 ± 36) in weight, and 5 - 6.4 ft (5.5 ± 0.3) in height] over a period of 3 weeks at baseline and at the end of each week afterwards. Baseline data were acquired from all subjects at the beginning of the study period before wearing the Silent Night Patch. After one week of accommodation to wearing the Actiwatchs, Silent Night Patch was worn nightly on the right temple 1 hour before sleep for 2 weeks. Subjects were instructed to keep well hydrated during the study period. All subjects served as their own control. The effects of Silent Night Patch on qualitative and quantitative measures of sleep were evaluated and the impact of quality of sleep on organ function was analyzed. The hypothesis to be tested was: *The Silent Night patch worn on the right temple nightly 1 hour before sleep for two weeks significantly improves cellular physiologic functional status in different parts of the brain, cardiac ventricles, adrenals, and thyroid gland.*

Actigraphic data analysis demonstrated that compared to baseline on average there was 29% reduction in *activity level during sleep*, 22% reduction in *total awake time*, 28% increase in *ratio of time in bed over awake time*, and 28% reduction in *restlessness* after wearing the Silent Night Patch for 2 weeks. The Leeds Sleep Evaluation Questionnaire and sleep diary data on average showed considerable qualitative improvements at the end of the study period in a number of sleep attributes such as: easier and quicker than usual getting to sleep, calmer with less wakeful periods than usual during sleep (better sleep quality), easier and requiring less time to waking up than usual in the mornings, feeling more alert than usual, and less disrupted balance and coordination upon awakening.

Statistical analysis of the EIS data revealed that there was significant improvement in cellular physiologic functional status of the brain (frontal lobe, temporal lobe, hippocampus, hypothalamus), cardiac ventricles, adrenals, and thyroid gland at the end of the study period with respect to the corresponding baseline data. The results showed a *highly significant* ($p < 0.001$) improvement in the physiologic functional status of the temporal lobe, hippocampus, hypothalamus (average statistical power = 100%) and adrenal glands (statistical power = 96%) with a *very significant* improvement ($p < 0.01$) in the functioning of the frontal lobe (statistical power = 75%). There was a *significant* ($p < 0.05$) improvement with an average statistical power of at least 72% in the functional status of the thyroid gland and cardiac ventricles. The liver, kidneys, and intestines did not achieve statistical significance over this period.

In summary, the overall data in this pilot investigation demonstrated that the Silent Night Patch worn on

the right temple nightly 1 hour before sleep for 2 weeks produced considerable improvements in the objective and subjective measures of sleep and caused an impressive improvement in the physiologic functional status of different parts of the brain and adrenal glands with significant enhancement on the functioning of the cardiac ventricles and thyroid glands. Therefore, the *hypothesis was accepted as true*.

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Shealy N. TREATMENT OF INSOMNIA WITH NONTRANSDERMAL ACUPUNCTURE POINT ACTIVATION. October 2010.

Pursuing Publication

Safety:

- 25 subjects used LifeWave Silent Nights patches at night for 30 days in an open-label study.
- These subjects had self-assessed sleep difficulties and they measured changes in sleep over a 30 day period with validated sleep scales and questionnaires.
- **There were no negative reports or adverse reactions reported in the group.**

Patch instructions and study procedures:

- Individuals were instructed to place one of the patches on 1 of 5 specific acupuncture points at bedtime.
- If individuals did not sleep adequately, on the next night they would move the Silent Nights patch to another one of these acupuncture points until they found a placement that achieved the best possible sleep. Once they found an acupuncture point that worked for them then they would continue using the patch on that particular point on successive nights.
- The acupoints tested were:
 - A. Right Liver 3
 - B. Right Triple Heater 23
 - C. Right Triple Heater 17
 - D. Governing Vessel 24.5 or
 - E. Right Stomach 36
- Validated sleep scales and questionnaires were used and recorded as baseline prior to patch wearing and then at the end of the study period.

Efficacy of patches in this study:

- Overall, 72% percent of the individuals were able to decrease their daytime sleepiness,
- 80% noted improved quality of sleep on the Leeds Sleep Evaluation Questionnaire (LESQ Test) and
- 88% had improved length of sleep on the Pittsburgh Sleep Quality Index (PSQ Test).
- Considering the safety and results obtained in this study of LifeWave Silent Nights® Patches, it is reasonable to suggest that they may well be one of the preferred potential approaches to insomnia, since 72 to 88% of the subjects experienced significant improvement in sleep.