Somneo: Device with Thermal Stimulation for Modulating Sleep Architecture and Enhancing Neuro-Cognitive Function

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Abstract. Sleep deprivation and inefficiency can have a crucial impact on performance. One potential method for ameliorating the impact of bad sleep, or eliminating it all-together, is with sleep stage-dependent sensory stimulation. The effect of superficial facial heating on sleep architecture was studied in 10 subjects. A 20% decrease in sleep onset latency ($p < 0.05$) was measured when the face was heated by 1°C. These results are support for further development of the patented Somneo, a ubiquitous feedback device for optimizing sleep architecture and duration; through the real-time assessment of sleep stage, and delivery of stage-dependent thermal, visual and/or auditory sensory stimulation.

Keywords: Sleep, Sleep Deprivation, Sensory Stimulation, Performance Optimization, Wearable Devices.

1 Introduction/Background

Sleep restriction or inefficient sleep occur frequently in a wide range of populations, and may have drastic effects on behavior, performance and overall health [1]. Efficient ways to remedy these negative effects are therefore desirable. Sensory stimulation is one potential method and is the basis for the patented, Somneo device from Advanced Brain Monitoring, Inc. (ABM). Essentially an advanced sleep mask (Fig. 1), the Somneo device stages sleep in real time from three EEG sensors on the forehead, and delivers a variety of sensory stimulations in response. The mask incorporates textile heaters for facilitation of sleep onset, blue light sources for modulation of sleep inertia (post-nap grogginess), and small speakers that deliver user-selected music or white noise to create a comfortable environment and dampen ambient disturbances. The end goal of the device is to optimize the user's sleep period by controlling sleep onset, maintenance and period length, as well as increasing post-nap performance.

Situational as well as induced changes in skin temperature are known to influence one's ability to fall and stay asleep. Spontaneous sleep onset is paralleled by a slight decrease in core body temperature; and preceding this decrease, is an increase in the difference between the distal (e.g. hands, feet, ears, etc.) and proximal (e.g. stomach,

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thigh, etc.) skin temperatures, or the distal-proximal gradient (DPG) [3-7]. The potential mechanism behind the DPG is peripheral vasodilatation which increases the vascular surface area for heat loss, which is at least thought to contribute to a decrease body temperature. Several studies have also shown that an external increase of this DPG at specific periods during a sleep cycle may help initiate sleep onset [4-5] and enhance alertness upon waking [7]. A system incorporating this functionality would therefore be a minimally obtrusive way for obtaining better, more restorative sleep.

While studies of whole-body skin temperature variation have been completed and shown the potential of a DPG in affecting sleep architecture [5], [7], controlling the temperatures of these multiple areas is cumbersome. With the goal of easily controlling sleep architecture without negatively disrupting a user, other studies have applied heat to smaller areas such as the feet only [4]. Heat application for the study reported here was restricted to the cheeks and forehead, as the face is one area (besides hands and feet) that is rich in arterioles that strongly respond to changes in the local temperature; and an area that could be most easily modulated with the Somneo. The effects of this superficial facial warming on sleep onset were investigated and the results contrasted those previously reported by ABM [2] and show a decrease in sleep onset latency with mild facial warming. This study expands our earlier analyses and analyzes the relationship between the facial temperatures, concurrent distal-proximal gradients (DPG) and sleep onset latencies.

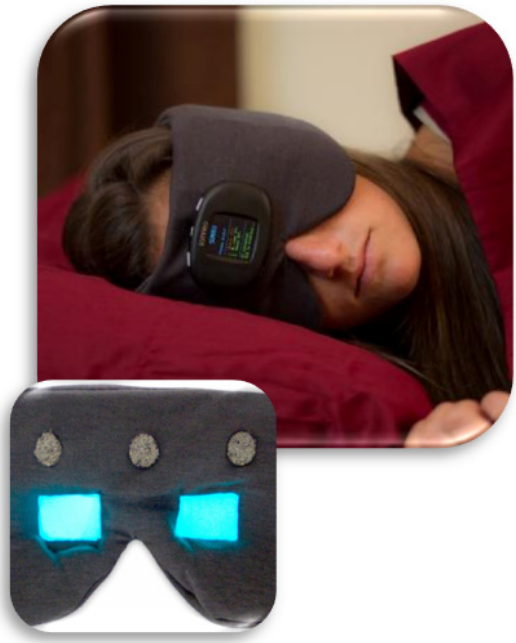

Fig. 1. Somneo device exterior (top) and interior (bottom) for automated, feedback of stage-dependent sensory stimulation for augmenting sleep efficiency and post-sleep function

