Universidad de Granada

Programa de Doctorado en Tecnologías de la Información y la Comunicación

# Desarrollo de una plataforma de seguridad preventiva (HW/SW) para valorar la aptitud psicofísica del operador en tiempo real e intentar reducir la accidentalidad


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Doctoral Program in Information and Communication Technologies

# Development of a preventive safety platform (HW/SW) for the online assessment of the operator psychophysical state with the aim to reduce the accident rate

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# Resumen

En entornos complejos y dinámicos, el estado psicofísico del operador puede ser la causa de graves errores que conllevan la ocurrencia de incidentes y accidentes. Dadas las dificultades para abordar individualmente el error humano como factor de siniestralidad, la mayoría de las acciones para evitar estos accidentes no van más allá de la gestión de turnos, la formación o las campañas de concienciación. En este tipo de entornos, las innovaciones tecnológicas aplicadas a la seguridad del operador individual podrían revolucionar el concepto de cultura de seguridad. El objetivo de esta tesis doctoral ha sido el desarrollo y validación de un prototipo de sistema vestible y de bajo coste para la detección del estado psicofísico del operador en tiempo real.

En primer lugar, se ha llevado a cabo un análisis de los dispositivos comerciales para la monitorización del estado psicofísico del operador. Como resultado de este análisis, se han puesto en evidencia las limitaciones relacionadas con la falta de validación científica y el elevado coste asociados a los dispositivos. Considerando estos dos puntos, se decidió diseñar y validar científicamente un dispositivo vestible y de bajo coste que permitiera la detección del estado psicofísico del operador en situaciones tanto de infracarga como de sobrecarga mental, en entornos reales.

El primer estudio que se presenta consiste en la validación del registro electroencefalográfico (EEG) obtenido con un dispositivo basado en un solo electrodo seco construido en torno al módulo TGAM1 (ThinkGear ASIC module). Una vez comprobada la calidad de la señal registrada (e.g., relación señal/ruido), en el segundo estudio se decidió corroborar la validez de la frecuencia espectral del registro EEG para la detección de fatiga (situación de infracarga mental). En este estudio, se utilizó como medida de referencia (gold standard) la velocidad de los movimientos sacádicos (i.e., movimientos oculares) que se registraron de forma síncrona durante dos horas de conducción simulada. Por último, en el tercer estudio, se realizó una validación de las frecuencias espectrales del registro EEG como medida para monitorizar la sobrecarga mental experimentada en cirujanos durante operaciones laparoscópicas en modelos porcinos vivos.

A partir de los resultados obtenidos, se decidió desarrollar un prototipo de sistema vestible y de bajo coste basado en el módulo TGAM1 para el reg-

istro EEG y sensores infrarrojos para el registro de movimientos oculares. El dispositivo se ha montado sobre un soporte de plástico transparente (gafas de seguridad) y ha sido validado satisfactoriamente mediante diferentes pruebas de laboratorio.

De los estudios de investigación y de prototipado se han obtenido valiosos resultados que demuestran la utilidad de la tecnología desarrollada y que han dado lugar a varias publicaciones en revistas internacionales con factor de impacto. Los resultados de esta tesis doctoral pueden tener consecuencias relevantes en la comunidad investigadora y, potencialmente, en varias áreas de la sociedad tales como la seguridad vial y la seguridad del paciente.

# Abstract

In complex and dynamic systems, the inappropriate psychophysical state of the operator can cause serious errors leading to incidents and accidents. Given the difficulties of dealing individually with the human error as an accidental factor, most risk management processes are based on shifting programs, training or awareness-raising campaigns. In this vein, technological innovations applied to individual operator's safety could revolutionize the concept of safety culture. The objective of this doctoral thesis was to develop and to validate a prototype of a low-cost wearable system for the online detection of the operator's psychophysical state.

Firstly, we carried out a deep analysis of existing commercial devices for monitoring the operator's psychophysical state. Specific limitations related to the lack of scientific validation and the high costs of the devices were identified. Thus, we decided to design and to validate a low-cost wearable device that allows the detection of the psychophysical state of the operator in situations of both mental underload and overload in real environments.

The first study was aimed to validate the electroencephalographic recording (EEG) obtained with a single dry electrode device built around the TGAM1 module (ThinkGear ASIC module). The second study was aimed to corroborate the validity of the spectral information of EEG signal to detect driver's fatigue (mental underload situations). We simultaneously recorded driver's eye movements, and used the saccadic velocity as the gold standard for mental fatigue detection. In this study, we use a driving simulator. Finally, the third study was aimed to validate the spectral information of the EEG signal as a mental overload index while expert surgeons were performing laparoscopic surgeries in live porcine models.

Based on the results obtained, we have developed a prototype of a wearable low-cost system to detect the psychophysical state of the operator in real time based on the TGAM1 module to record EEG and infrared sensors to track eye movements. The device, mounted on safety glasses, has been successfully validated through different laboratory tests.

Valuable results have been obtained from the research and prototyping studies carried out. These have been published in international journals indexed by Journal Citation Reports. The results of this doctoral thesis might have great impact among researchers working in risk managements

as well as in several areas of society, such as road safety and patient safety.

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# Acronyms

| | |
|---|---|
| **ADC** | Analog to Digital Converter |
| **BCI** | Brain Computer Interface |
| **COTS** | Commercial Off-The-Shelf |
| **dB** | Decibel |
| **DGT** | Dirección General de Tráfico |
| **ECG** | Electrocardiogram |
| **EEG** | Electroencephalography |
| **GSR** | Galvanic Skin Resistance |
| **GUI** | Graphical User Interface |
| **HRV** | Heart Rate Variability |
| **HW** | Hardware |
| **Hz** | Hertz |
| **JCR** | Journal Citation Reports |
| **KBA** | Kraftfahrt-Bundesamt |
| **LED** | Light-Emitting Diode |
| **LESS** | Laparo-Endoscopic Single-Site |
| **MPS** | Multiport Laparoscopic Surgery |
| **NHTSA** | National Highway Traffic Safety Administration |
| **NTSB** | National Transportation Safety Board |
| **PC** | Personal Computer |
| **PCB** | Printed Circuit Board |
| **PLA** | Polylactic Acid |
| **PnP** | Plug-and-Play |
| **SD** | Standard Deviation |
| **SE** | Standard Error |
| **SNR** | Signal to Noise Ratio |
| **SoC** | System on Chip |
| **SW** | Software |
| **SWM** | Steering Wheel Movements |
| **TOD** | Time On Driving |
| **UDP** | User Datagram Protocol |
| **UML** | Unified Model Language |

# Chapter 1

# Introduction

## 1.1 Motivación (en castellano)

Ciertas actividades requieren para su desarrollo que se mantenga un alto nivel de atención durante un período prolongado de tiempo. Algunas son actividades cotidianas que realizamos en nuestro día a día (ej. conducir un coche o una moto), mientras que otras son parte fundamental del trabajo de algunas profesiones (ej. realizar operaciones quirúrgicas, pilotar un avión o helicóptero, etc). El sistema cognitivo tiene una capacidad limitada para procesar información y necesita distribuir los recursos de manera efectiva en cada momento (para una revisión completa ver [1]). Cualquier factor que pueda alterar la percepción del entorno o influir negativamente en la capacidad de atención durante el desarrollo de la tarea puede suponer un grave riesgo para el operador (persona que está realizando la tarea), así como, para terceras personas que también pueden verse afectadas (ej. acompañantes en el vehículo o viandantes; el paciente que está siendo operado por un cirujano, etc). Así, dado que la realización exitosa de una tarea tan compleja las mencionadas anteriormente tiene un "coste" en el procesamiento cognitivo, ya que requiere de, entre otros, importantes recursos perceptuales, motores y atencionales, tanto la sobrecarga mental (ej. la atención simultánea a la conducción y al móvil) como la infracarga mental (ej. fatiga debido a la monotonía de la tarea, falta de descanso o hipnosis de la autopista) pueden producir deficiencias en la ejecución de la misma.

Una de las causas más común de la infracarga y con un gran impacto en nuestra capacidad de atención es la fatiga [2]. De hecho, hace algo más de una década Dawson & Reid publicaron los resultados de una investigación de referencia *"Fatigue, alcohol and performance impairment"* [3] en la que se estimaba que la disminución en el rendimiento después de 17 horas de alerta era equivalente a la que se observa con una concentración de alcohol en sangre de 0.05% y que, tras 24 horas, el deterioro era equivalente a una concentración de alcohol en sangre de 0.10%.

