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Wearable Sleep Technology

WHAT'S INSIDE

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The use of wearable sleep technology (i.e., devices worn on the body to measure aspects of sleep such as sleep/wake cycles) is increasing among consumers. Benefits of wearable sleep technology are that it collects information about a person's sleep in their natural environment and can record information over an extended period of time, compared to having a polysomnographic study in which the "first night effect" and having incomplete data in a sleep diary can negatively impact results. However, little guidance exists regarding how to use these devices effectively in clinical and nonclinical settings (e.g., sleep research, consumer market). In addition, scientists have concerns regarding the devices' validity, accuracy and reliability in measuring various sleep parameters (e.g., sleep stages, sleep/wake cycles).

In 1978, Kripke and colleagues[1] described an accelerometer-based wrist actigraph that measured sleep/wake cycles based on changes in a person's general activity level between sleep (i.e., less active) and wake (i.e., more active). In their study, wrist actigraphy, electroencephalography (EEG), electrooculography (EOG) and electromyography (EMG) data were obtained simultaneously. They compared the total sleep time as measured with wrist actigraphy and manual scoring (based on EEG-EOG-EMG recordings). The correlation between wrist actigraphy and EEG-EOG-EMG with regard to minutes of sleep, total sleep period and minutes of wake during a sleep period was high at 98%, 95% and 85%, respectively. Based on these findings, Kripke suggested that continuous wrist activity recordings could provide very accurate estimates of sleep time.

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Since then, wearable sleep-trackers have been developed in many forms: wristband, armband, smartwatch, headband, finger ring and sensor clip. Some popular manufacturers of consumer sleep technology (CST) devices and their products are as follows:

- Fitbit, Inc. (San Francisco, CA): Charge 3-5, Charge HR, Versa and Versa 2-3
- ActiGraph Corporation (Pensacola, FL): GT9X Link and wGT3X
- Ōura Health Ltd. (Oulu, Finland): Smart Ring
- Apple, Inc. (Cupertino, CA): Apple Watch

Many CST devices purport to track a consumer's sleep, provide sleep-related metrics (e.g., sleep architecture, sleep stages), improve sleep quality or screen for sleep disorders (e.g., obstructive sleep apnea [OSA], periodic leg movements). However, the extent that these claims are true when compared to objective data obtained with polysomnography (PSG) has shown conflicting results with regard to accuracy and reliability.

For example, de Zambotti and colleagues[2,3] evaluated the accuracy of a wearable sleep device, the Fitbit Charge HR wristband tracker, in measuring heart rate variability during sleep when compared to electrocardiography (ECG) data. In this device, heart rate is determined by an optical sensor (i.e., a photoplethysmograph [PPG]), which flashes a strobing green light onto the skin at hundreds of times per second. Capillaries in the skin reflect some of the light back to light-sensitive photodiodes. The amount of reflected light varies with blood volume changes in capillaries with each heartbeat. This variation is used to determine the heart rate.

de Zambotti found an average discrepancy of <1 beat per minute in the heart rate between the ECG and PPG data. Thus, the device showed good agreement with ECG in measuring HR during sleep. However, their comparison was based on minute-by-minute averages of the heart rate throughout the night rather than beat-to-beat data because beat-to-beat monitoring is unavailable in consumer wearables. Thus, the beat-to-beat accuracy level could not be determined.

Some CST devices use heart rate variability to determine sleep stages — more accurately, to determine whether someone is in "light sleep" (i.e., stages 1 and 2), "deep sleep" (i.e., slow wave sleep [SWS]) or rapid eye movement (REM) sleep.[4,5] Changes in EEG activity (i.e., central nervous system activity) are strongly coupled to changes in the autonomic nervous system, which is involved in regulating myocardial function.[6-8] For example, non-REM sleep stages are associated with a stable heart rate, whereas REM sleep is associated with an increased and more variable heart rate. Heart rate variability (i.e., beat-to-beat variations in the heart rate) is less pronounced between SWS and the lighter stages of sleep (i.e., stages 1 and 2) than it is between REM and non-REM sleep.