2 Methods and Materials

2.1 Study Design

Ten subjects (2 females; age: 23.8±2.8 years) of good physical and psychological health participated in the study requiring two consecutive days in the sleep lab under the modified Constant Routine protocol. Each day entailed a preparation period preceding eight, 1 hour long and repeating, sleep latency test (SLT) blocks. The face was warmed during half of the SLTs; alternating each SLT block. Rectal, facial, proximal (trunk) and distal (hands and feet) skin temperature were also recorded during the SLTs to make sure only the facial temperature changed and initiated a DPG gradient. SLT records were then scored according to the AASM rules. Sleep latencies were subsequently calculated as a time difference between sleep onset (defined as 3 consecutive epochs of any stage of sleep) and lights off time.

2.2 Equipment

To deliver heat, an off-the-shelf heat mask was modified and applied to the forehead and cheeks of the subjects. The 8Ω resistive heating element was removed and rewired for remote technician control with MATLAB, and through USB 5V. Temperature was obtained from 10 temperature sensor (Texas Instruments LM35CAH transducer, -40-110oC, linear voltage, 4-30V). These temperature sensors were hardwired to a Measurement Computing USB-1208fs data acquisition unit (DAQ) and consistently monitored by the technician with a custom MATLAB GUI (Fig. 2) from an adjacent room. EEG was recorded with a wireless, wearable 9-channel headset (Advanced Brain Monitoring Inc., Carlsbad, CA). Recorded channels include C3-A2, C4-A1, Fp-Fp2, Fz-PO, Cz-PO, vertical and horizontal electrooculogram, submental electromyogram (EMG) and electrocardiogram (EKG). Each subject took 8 naps on two experimental days in an isolated napping room with sound insulation and a comfortable, twin size bed with standard bed pillows and sheets.

2.3 Screening

Initial screening criteria included a basic screening questionnaire to rule out any significant previous or existing health problems including neurological disorders, sleep problems or mental illness. Following pass of the initial screening criteria, a potential subject was scheduled for three visits; an orientation and two experimental study sessions. Potentials subjects were asked to fill-out several computerized versions of behavioral questionnaires at the orientation to further confirm their eligibility. Questionnaires required were the Pittsburg Sleep Quality Inventory (PSQI), Sleep Disorder Questionnaire (SDQ), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI) and the Bergen Insomnia Scale (BIS). Also at the orientation, potential subjects were given wrist actigraphs to wear and sleep logs to fill-out throughout the study to monitor sleep patterns.