Si nos centramos en vehículos de carretera, la fatiga en conductores es un factor que está presente en entre el 3 y el 33% de todos los accidentes que se producen [4, 5, 6, 7]. Este porcentaje varía mucho entre países. Así, en Estados Unidos nos encontramos con un 3% [6, 8], en España con un 12% [7], en Finlandia con un 25% [7] y, por último, en Australia con un 33% [9] de accidentes debidos a la fatiga (Figura 1.1). En otros ámbitos no existe tanta bibliografía que aporte cifras oficiales sobre accidentes debidos a la fatiga, no obstante, podemos encontrar algunos estudios en algunos casos concretos. La Junta Nacional de Seguridad en el Transporte de Estados Unidos (US National Transportation Safety Board, NTSB por sus siglas en inglés) mostró que el porcentaje de accidentes relacionados con fatiga en la aviación entre los años 2001 y 2017 fue del 20% [10]. Un ejemplo real del riesgo que supone la presencia de fatiga en pilotos es el accidente que ocurrió el 14 de agosto de 2013; el vuelo 1354 de United Parcel Service (UPS) se estrelló en la pista 18 del Aeropuerto Internacional de Birmingham-Shuttlesworth (Alabama, EEUU). El capitán y el primer oficial murieron, y el avión quedo totalmente destruido por las fuerzas del impacto y el fuego posterior al accidente. La NTSB determinó que la causa de este accidente fue la vigilancia no correcta de los instrumentos de altitud durante una aproximación de no precisión a la pista de aterrizaje. Todo esto condujo a un descenso involuntario por debajo de la altitud mínima de aproximación impactando el avión con tierra antes de llegar a la pista. Las deficiencias en el desempeño del capitán contribuyeron al accidente, probablemente debido a factores que incluían la distracción, confusión y fatiga. También contribuyó la fatiga del primer oficial debido a la pérdida aguda de sueño como resultado de su ineficaz manejo del tiempo fuera de servicio [11].

De acuerdo con la NTSB, solo entre 2016 y 2017, siete de los accidentes marítimos investigados por esta entidad estaban directamente relacionados con la fatiga [12]. La catástrofe causada por el buque petrolero Exxon Valdez es un ejemplo de las dramáticas consecuencias que pueden tener este tipo de accidentes. Este accidente es el desastre medioambiental más importante que ha sufrido Alaska (EEUU) y uno de los más importantes del mundo. El 24 de marzo de 1989 el buque vertió más de 40,9 millones de toneladas de petróleo en una extensión aproximada de unos 2000 km a lo largo de las costas de Alaska. Se descubrió que el miembro de la tripulación que se encontraba al mando en el momento del accidente no había descansado el tiempo reglamentario antes de comenzar el nuevo turno y que fue, de hecho, este estado de fatiga lo que le llevó a no percibir a tiempo los avisos que habrían podido evitar la tragedia. En repetidas ocasiones, hizo caso omiso a las advertencias, cuando finalmente reaccionó era demasiado tarde para cambiar el rumbo del buque [13]. Si nos movemos al ámbito ferroviario, en la

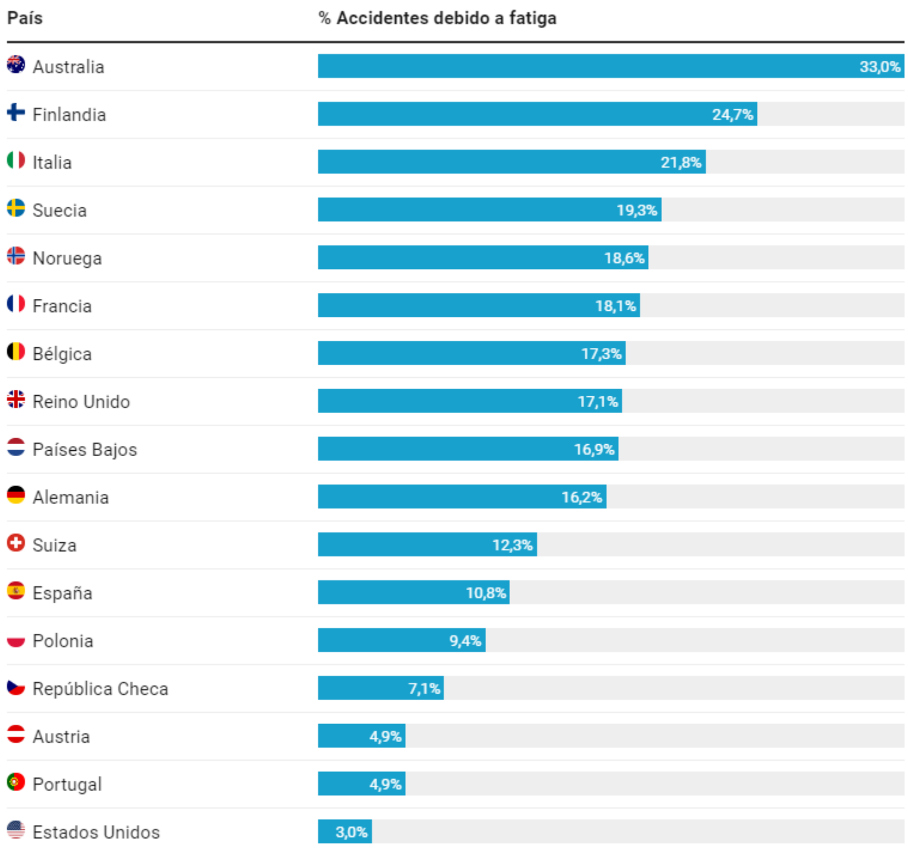


Figure 1.1: Porcentaje de accidentes en carretera debido a la fatiga. Fuente: [4, 5, 6, 7].

nota técnica 2019-2020 de la NTSB [12] se indica que en siete de los grandes accidentes ferroviarios investigados por este organismo en los últimos años se ha identificado la fatiga como una causa probable de los accidentes. Otro ejemplo de accidente es el ocurrido el 29 de septiembre de 2016, donde un tren de New Jersey Transit (NJT) chocó contra una pared de la estación de tren de Hoboken (Nueva Jersey, EEUU). Una persona que esperaba en el andén murió; 110 pasajeros y miembros de la tripulación del tren resultaron heridos. La NTSB determinó que la causa del accidente fue el fallo del ingeniero del tren de NJT al detener el tren después de entrar en la terminal de Hoboken debido a la fatiga acumulada como resultado de su apnea del sueño no diagnosticada [14].

Los datos mostrados anteriormente, son solo una muestra de los riesgos que puede entrañar realizar una tarea con infra/sobrecarga mental. En la Tabla 1.1 se muestra un resumen clasificando diferentes profesiones en tres niveles de riesgo, en función del daño que podría ocasionarse a sí mismo y a los demás (ej. un grupo pequeño de personas vs. una población entera) uno o varios operadores.

Table 1.1: Clasificación de riesgos según las profesiones. En la tabla se muestran un conjunto de profesiones divididas en tres categorías diferentes, en función de los riesgos que implica cada una. La categoría 1 se corresponde con un riesgo bajo y en ella se encuentran las profesiones que normalmente no conllevan un riesgo para el operador que la desarrolla o los que trabajan alrededor. La categoría 2 se corresponde con aquellas profesiones en las que los operadores pueden poner en riesgo su salud y la de los demás. Por último la categoría 3 muestra aquellas profesiones con un riesgo alto, en las que un problema con un operador puede suponer un riesgo muy significativo tanto para su seguridad como para la de los demás. La fuente de los datos utilizados para la confección de la tabla es [15].

| **Profesión** | **Riesgo bajo** | **Riesgo medio** | **Riesgo alto** |
|---|---|---|---|
| Albañil | | × | × |
| Carpintero | | × | |
| Cirujano | | × | × |
| Conductor | | × | × |
| Cristalero | | × | |
| Electricista | | × | |
| Fabricante de acero | | × | × |
| Fontanero | | × | × |
| Marinero | | × | × |
| Oficinista | × | | |
| Operador de autopistas | | × | × |
| Operador de demoliciones | | × | × |
| Operador de grúas | | × | × |
| Operador de maquinaria | | × | × |
| Piloto de avión | | × | × |
| Pintor | | × | |
| Soldador | | × | × |
| Supervisor | × | × | × |
| Yesero | | × | |

De los elevados costes de accidentes como los mencionados, la importancia de estudiar este tipo de comportamientos para aprender a detectarlos a tiempo. De hecho, grandes entidades como, por ejemplo, la Dirección General de Tráfico (DGT); su equivalente en Alemania, Kraftfahrt-Bundesamt (KBA), o la National Highway Traffic Safety Administration (NHTSA) están centrando sus esfuerzos en realizar estudios relacionados con la infra/sobrecarga y sus consecuencias [6, 16, 17]. Desarrollar dispositivos que sean capaces de monitorizar y detectar el estado psicofísico del operador en tiempo real ayudaría a aumentar su seguridad, y podría contribuir a reducir la accidentalidad.