PPG technology has shown moderate to excellent results in research regarding sleep stages. For example, Finnish researchers Kuula and Pesonen[5] examined the validity of the Firstbeat sleep analysis method versus PSG assessment of sleep stages. The Firstbeat sleep analysis method uses an algorithm (i.e., a specialized mathematical formula) to evaluate the physiological state of the person as "wake" or "sleep," based on heart rate variability and accelerometry data. It then rates sleep as "light sleep," "deep sleep" or REM sleep. The algorithm incorporates heart rate variability, respiration rate (based on heart rate variability), movement and time of day data to determine sleep, wake and sleep stages. In their study, healthy volunteers wore a heart rate monitor (Bodyguard 2 [Firstbeat; Jyväskylä, Finland]) and an actigraph device (Geneactiv; Activinsights, Ltd., Cambridgeshire, UK).

They found that for wake, the Firstbeat method had an accuracy of 93% with PSG data and accurately detected when a person was not awake 77% of the time and when a person was awake 95% of the time. For light sleep, Firstbeat had an accuracy of 69% and accurately detected when a person was not in light sleep 69% of the time and when a person was in light sleep 67% of the time. For SWS, Firstbeat had an accuracy of 87% and accurately

detected when a person was not in SWS 91% of the time and when a person was in SWS 72% of the time. For REM sleep, Firstbeat had an accuracy of 84% and accurately detected when a person was not in REM sleep 92% of the time and when a person was in REM sleep 60% of the time. However, Firstbeat underestimated REM sleep (by a mean of 18 minutes) and overestimated wake (by a mean of 14 minutes). Despite this discovery, they believe their findings sufficiently validated that heart rate variability monitoring combined with accelerometry could be used to distinguish sleep from wake and determine sleep stages.

Most CSTs are sold as lifestyle or entertainment devices rather than as medical devices or medical applications (apps). Therefore, they do not have United States Food and Drug Administration (FDA) oversight. With this in mind, the American Academy of Sleep Medicine (AASM) in 2018 stated:

"It is the position of the AASM that CST must be FDA cleared and rigorously tested against current gold standards if it is intended to render a diagnosis and/or treatment. Given the unknown potential of CST to measure sleep or assess for sleep disorders, these tools are not substitutes for medical evaluation. However, CSTs may be utilized to enhance the patient-clinician interaction when presented in the context of an appropriate clinical evaluation."[9]

Some research regarding how to appropriately use CST data in sleep settings has been reported. de Weerd and colleagues[10] described their experience in combining CST data with PSG data to successfully treat three patients. Patient 1 was a three-year-old boy who had difficulty going to sleep at night. Actigraphy data collected over a period of eight days revealed he had somewhat regular bedtimes and active periods. He was diagnosed with insomnia and limit-setting disorder and was successfully treated with cognitive and behavioral therapy (in particular limit setting by the parents). Patient 2 was a 12-year-girl who had insomnia and daytime tiredness. Actigraphy data (eight days) revealed a prolonged sleep time (approximately 12 hours) and regular naps after lunch time. PSG revealed frequent spontaneous arousals and short awakenings. She was diagnosed with poor sleep hygiene. Cognitive and behavioral therapy reduced her sleep time to 10 hours. Patient 3 was a 14-year-old boy who was unable to go to sleep before 2 a.m. and had difficulty in getting out of bed (at 11 a.m.). Actigraphy data (eight days) revealed delayed sleep phase syndrome. He was successfully treated with cognitive, behavioral and bright light therapy to advance his sleep/wake cycles.

Patients who come to a sleep center may present sleep professionals with data from their CST device. To give appropriate feedback, sleep professionals need to be aware of the pros and cons of these devices. Some benefits of using these devices are that they improve patients' awareness of sleep and can enhance patients' willingness to take an active role in their sleep health. They can improve patient–physician interactions and are relatively inexpensive, easy to use and comfortable to wear. Additionally, they can alert a patient to sleep problems and can collect data over a long period. Some drawbacks of these devices are raw data collection (e.g., epoch length) and a lack of standardization of the algorithms used, which can make comparing information derived from the devices difficult. The devices can give inaccurate data and they are not truly a medical device (i.e., their use is considered "entertainment") as they do not have FDA approval. Lastly, they can have unintended clinical consequences (e.g., a patient may worry if the device indicates a sleep problem or a person may not seek help if the device indicates no sleep problem).

Although CST devices have not been validated in clinical studies, they can be useful in gathering information about a patient's sleep that is not possible with PSG. And they can be useful in gathering sleep/wake information of patients (e.g., autistic patients, patients with dementia) who would have difficulty in undergoing a PSG study. For now, researchers continue to evaluate CST devices with regard to their accuracy and reliability. With greater information, guidelines could potentially be determined for how to use these devices clinically and in sleep research. Wearable sleep technology could contribute greatly to advancing the understanding of sleep.

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