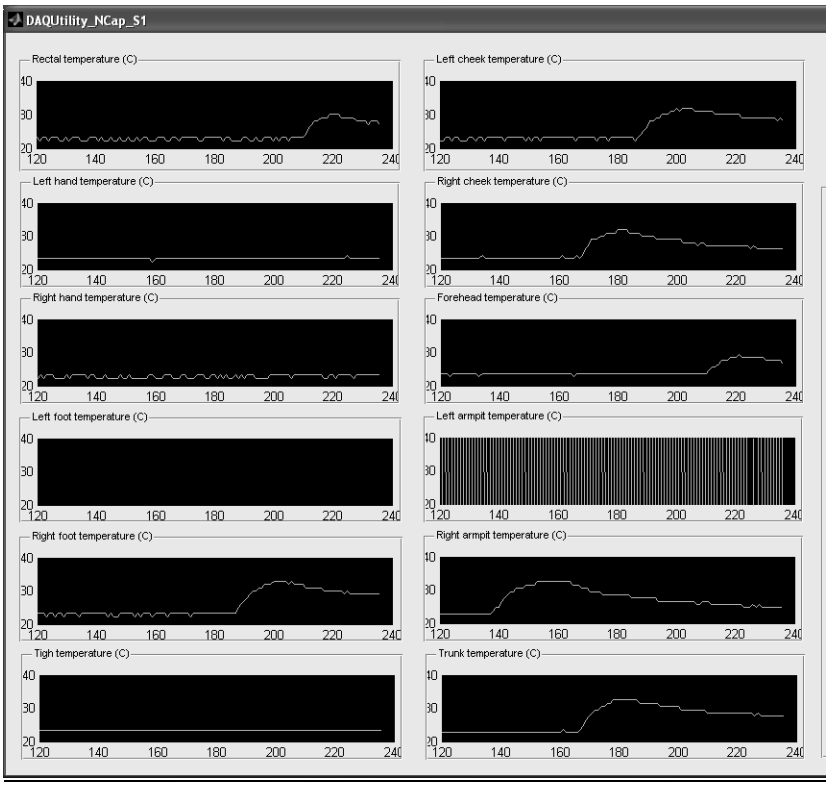

Fig. 2. A screenshot taken during a data acquisition session showing real-time temperature data obtained from each position on a subject. ABM's proprietary EEG acquisition software, B-Alert, was simultaneously running and obtaining corresponding temperature markers.

The difference between the orientation and experimental study session 1 was between 1 and 7 days and previous to each study session were in-home, overnight recordings with wrist actigraphs. The subjects were required to maintain consistent sleep schedules from the orientation to the first experimental study session where the difference between the earliest and latest times to sleep, and earliest and latest times awoken over the 1 to 7 days were no more than two hours apart and verified by sleep logs that each subject was required to keep. Subjects were also required to abstain from caffeinated beverages on the days the experimental sessions were conducted.

2.4 Experimental Sessions

Each experimental study session followed the same structure (Table 1) where heat stimuli delivery was alternated every SLT block (subjects to receive heat first SLT block, day 1: 2, day 2: 9). The heat stimulus was delivered consistently throughout each block. The 30 minutes of preparation included orienting the subject with the testing area, as well as outfitting them with the EEG headset, heat mask and temperature sensors.

Table 1. The experimental study session schedule; where heat stimulus was alternated

Time	Activity
8:00–8:30AM	Preparation
8:30-9:30AM	SLT block 1
9:30-10:30AM	SLT block 2
10:30-11:30AM	SLT block 3
11:30-12:30PM	SLT block 4
12:30-13:30PM	SLT block 5
13:30-14:30PM	SLT block 6
14:30-15:30PM	SLT block 7
15:30-16:30PM	SLT block 8

During each experimental session, subjects were outfitted with 10 temperature sensors. 1 rectal thermometer which was wrapped in a condom and that the subject entered themselves, 1 in the center of the forehead , 1 on each cheek, 1 on the neck along the carotid artery, 1 on the chest, 1 on each hand, and 1 on each foot. Each external temperature sensor was attached to the subject's skin with medical-grade first-aid cloth tape. These body temperatures were monitored throughout the sessions by a technician and from an adjacent room.

Each SLT Block consisted of 4 main parts; 20 minutes of napping, a 10-minute break, then 30 minutes of psycho-physiological testing (Fig. 3). On the break, subjects could use the restroom and/or eat the mandatory 200 calorie snack, before completing a brief post-nap questionnaire on the comfort of the heat, and finally taking 30 minutes to complete the 3-choice Vigilance Task (3CVT) of the ABM proprietary batter of psycho-physiological tests called the Attention and Memory Profiler (AMP).

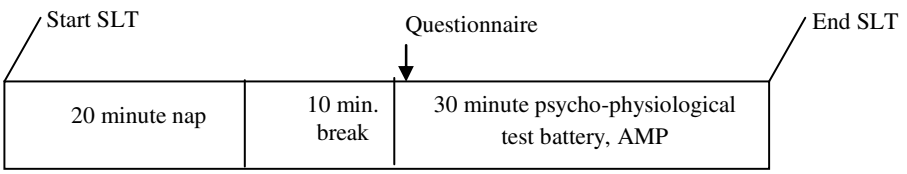

Fig. 3. SLT block components

Napping. The subjects napped in a room at the temperature of 24-25°C, lying supine in a medical-grade bed of twin size reclined completely. The bed was outfitted with home-grade sheets and pillows. The lights in the room were turned off and the room was insulated from external noises. The subject was constantly monitored through a camera mounted next to the bed, and the video and recorded EEG was transmitted in real-time to an adjacent room where the technician monitored the session. Once a subject fell asleep, they were allowed to remain asleep until 5 minutes of slow-wave-sleep (SWS) or 20 minutes had passed, whichever was soonest.