Históricamente, la investigación sobre la infra/sobrecarga mental ha estado dominada por estudios de laboratorio, por lo invasivo y voluminoso de los equipos de medición [18]. Dos de las medidas más fiables para conocer el desempeño del operador son el registro de la actividad electroencefalográfíca (EEG) y la evaluación de los movimientos oculares [19, 20, 21]. Parte de la idoneidad de estas medidas se debe a que ofrecen la posibilidad de estudiar el funcionamiento del cerebro humano de una forma "no invasiva". Sin embargo, estos marcadores psicofisiológicos no han conseguido hacerse un hueco en el día a día de los operadores. La falta de un equipamiento poco intrusivo y suficientemente pequeño y ligero hacía muy difícil, sino imposible, realizar mediciones de estos marcadores en entornos reales [22, 23] (Figura 1.2A). Gracias a la miniaturización de los sistemas y a los nuevos enfoques electrónicos (ej. plataformas de hardware abierto), actualmente existen soluciones móviles y portátiles para medir bioseñales. De hecho, es clara, dentro del mundo de la tecnología de la información sanitaria, la tendencia de creciente popularidad de los sistemas vestibles, sistemas que hacen posible el control y gestión de la salud en tiempo real. Según los análisis de la consultora tecnológica Gartner, en 2018 se vendieron un total de 178,91 millones de sistemas vestibles [24], y está previsto que para 2021 se vendan más de 184 millones según la consultora CCS Insight (Figura 1.2B) [25]. Se prevé que para 2022 el mercado mundial relacionado con este tipo de dispositivos tenga un valor de 84.000 millones de dólares [26]. En la actualidad, existe una gran variedad de dispositivos vestibles que permiten medir una amplia gama de bioseñales, incluidos electroencefalografía y eyetracking, muy cómodos y ligeros que no interfieren con el normal desarrollo por parte del operador de sus actividades. En la Figura 1.2A se pueden observar ejemplos de la evolución de algunos dispositivos que permiten registrar este tipo de señales. Podemos ver como los dispositivos disponibles actualmente poseen un diseño que permite el registro de la señal en entornos reales sin interferir con la tarea que realiza el operador. A pesar de que la aplicación de estos sistemas a la medición de la infra/sobrecarga mental en entorno real se encuentra poco investigada a día de hoy, los datos presentan elevadas expectativas de futuro [27].

## 1.2 Objetivos (en castellano)

Entre los sistemas de seguridad preventiva, los detectores del estado psicofísico son muy relevantes para la mejora de la seguridad de los sistemas. Para obtener un sistema robusto, capaz de detectar situaciones de distracción en el puesto de trabajo (por infracarga: fatiga o sobrecarga: hablar

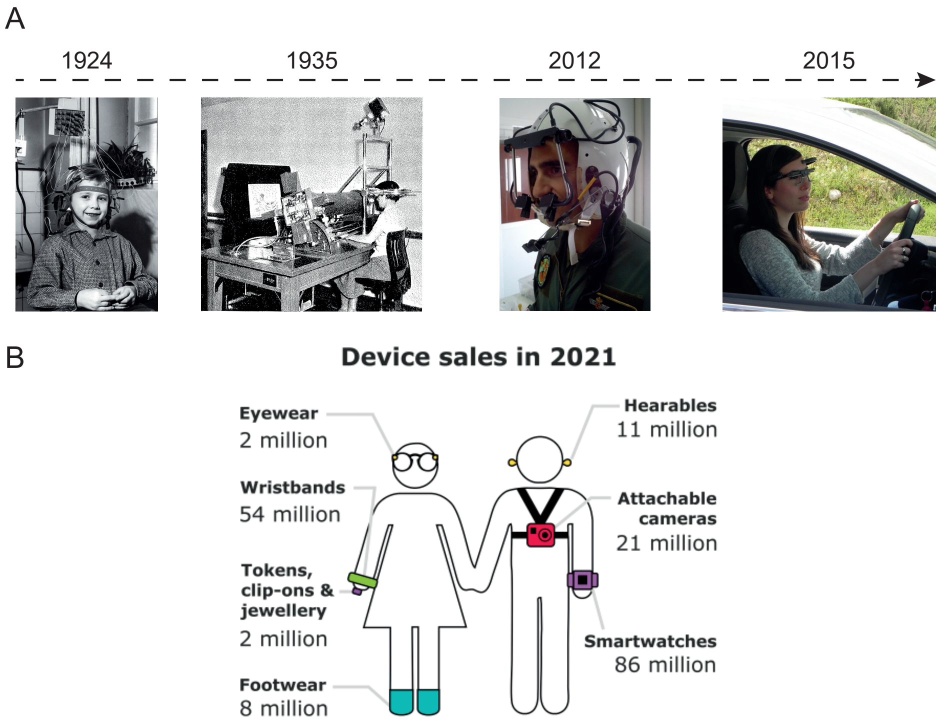


Figure 1.2: Evolución de los dispositivos a lo largo del tiempo y previsión de ventas globales de dispositivos portátiles para 2021. **A)** Cronología que muestra la evolución de los dispositivos para medir la actividad cerebral y los movimientos oculares. Desde los estudios de laboratorio debido a la naturaleza invasiva y voluminosa de los dispositivos (1924-1935) [28, 29], hasta los estudios que utilizan dispositivos de bajo coste y vestibles [30] que permiten realizar experimentos fuera del laboratorio (2015). **B)** Previsión de ventas de dispositivos vestibles para 2021 estimada por CCS Insight Consulting [25]. Imagen adaptada de [25].

por teléfono), se han de integrar informaciones procedentes de todo el sistema entorno-operador. Lo que se propone en esta tesis es dar el primer paso para el desarrollo de una plataforma (software/ hardware) capaz de monitorizar de forma continuada índices neuroergonómicos del estado psicofísico para el operador, previamente validados por el Equipo de Investigación. Los objetivos que se proponen en esta tesis son:

- Validar dispositivos de bajo coste disponibles comercialmente (COTS Commercial Off-The-Shelf) para la monitorización del estado psicofísico del operador, en sucesivas pruebas en entorno real y/o laboratorio, apoyadas por grupos focales de expertos y usuarios.

- Crear un prototipo de sistema no invasivo de bajo coste (500€ de material frente a los >5000€ que cuestan equipos clínicos convencionales) basado en estos dispositivos comerciales en torno a una plataforma computacional para la monitorización del estado psicofísico del operador. Una vez integrada de forma sincronizada la información de las modalidades consideradas se llevará a cabo su transmisión a un dispositivo host externo, específicamente un móvil, tableta o PC, mediante distintas opciones de comunicación (USB, Bluetooth LE y/o WiFi).

## 1.3 Fields of study

The work period of this thesis has covered different fields of study, resulting in a multidisciplinary research, including two fields:

- Information and communication technologies. Design and development of hardware and software systems; signal acquisition and data processing.

- Ergonomics and human factor. Physiological processes associated with brain activity and eye movements. Study of fatigue and mental workload in humans.

This research has been mainly carried out in two research groups of the University of Granada: Brain Computer Interface Lab (CITIC-UGR) and Neuroergonomics & Operator Performance Lab (CIMCYC-UGR). International research has also been carried out in Faculty of Psychology of Taras Shevchenko National University of Kyiv (Ukraine), University of Padova (Italy) and Mid Sweden University in Östersund (Sweden).

## 1.4 Contributions

Three research articles (JCR) have been published during the development of the thesis and they are part of the "group of publications" that form the thesis. In two of them, the PhD candidate is the first author:

- H. Rieiro, C. Díaz-Piedra, **J.M. Morales**, A. Catena, S. Romero, J. Roca-González, L. J. Fuentes & L.L. Di Stasi (2019). Validation of electroencephalographic recordings obtained with a consumer-grade, single dry electrode, low-cost device: A comparative study. *Sensors*. 19(12), 2808. Appendix A.

- **J.M. Morales**, C. Diaz-Piedra, H. Rieiro, J. Roca-Gonzalez, S. Romero, A. Catena, L.J. Fuentes & L.L. Di Stasi (2017). Monitoring driver fatigue using a single-channel electroencephalographic device: A validation study by gaze-based, driving performance, and subjective data. *Accident Analysis & Prevention.* 109, 62-69. Appendix Appendix B.

- **J.M. Morales**, J.F. Ruiz-Rabelo, C. Diaz-Piedra & L.L. Di Stasi (2019). Detecting mental workload in surgical teams using a wearable single-channel electroencephalographic device. *Journal of Surgical Education.* 76(4), 1107-1115. Appendix C.

## 1.5 Thesis organization

The rest of this document is organized as follows. **Chapter 2** provides a brief state-of-the-art about commercial devices and applications to assess the psychophysical state of the operators. **Chapter 3** gives an overview of the main methods used to evaluate the psychophysical state of the operator and the main methods to develop the biosignals acquisition system NeuroSafety. **Chapter 4** highlights the main results related to the use of a commercial low-cost device to detect the psychophysical state of the operator and the main results related to the developed prototype of NeuroSafety. Finally, **Chapter 5** provides a general conclusion of the main contributions and future work of this thesis.

# Chapter 2

# State of the art

As we mentioned in Chapter 1, the main objective of this thesis was the development of a low-cost platform able to continuously monitor neuroergonomic indices of psychophysical state (mental under/overload), based on commercially available previously validated sensors. Due to the purpose of this thesis, the state-of-the-art has been focused on studying the characteristics of systems currently on the market, as well as their main advantages and disadvantages.

Ideally, a system that is capable of monitoring the operator's psychophysical state should be validated scientifically being able to detect mental underload and/or overload situations in real-time. It must be sensitive (predicting unacceptable psychophysical states levels such as fatigue or mental overload, and minimizing missed events), specific (minimizing false alarms) and extensible (for all users, taking into account that each of them is different). In addition, systems should demonstrate that they can collect high quality data with minimal interference, be portable, non-intrusive and accepted by users. Finally, in order to reach a greater number of users, the devices should be low-cost.

The devices must reliably distinguish mental under/overload states (e.g., from alertness to fatigue). Their capabilities should be tested and proved in both laboratory and field studies conducted on a significant sample of the population of interest (e.g., vehicle drivers or surgeons). In addition, the performance comparison between the sensors integrated in the systems and current gold standard devices can be of great interest. All these studies and the evidences resulting from them must be published in peer-reviewed journals or collected in reports giving veracity to the marketing of the system.

Based on the characteristics above mentioned, we present a classification depending on the nature of the system: operator monitoring systems using physiological variables and operator monitoring systems using behavioral variables. In turn, within these categories, the systems are grouped according to the type of measurement they use to detect the status of the operator (e.g., electroencephalography in the first case systems or steering wheel movements in the second case). In addition, we show the general characteristics of some systems.

All the data shown here were obtained by consulting academic search engines (e.g., Google Scholar, Google Patents, Scopus), industry websites (e.g., car manufacturers websites, Euro-NCAP, whitepapers), companies that developed fatigue detection devices (e.g., Optalert, Seeing Machines) and online literature (e.g., online news) using the keywords attention, assistance, fatigue, sleepiness, drowsiness, device, detection, monitor and workload (and variations thereof). The result of this search shows that there are currently 44 systems with diverse characteristics on the market.

## 2.1 Monitoring systems using physiological variables

Some systems are capable of continuously monitoring the state of the operator during the performance of his/her tasks using physiological measures, such as: electroencephalography, oculomotor measurement, heart rate variability, galvanic response, head movements, body temperature and actigraphy. The main advantage that most of the devices using this type of measures have is the capability of being used in different tasks.

### 2.1.1 Electroencephalography

Historically, the measurement of brain activity has been one of the most commonly used techniques for the evaluation of the psychophysical state. It has been shown that depending on the frequency bands that are measured, it is possible to detect both mental under and overload of the operator [31, 32]. However, these measures are not widely used at present due to the intrusiveness of the sensors, although this is changing thanks to the use of wearable devices that are usually low-cost.

SmartCap (SmartCap Technologies, Brisbane, Australia) [33] is a portable system which uses five EEG electrodes embedded under a cap using a headband (Figure 2.1A). It transmits the data wirelessly to a small dashboard-mounted monitor, and can transmit to a central dispatcher for remote monitoring. It uses different thresholds scores derived from the Oxford sleep resistance test (OSLER) [34] to indicate the state of the operator. Actually, the system is implemented in different transport fleets including mining and road transport (Figure 2.1B).

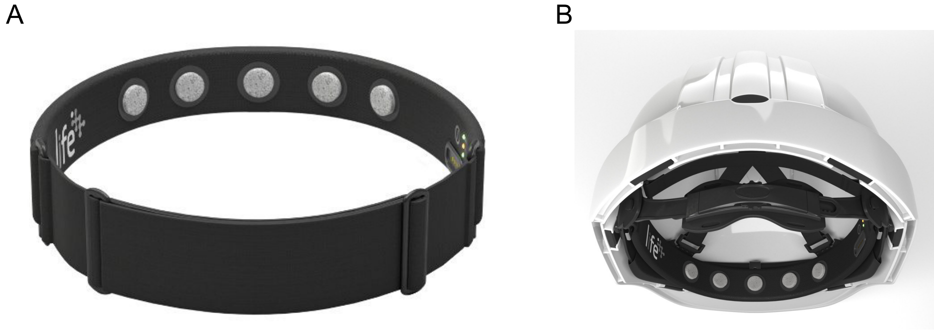

Figure 2.1: **A)** SmartCap system with 5 electrodes. **B)** SmartCap system embedded under a helmet used in mining transport. Images retrieved from [33].

### 2.1.2 Oculomotor measurement

The systems based on ocular measurements are the most used today, with a wide variety of products available. Commercially available systems measure the frequency and duration of blink, as well as pupil diameter. These measurements are usually obtained in two different ways. The first one is through the assembly of some kind of glasses or similar system that makes the continuous monitoring of the operator possible [35, 36]. The second is by mounting a camera in front of the operator, which uses facial recognition algorithms to detect the eyes and pupils [37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55]. In particular, all these systems based on these ocular measurements show that such indices are unreliable in contexts outside the laboratory [56].

Optalert (Optalert, Melbourne, Australia) [35] is a portable system that uses infrared oculography to detect blink frequency, velocity and duration (Figure 2.2A). Small sensors and light emitting diodes are mounted on the bottom of normal spectacle frames, pointing directly at the wearer's eye. The advantage of this device is that it has been tested in different tasks obtaining satisfactory results [57, 58].

Vigo (Vigo Technologies Inc., San Francisco, CA, USA) is a low cost (99€) Bluetooth headset which uses an infrared sensor to track eyelid motion such as blink rates and blink durations [36] (Figure 2.2B). Additionally, a 6-axis accelerometer and gyroscope sensor measures the head nods, lowered gaze and slouched postures. Using an algorithm, the device emits both sound alerts and vibrations to prevent the operator from falling asleep. Although manufacturers advertise it for use in cars, its status as a wearable device makes it possible to use it in different vehicles.

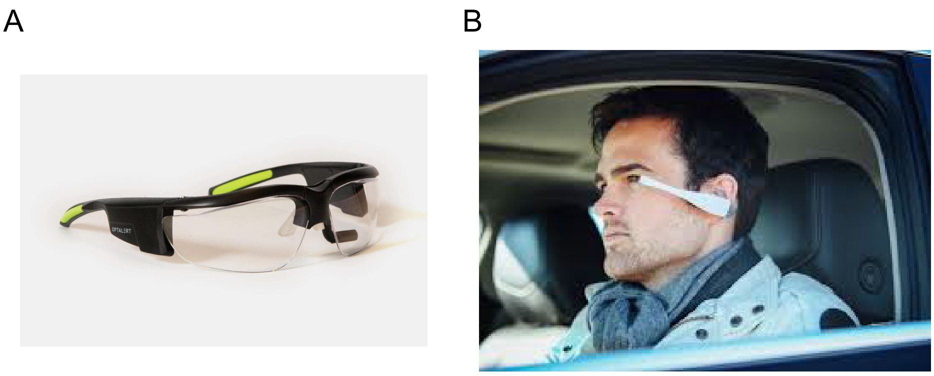


Figure 2.2: **A)** Optalert system. It is a portable system that uses infrared oculography to detect blink frequency, velocity and duration. **B)** User wearing the Vigo headset. It uses an infrared sensor to track eyelid motion such as blink rates and blink durations. Images retrieved from [35, 36].

### 2.1.3 Galvanic skin resistance

Galvanic skin resistance (GSR) systems use easy-to-apply skin electrodes to measure the changes in sweat gland activity [59, 60]. GSR has been shown to change when operator fatigue levels increase and is a good indicator of operator condition [61]. However, problems such as sweating make this measure unrealistic enough.

StopSleep (StopSleep, Stuttgart, Germany) (Figure 2.3A) is a low-cost device (189€) which measures the levels of awareness of drivers wearing the device in two fingers [60] (Figure 2.3B). It uses 8 built-in cutaneous sensors which monitor the electrodermal activity. As soon as the levels of concentration start to drop, StopSleep alerts the driver using an audible and vibration alarm.

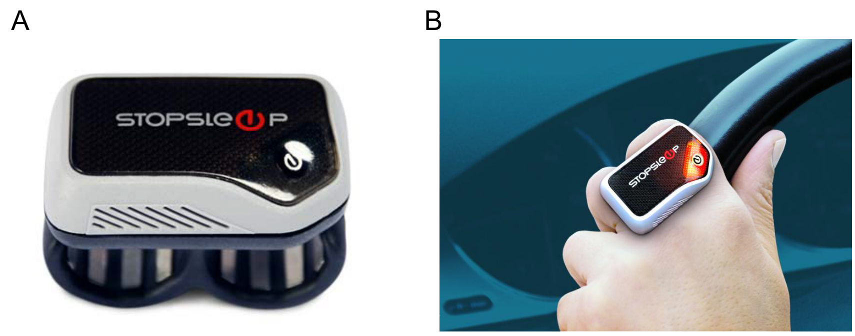


Figure 2.3: **A)** StopSleep system. **B)** User wearing the StopSleep system. Images retrieved from [60].

### 2.1.4 Head movements

These systems measure the state of the operator detecting the posture changes that accompany fatigue, in particular, head. There are two ways to measure these movements; the first way is to use a hearing aid-shaped device behind the ear that detects the inclinations of the operator's neck [35, 62]. When it exceeds a certain level of inclination (usually 15 degrees) for a certain period of time, the device activates an audible alarm. The second way to detect these movements is by using a camera located in front of the operator, which using facial detection algorithms do the same as the first type of systems [36, 37, 38, 39, 40, 41, 42, 44, 47, 48, 49, 50, 51, 52, 53, 54, 55]. The second way usually is combined with the detection of the oculomotor measurement (see Section 2.1.2).

Cat Driver Safety System (Caterpillar Inc., Peoria, IL, USA) [55] is in-cab fatigue detection technology that instantly alerts operators the moment fatigue or distraction is identified, developed in collaboration with Seeing Machines Inc. (Canberra, Australia) (Figure 2.4A). It uses cameras to monitor and identify the head and eyes of the operator. Different algorithms process all the data, providing real-time warnings. Additionally, the system is connected with a monitoring center which can contact with the operator if the fatigue appears.