AMP Evaluation. The AMP evaluation consisted of the 20-minute 3CVT. The 3C-VT required the subjects to discriminate primary (70%; upward triangle) from two secondary geometric shapes (downward triangle and diamond) and respond as quickly as possible over a 20-minute test period. Five-minute breaks were given to the subjects after each test, and about five minutes were used to re-outfit the subject with the mask; thus the total duration of the AMP block was about half an hour.

2.5 Outcome Measures

Sleep Staging and Sleep Variables. The EEG records of the naps were scored by a board-certified sleep specialist in 30 second epochs according to the AASM standard rules [8]. Hypnograms were then used to calculate total sleep time (TST) and sleep onset latency (SOL). Sleep onset latency (SOL) was defined as time from the beginning of each part of a nap until the first occurrence of 3 or more consecutive epochs of Stage 1, or 1 epoch of any deeper stage of sleep.

Performance Measures. Reaction times and percentages of correct responses on 3CVT AMP tests were obtained, however, baseline AMP tests were not completed thus this variable is not evaluated here.

Questionnaire. Degree of sleepiness was evaluated with the Stanford Sleepiness Scale (SSS) questionnaire during each 10 minute break and during both experimental sessions.

Statistical Analyses. The effects of experimental conditions on the sleep variables was tested by a 4-way ANOVA, with subject, session (day 1 and 2), time (SLT blocks 1-8) and heat (off, on) as the factors. Only main effects were tested because of the small sample size which created numerical problems in a model with interactions. The results of the questionnaire and performance measures were analyzed only descriptively.

3 Results

4-way ANOVA with Subject, Day (first/second), Time of the day (1 to 8) and Heat (On/Off) factors revealed a significant main effect of the facial warming on sleep latencies (ON: 5.1±5.3 minutes; OFF: 7.5±6.1 minutes; $F = 8.67$, $p < 0.001$) (Fig. 4). Significant main effects also existed for Subjects, Day (likely due to adaptation) and time of the day (all $p<0.001$).

The range of facial temperatures achieved for both conditions and all sessions, was 32.5 - 40°C (heat: 32.5 – 40°C; 36.6°C ± 1.2; no heat: 33 – 37.9°C, 35.5 ± 0.9). Despite similar temperature ranges and means, the distal-proximal; cheek-neck gradient at sleep onset in those cases without heat application was indeed much lower than when heat was applied (heat: 1.3°C ± 1.9, n = 7 subjects, 53 SLT blocks; no heat: 0.1°C ± 1.1, n = 7 subjects, 49 SLT blocks).

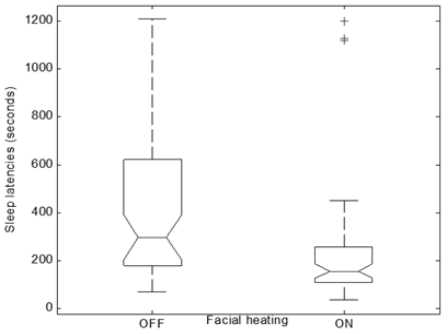

Fig. 4. The results of initial ABM studies show a 2 minute, ~20%, acceleration in sleep onset with mild facial warming by 1°C

When comparing the averages of heat versus no heat blocks for each subject, by day, facial warming accelerated SOL in 16 sessions, didn't change it in 2 sessions and increased SOL in 2 (Table 2). The DPGs at sleep onset for the subjects and sessions whose SOL didn't change, or increased, with facial warming were still higher in the heat section than in the non, however (heat: 1.5°C ± 1.6; no heat: 0.1°C ± 0.7).

Table 2. Average sleep onset latencies, averaged for entire days by subject

	Average sleep onset latencies (SOL), blocks 1-8 (seconds)			
	day 1		day 2	
	Heat ON	Heat OFF	Heat ON	Heat OFF
7101	855	930	818	818
7102	855	923	904	950
7103	428	495	368	473
7104	255	255	233	668
7106	518	600	540	548
7107	830	458	553	1113
7108	135	188	293	405
7109	467	240	488	630
7110	593	660	798	1053
7115	203	218	233	420

Comparison of DPG slope (from the point the lights were turned out to the point that the subject fell asleep) to SOL revealed no relationship between speed of DPG increase and SOL (R2 = 0.1, n= 8 subjects, 104 SLT blocks).