Nap Zapper (Zhenjiang Welkin Electronics Co. Ltd, Jiangsu, China) [62] is the cheapest device device in the market (<10€) to raise driver awareness of momentary lapses caused by sleepiness (Figure 2.4B). The device is worn behind the operator's ear. If the head nods below a pre-established angle it emits an alarm sound, effectively zapping a nodding driver back to full concentration.

A B

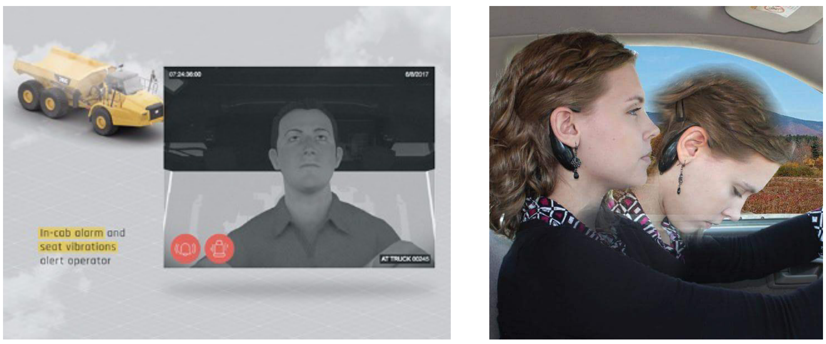


Figure 2.4: **A)** Cat Driver Safety System mounted on a mine truck to monitor the psychophysical state of the operator. **B)** User wearing the Nap Zapper. Images retrieved from [55, 62].

### 2.1.5 Other not-so-common measures

Other not-so-common measures to monitor the psychophysical state of the operators that are currently implemented in some systems are the actigraphy, heart rate variability and body temperature.

Actigraphy systems [63, 64] usually use wristbands with a 6-axis or 9-axis accelerometer to track accurately and unobtrusively sleep information and aspects of circadian rhythms useful for predicting fatigue states in operators [65]. Readiband (Fatigue Science, Vancouver, Canada) is a wearable device to help organizations manage human sleep and fatigue, to improve safety, health and performance [63] (Figure 2.5A). They measure the daily activity of the operators during a predefined time (aprox. 20 days), creating an individualized profile (baseline). After that, the daily data are compared with the baseline, providing an accurately level of fatigue (between 0 and 100).

Another way to monitor the psychophysical state of the operators is the heart rate variability (HRV) which is the physiological phenomenon of the beat-to-beat temporal variation of the heart. WARDEN$^{\mathrm{TM}}$ (Plessey Semiconductors Ltd., Plymouth, UK) [66] is a system which uses an array of sensors to detect changes in electric potential in the human body. The array of sensors is placed between the human body and the seatback of the car (Figure 2.5B). The system senses the electrical impulses of the heart without direct skin contact and returns an accurate R peak signal from the users ECG (Electrocardiogram) [67], this in turn can be used to calculate the HRV.

Finally, a last measure that has begun to be used is the body temperature. Currently, there is only one system on the market that uses this variable to monitor the operator's psychophysical state, the Drowsiness-Control Technology developed by Panasonic Corp. (Osaka, Japan) [43]. It uses an infrared camera situated in the car dashboard and measures continuously the heat loss of the body adjusting room temperature or airflow based on an individual's estimated level of drowsiness, keeping the operator awake.

## 2.2 Behavioral variable monitoring systems

These systems are responsible for monitoring the status of the operators during the performance of their tasks by measuring behavioral variables, such as: lane deviation, steering wheel movements and reaction time. Usually these systems are embedded in a vehicle, so they have the disadvantage that operators only can use them when driving.

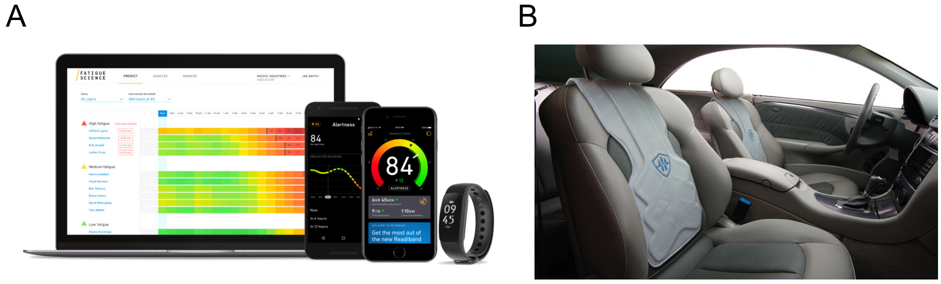


Figure 2.5: **A)** Readiband wearable system. The wristband calculates the level of activity of the operator and sends the data to a mobile application or data center management. **B)** WARDEN$^{TM}$ system placed in the seat of a car. It uses non-contact HRV to measure the state of the operator. Images retrieved from [63, 66].

### 2.2.1 Lane deviation

To measure the lane deviation, systems include a camera mounted in the front side of the vehicle detects lane markings and other road features [42, 44, 47, 51, 52, 68, 69, 70, 71, 72, 73, 74, 75]. Subsequently an algorithm interprets these road features and alerts drivers to unintentional road departures (e.g., when starts to sleep and move to other lane) [76]. Usually these devices are robust to different road and weather conditions, but there are some environments that can cause the camera to fail (e.g., unmarked road lines). Another disadvantage of this type of systems is that they are embedded in the vehicles, so to be able to use them it is necessary to buy a vehicle that includes it.

Driver Alert Control & Lane Departure Warning (AB Volvo, Gothenburg, Sweden) was the first lane deviation system implemented in a car (2007) [68]. With the camera mounted in the front side (Figure 2.6A), an algorithm shows a notification in the control panel of the car warning that the vehicle is being driven irregularly, inviting the driver to stop (Figure 2.6B).

### 2.2.2 Steering wheel movements

These kinds of systems analyze the steering wheel movement data collected from sensors mounted on the steering lever [37, 39, 42, 44, 47, 69, 71, 72, 73, 74, 75, 77, 78, 79, 80, 81, 82, 83] (Figure 2.7A). They only measure the fatigue state (mental underload) based on the frequency of minor steering corrections [84]. When the driver is in a drowsy state, the frequency of his steering corrections reduces markedly. At that moment the system emits visual and customs signals informing of a state not optimal to continue with

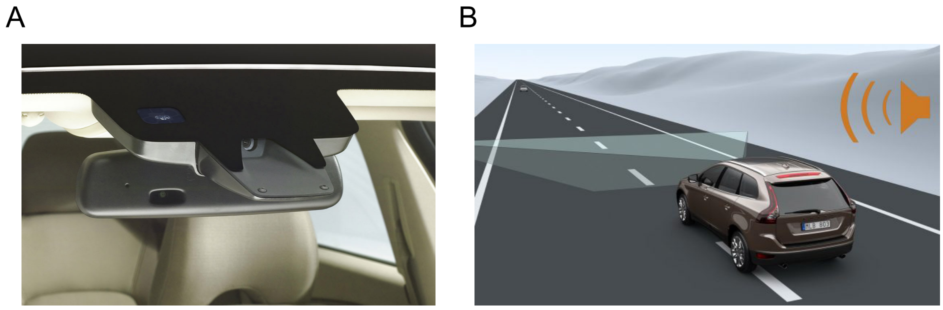


Figure 2.6: Driver Alert Control & Lane Departure Warning. **A)** Camera situated in the front part of the car to detect the road. **B)** System warning of an involuntary lane change using an audible alarm. Images retrieved from [68].

the driving. The problem of these systems is that they can only work in certain situations (e.g., highways).

Attention Assist (Daimler AG, Stuttgart, Germany) is a system to monitor the driver's state implemented in Mercedes-Benz cars [77]. This system uses a sensor integrated in the steering wheel of the car to examine considerations such as time behind the wheel and driver activity (Figure 2.7B). If the system determines the drowsiness state, it will send an audible and visible alert letting the driver know it is time to take a break. Prior to start analyzing the driver state, the system collects data of the driving behavior during 20 min approximately to create a baseline, which it then uses to compare the driver's states. The system only works when the speed of the vehicle is above 60 Km/h.

### 2.2.3 Reaction time

The systems that use the reaction time as a measure to monitor the psychophysical state of the operator usually use a kind of push button, which can be placed anywhere that does not disturb the task being performed by the operator. From time to time it emits an alarm and counts the time it takes for the operator to press the button. In this way it is possible to estimate the level of operator fatigue [85]. The Anti Sleep Pilot (Anti Sleep Pilot DK, Copenhagen, Denmark) [86] system is the only device that currently exists commercially, with an approximate cost of 180€(Figure 2.8).

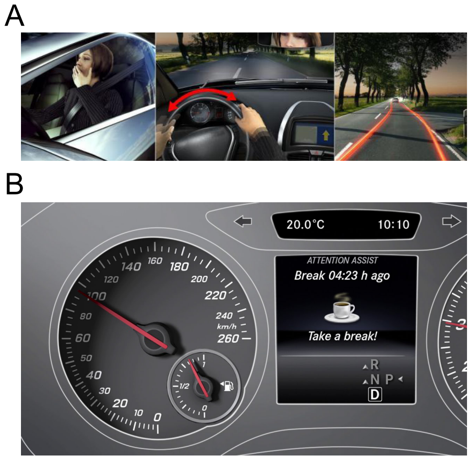


Figure 2.7: **A)** Steering wheel movement system. **B)** Attention Assist system showing a notification inviting the driver to take a rest. Images retrieved from [83, 77].


Figure 2.8: Anti Sleep Pilot. The system is placed on the dashboard of the vehicle and from time to time it emits an alarm and counts the time it takes for the operator to press the button. Image retrieved from [86].

## 2.3 Analysis of the available monitoring systems in the market

The main problems of the devices presented above is that most are not scientifically validated to monitor the psychophysical state of the operator, are expensive, and are embedded so they cannot be used to perform different tasks (only 15 out of 44 systems can be used in different tasks).

On the one hand, several devices were commercially available despite having no evidence of scientific effectiveness (e.g., head movements and lane deviation systems). On the other hand, further devices were developed using lab-derived correlates of fatigue, but had not yet demonstrated that they could validly detect under/overload situations in a field-based setting. Of all the devices analyzed, none is capable of detecting both mental situations. They usually focus on the detection of mental underload (e.g., fatigue) because most of the systems are developed by automotive companies with the aim of introducing in their vehicles.

A remarkable feature is the inclusion in some systems of a baseline (10 out of 44 [33, 35, 55, 63, 64, 72, 74, 77, 79, 81]). Some companies make a registration of data for several days to operators who will use their systems under different conditions and create an exact profile of the operator with which to compare data later. This feature should be implemented in all the systems to provide more robust and realistic measures.

Finally, low-cost devices (5 out 44 [36, 53, 60, 62]) showed promising preliminary results, usually in the white papers (e.g., Smart Cap, Vigo) but appear to be moving rapidly to implementation without sufficient validation and reliability studies. Probably it exists a significant pressure to produce sales and it can take a long time to build an evidence base that would ensure the technology is scientifically defensible. Detailed information about all the systems can be found in the table annexed in Appendix D.

# Chapter 3

# Methods

As a multidisciplinary thesis, this chapter offers the main methods used for the scientific (Section 3.1) and real environment validation of a commercial low-cost device (Section 3.2) that is intended to be used later in the development of a low-cost non-invasive system based on COTS devices around a computational platform (HW/SW) (Section 3.2) and the validation tests carried out for the first version of the prototype that integrates an eye movement sensor (Section 3.3).

## 3.1 Validation of a low-cost wearable device to detect the psychophysical aptitude of the operator

As we mentioned in Chapter 1, the need to scientifically validate the measurements of commercial devices against gold standards in neuroergonomics, whether low-cost or not, through laboratory testing and real-world testing is essential, as it is the starting point to develop a robust system. This section shows the validation studies carried out for monitoring the operator's psychophysical state using the NeuroSky MindWave Mobile (NeuroSky Inc., San Jose, CA, USA, henceforth MindWave) built around the TGAM1 module (ThinkGear ASIC module) technology (Figure 3.1) [87]. This device was chosen because of its low cost (<500€), its use of a front dry electrode so no training is needed to correctly place it on the user and the fact that new versions that use the same communication protocols but improve the quality of the signal are currently continuing to be developed/are currently being developed/have been planned to be developed. Three studies have been carried out and published in different journal articles indexed by JCR. The first one (Section 3.1.1) is a scientific validation, while the other two studies are a validation in real environment which justify the use of the sensor for the monitoring of psychophysical state both in environments that produce mental underload (section 3.1.2) and mental overload in the operator (section 3.1.3).

Figure 3.1: NeuroSky MindWave Mobile headset. This device consists of a single dry electrode (12 mm x 16 mm) placed on Fp1, according to the international 10-20 system [88], which inputs data to a TGAM1 (ThinkGear ASIC Module) integrated circuit able to record data at 512 Hz. These two elements are mounted on a light headset (90 g). The device uses a monopolar montage with one active site, and employs a pea-sized (∼0.8mm diameter) electrode clipped to the left earlobe as reference. Image retrieved from [87].

### 3.1.1 Validation of electroencephalographic recordings obtained with a consumer-grade, single dry electrode, low-cost device: a comparative study

In this work [89], we studied the recording quality of the MindWave device by performing concurrent recordings with a medical-grade ambulatory electroencephalograph (SOMNOwatch+EEG-6, henceforth SOMNOwatch). We compared EEG signals acquired from virtually the same scalp place (Fp1 vs. AF3) while participants performed two different laboratory tasks (closed eyes and open eyes tasks) (Figure 3.2).

In addition, considering the growing interest for implementing tools to monitor cognitive performance in realistic conditions [90], EEG signals were recorded likewise during a 1-hour simulated driving task (a common daily-life activity) (Figure 3.3). We recruited 21 drivers (mean age ± standard deviation [SD] = 25.14 ± 4.69 years) to perform the experiment. Detailed information can be found in the original article (Appendix A or [89]).

Figure 3.2: Participant wearing simultaneously SOMNOwatch+EEG-6 and NeuroSky MindWave Mobile headset seated in an driving simulator ready to perform the experiment.

### 3.1.2 Monitoring driver fatigue using a single-channel electroencephalographic device: a validation study by gaze-based, driving performance, and subjective data

In this work [31], we examined the first conclusive evidence about the sensitivity and validity of a single electrode EEG device (MindWave) as a driver fatigue monitor. We investigated the effects of a 2-h driving time – a common inducer of fatigue at the wheel [56, 91, 92] – while we continuously monitored drivers' brain activity as well as their saccadic velocity (Figure 3.4). As saccadic velocity is a well-known fatigue index [92, 93, 94, 95, 96], we used it as a standard reference measure for fatigue. We also measured driver performance and subjective ratings of alertness and fatigue to corroborate the correct state of fatigue of the participant. Seventeen active drivers (mean age [±standard deviation, SD] = 25 ± 3.45 years, range 22–34; 12 men) volunteered to participate in this study, and they attended to the Mind, Brain and Behavior Research Center (CIMCYC-UGR). All participants had normal or corrected-to-normal vision and held a valid driver license (average number years of driving experience [±SD] = 5.94 ± 2.74 years). Detailed information can be found in the article preprint (Appendix B) or in the original article [31].

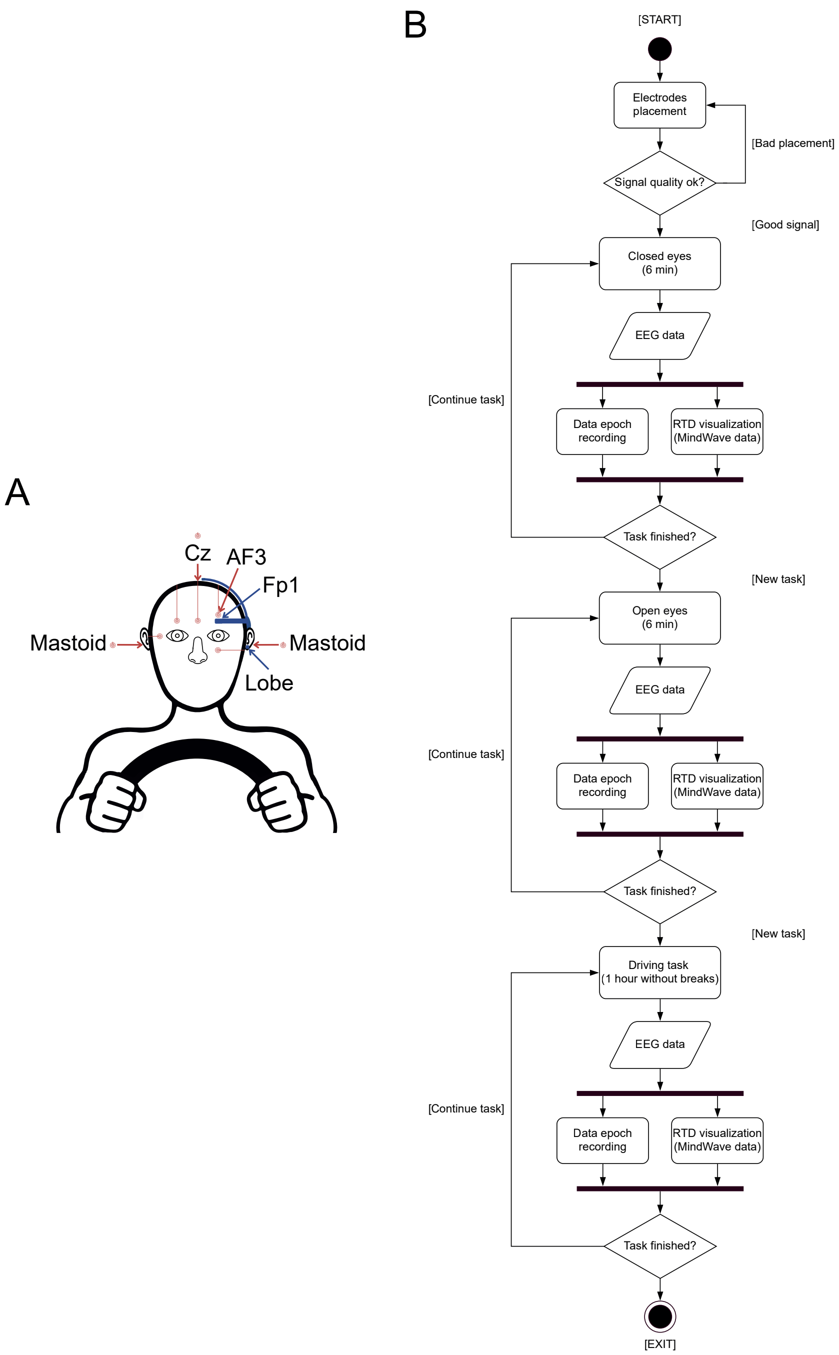


Figure 3.3: Experiment structure. **A)** EEG electrodes placement used in the experiment. Red elements and arrows indicate the electrodes used by the SOMNOwatch device and blue elements and arrows indicate electrodes used by the MindWave device. **B)** Unified Modeling Language (UML) activity diagram for the implementation and data acquisition of the experiment. Image adapted from [89].