4 Discussion

The results of the study indicate that mild facial warming by only 1°C, or 1.8°F, can accelerate sleep onset. Based on the study design where only the face was warmed

and the room temperature was maintained, this implies a DPG in the heat group and such was verified. This study design did not include enough subjects and variation to determine a truly optimizing heat treatment paradigm for the Somneo device, however. More details on the effects of a temperature gradient on SOL, including maximum temperature and speed of increase, are desirable for designing a schema for true sleep optimization with the Somneo. More control over the heat and variability of the temperature is necessary in a larger group of subjects. Though an optimization paradigm could not be determined from this study, a benefiting paradigm was; the use of 5V, 8Ω facial heating to decrease the facial temperature by 1°C and decrease sleep onset latency by approximately 20%.

The ABM Somneo mask design (Fig. 5) includes 4 heaters that cover the forehead and each cheek but are behind a layer of polyester fabric with high thermal conductivity and in front of ½" thick viscoelastic polyurethane foam of low thermal conductivity for maximizing heat transfer toward the face. These heaters are currently resistive, kapton-based heaters, though a earlier design iteration included completely textile heating elements. Problems with this type, especially the difficulty with creating a robust connection to the hardware device, outweighed the benefits a completely soft mask offers. Other components of the Somneo include blue lights, audio speakers and three EEG sensors across the forehead. Blue LED fiber optic light panels are included behind the eye areas for transpalpebral delivery of blue light during slow-wave sleep (SWS) to decrease sleep inertia after waking.[1]

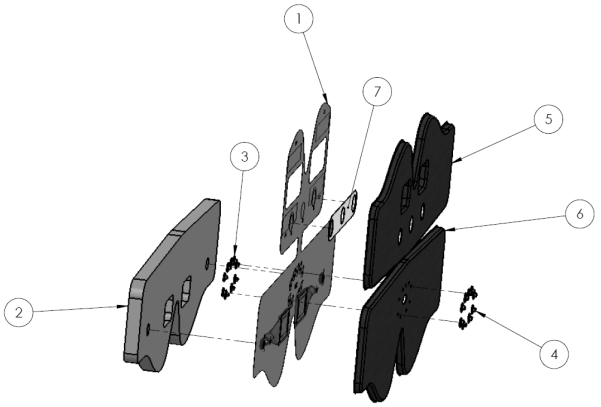

Fig. 5. The Somneo mask design includes a flex interior (1), insulating foam (2), snaps (3 and 4) for connecting the hardware device, and a fabric exterior (5). All the sensory stimulating components are contained on the single flex part; four heating panels, three EEG sensors (1 top), two light panels and low-profile speakers (1 bottom).

With two frontopolar channels (Fp1 and Fp2), advanced sleep staging algorithms are employed and enable real-time detection of a user's sleep state (Fig. 6). This

[1] ABM completed an additional research study (n=30) to determine the effects of SWS blue light stimulation on sleep inertia and a trend toward an effect was determined.

automated and sleep-specific waveform detection discriminates between 5 sleep stages (i.e., wake; REM; and NREM 1, 2 and 3) with an accuracy of 82% which is comparable to expert scoring.

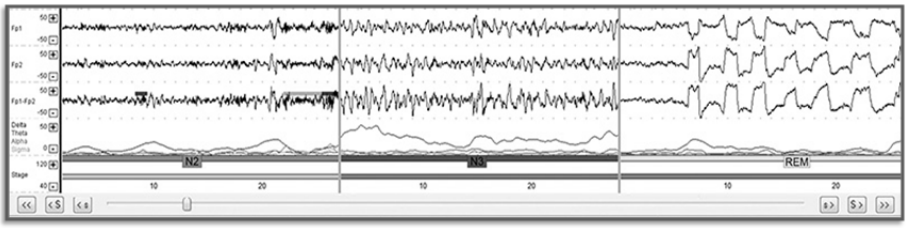

Fig. 6. Visualization of real-time monitoring of sleep quality and automated sleep staging

In conclusion, a heat stimulation paradigm has been determined that will benefit Somneo user's by contributing to a more restorative sleep period, though more research is required to determine an optimizing paradigm.

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