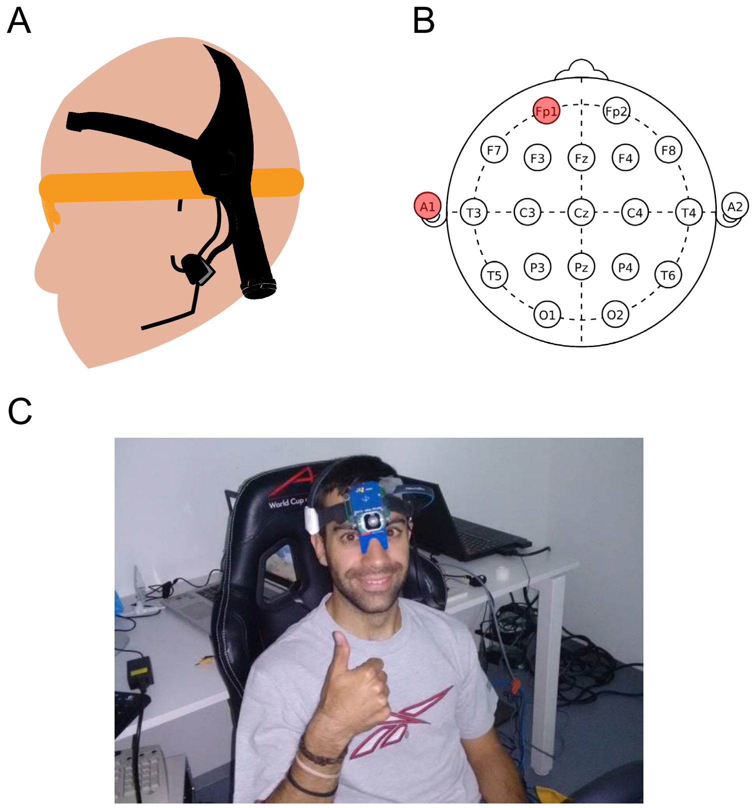


Figure 3.4: Devices used in the experiment. **A)** The configuration used to record EEG (black headset) and eye movements (orange element). **B)** The EEG device uses a monopolar montage with a single frontal dry electrode placed at Fp1, and uses the left ear-lobe as the reference/ground. **C)** Participant wearing both devices (Jazz-Novo and MindWave). Image adapted from [31].

### 3.1.3 Detecting mental workload in surgical teams using a wearable single-channel electroencephalographic device

In this work [32], we investigated if prefrontal beta EEG power activity (13-30 Hz) could differentiate the levels of task demands imposed by different surgical procedures of different complexity (high complexity: laparo-endoscopic single-site [LESS] surgery vs. low complexity: multiport laparoscopic surgery [MPS]) while using 2 suturing techniques (interrupted vs. continuous suture). We wanted to answer the question if prefrontal beta-activity measured with a low-cost wearable EEG could act as an useful cue to quantify the mental workload in surgeons in real scenarios. In addition, we wonder if prefrontal beta EEG power activity could also differentiate between the roles played in the surgical team (primary surgeon vs. assistant surgeon) (Figure 3.5). Four pairs of board certified surgeons (6 females and 2 males) participated in the study (mean age ± standard deviation [SD]: 31.37 ± 2.2 years; average number years of experience ± SD: 6.62 ± 1.78 years) (Figure 3.6). This study was in collaboration with IAVANTE (Andalusian Public Foundation for Progress and Health), placed in Granada (Spain). Detailed information can be found in the article preprint (Appendix C) or in the original article [32].

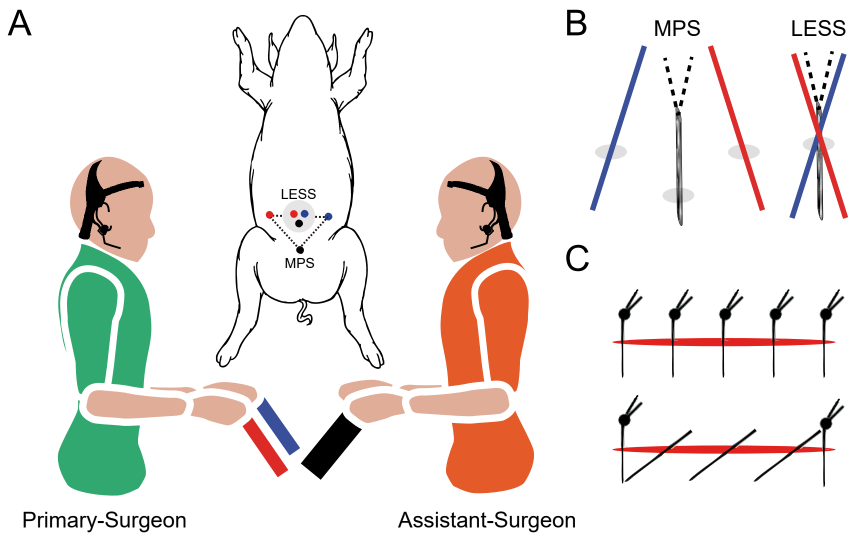


Figure 3.5: **A)** A surgical team wearing the MindWave while performing the surgical exercises. The green figure indicates the primary surgeon and the orange figure indicates the assistant surgeon. Real porcine models were used for the experiment. **B)** The multiport laparoscopic surgery (MPS) triangulated work configuration and the laparo-endoscopic single-site (LESS) surgery triangulated laparoscopic work configuration. **C)** Two suturing techniques were performed: interrupted suture (upper figure) and continuous suture (lower figure). Image adapted from [32].

## 3.2 NeuroSafety

After the validation of MindWave, a prototype of the NeuroSafety system was developed. A system will use different sensors to monitor the operator's psychophysical state. We decided to use EEG sensor and eye movement sensor as these measure have already been validated by the Research Team to monitor the psychophysical state of the operators (see Section 3.1).

In this first version of the prototype, we decided to focus on the con-

Figure 3.6: A surgical team wearing simultaneously the MindWave while performing a surgical exercise at IAVANTE (Andalusian Public Foundation for Progress and Health).

struction and validation of the eye movement sensor, since the EEG sensor had already been scientifically validated (see Section 3.1). The name NeuroSafety comes from a BBVA Foundation Grants to Researchers and Cultural Creators project (2015 call) granted to one of the supervisors of the thesis (Dr. Leandro Luigi Di Stasi).

### 3.2.1 Design criteria

In order to use NeuroSafety as a system to monitor the operator's psychophysical state, the design criteria used for the design of the first version of the prototype were based on the study of the systems currently on the market (see Chapter 2) trying to improve these proposals at both hardware and software level. The main design criteria were:

#### Hardware

- Portability. Small and wireless device in order not to disturb the tasks being performed by the operator.
- Configurable. Possibility of implementing sensors by the Plug-and-Play method (PnP) to achieve a more complete system that can be used in different situations.

- Connectivity. Wireless data transmission technology through the use of standardized protocols (e.g., WiFi or Bluetooth) and without having to use external adapters.

- Autonomy. Use of electronic components of low consumption, as well as rechargeable batteries.

- Robustness. The connections and components must be robust and soldered, as well as having a case to protect it from external agents (e.g., dust).

- Cost. Final price of the materials below 500€, in order to compete with the large number of devices that exists on the market (see Chapter 2).

#### Software

- Usability. Application or applications with graphical interfaces (GUI) friendly and easy to use by the user.

- Real-time data visualization and processing. Acquisition, visualization and processing of data in real-time to allow the operator's state to be known at all times.

### 3.2.2 Design and processing tools

In the design and development of a system from scratch integrating commercial sensors, different hardware and software tools were used to build a prototype able to monitor the operator's psychophysical state. The main tools used were:

#### Hardware

- We used Altium Designer (Altium Limited, San Diego, CA, USA) to design the printed circuit boards (PCB). The first and second versions of the PCBs were created in the Centro de Instrumentación Científica de la Universidad de Granada (CIC-UGR, Granada, Spain) and the final version were created for Millenium Dataware Srl (Tortona, Italy).

- We used the open source software FreeCAD 0.16 (Juergen Riegel y Werner Mayer) to design the parts to cover the PCBs and a 3D printer Prusa i3 model to create all models based on polylactic acid (PLA).

**Software**

- The firmware programming of the microcontroller was done in C++ language using a version of Eclipse (Eclipse Foundation, GNU Open Software) specially designed to program the selected microcontroller (Intel Edison).

- We developed software in LabVIEW 2014 (National Instruments Co., Austin, TX, USA) and MATLAB® R2013b (MathWorks Inc, Natick, MA, USA) for real-time acquisition and visualization of data.

- We used MATLAB® R2013b to process data from the different integrated sensors in the prototype.

### 3.2.3 Validation tests

- Validation of the design on a prototype board. Prior to the creation of the design on a PCB, the circuit was built on a prototype board and we made different measures with an oscilloscope to check that the prototype was working correctly.

- Electrical check. Once we created and soldered the electronic components into PCB board, we used an oscilloscope and voltmeter, to verify that the PCBs were manufactured correctly, did not present any defect and it operation was correct.

- Calculation of the irradiance values needed to estimate whether the LEDs used in the eye movement sensor could be used in humans.

- Laboratory and real-world studies. Various studies, in addition to the tests mentioned above, were carried out to test the proper functioning of NeuroSafety (Section 4.2).

## 3.3 Studies based on NeuroSafety

### 3.3.1 Validation of the NeuroSafety prototype (eye movement sensor) with standard calibration measurements

The main aim of this work was to determine the level of the eye movement sensor error and to assess the quality of its signal using a calibration process similar to the one presented in [97]. Six participants (mean age $\pm$ standard deviation [SD] = 21.6 $\pm$ 4.46 years, age range: 18–29; 2 men and 4 women) volunteered for the study and fulfilled the required tests at the Neuroergonomics & Operator Performance Lab (CIMCYC-UGR). During the test the participants had to observe one point that was appearing and disappearing at different positions of a screen (Figure 3.7A), remaining at each position for two seconds. Hence, the participants were forced to make a series of fixations that allow estimating the error between the eye movement sensor measure and the real point on the screen. We used a 15-inch screen (Dell Technologies, Texas, USA) to show the points. Such screen was placed in two positions at different distances from the participants' eyes (60 and 120 cm) so the behavior of the sensor when fixations are made in a more reduced field of view could be studied (Figure 3.7B).

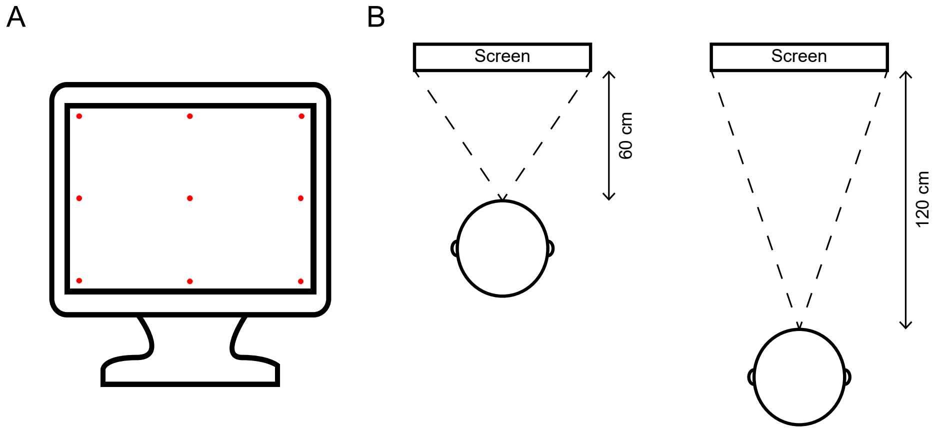


Figure 3.7: Experiment structure. **A)** Screen showing the fixation of the fixation points (red dots). **B)** Overhead shot of the position of the participant's head in relation to the screen at two different distances (60 cm to the and 120 cm to the right). It is possible to observe that with the change of distance the visual field (eyes-screen angle) is transformed.

## 3.4 Facilities

During the validation of MindWave and the design and development of NeuroSafety, different tools and materials were used to carry out tests in the Research Centres of the University of Granada CITIC-UGR and CIMCYC-UGR, IAVANTE Line -Progreso y Salud Foundation (Granada headquarters)- and Institute of Optics "Daza de Valdés" in Madrid (IO-CSIC):

- BCI Lab (CITIC-UGR). Tools to soldier electronic components and, oscilloscope and voltmeter to check that the different versions of the prototypes worked correctly.
- Neuroergonomics & Operator Performance Lab (CIMCYC-UGR). Computers to design the hardware/software of the prototype, software to

process physiological data, MindWave device and driving simulator for or laboratory validation studies.

- IAVANTE Line (Fundación Progreso y Salud). Access to participants (qualified surgeons), tools used in real operating rooms to perform device validation studies, and real porcine models to carry out operations.

- Institute of Optics "Daza de Valdés". Tools to certify the use in humans of infrared LEDs used in the eye movements sensor included in NeuroSafety.

# Chapter 4

# Results

This chapter provides an overview of the main results related to the validation of a low-cost wearable device to monitor the operator's psychophysical state (Section 4.1 and Section 4.2), the development of the first version of the NeuroSafety prototype (Section 4.3) and the validation tests carried out for the eye movement sensor included in the prototype (Section 4.3.3). For further information, please refer to the annexed articles which are part of the thesis publications group.

## 4.1 Validation of electroencephalographic recordings obtained with a consumer-grade, single dry electrode, low-cost device: a comparative study

The main goal of this work was to evaluate the recording quality of the MindWave by performing simultaneous recordings with the SOMNOwatch, comparing the signals obtained with both devices during the performance laboratory tasks (closed eyes, open eyes and 1-h simulated driving tasks).

On the one hand, qualitatively, the MindWave signal presents higher levels of noise and a biphasic shape of blinks (Figure 4.1A). The similarity metric shows that signals from both recording devices are correlated (Figure 4.1B).

On the other hand, quantitatively, the main difference between the devices is the attenuation that is introduced by the MindWave device at the low frequency components (<4 Hz) (Figure 4.2A). Our results suggest that the reason could be the spectral (linear) properties of the sensor and electronic combination present in the MindWave device, and not nonlinear effects. Moreover, according to the results the MindWave has also a lower

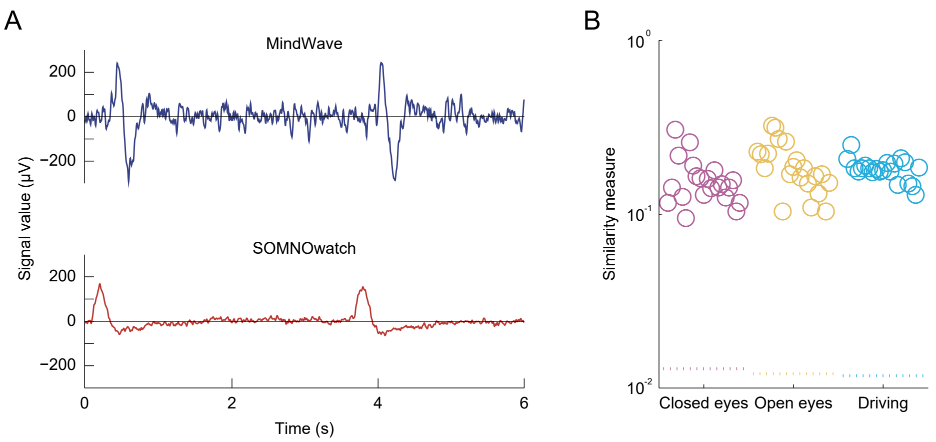


Figure 4.1: Comparison of temporal data series. **A)** Simultaneous fragment (6-seconds) of data recorded in one participant using both devices (blue line corresponds to MindWave and red line to the SOMNOwatch). It is easy to observe the different noise levels and shape of blinks in the raw signals. **B)** Similarity measure (open circles) for each participant and each of the three tasks (closed eyes –magenta–, open eyes –yellow– and driving –light blue–), as compared to a baseline value (dotted lines at the bottom of the graph). Image adapted from [89].

signal-to-noise ratio (SNR) than the reference device (Figure 4.2B). This fact constitutes a meaningful drawback since the performance of a Brain Computer Interface (BCI) application —or any EEG configuration for research— depends on its SNR. Detailed information can be found in the original article (Appendix A or [89]).

## 4.2 Validation of a low-cost wearable device to monitor psychophysical state of the operator

### 4.2.1 Monitoring driver fatigue using a single-channel electroencephalographic device: a validation study by gaze-based, driving performance, and subjective data

This work was aimed at demonstrating the validity of using a low-cost wearable EEG device (MindWave) to monitor driver fatigue. We combined this EEG device with high-speed eye tracking technology in order to gain understanding of how we can use wearable technologies for early detection of driver fatigue while driving. Hence, we studied how EEG data (i.e. power spectra density) and driver's saccadic peak velocity, a recognized index of

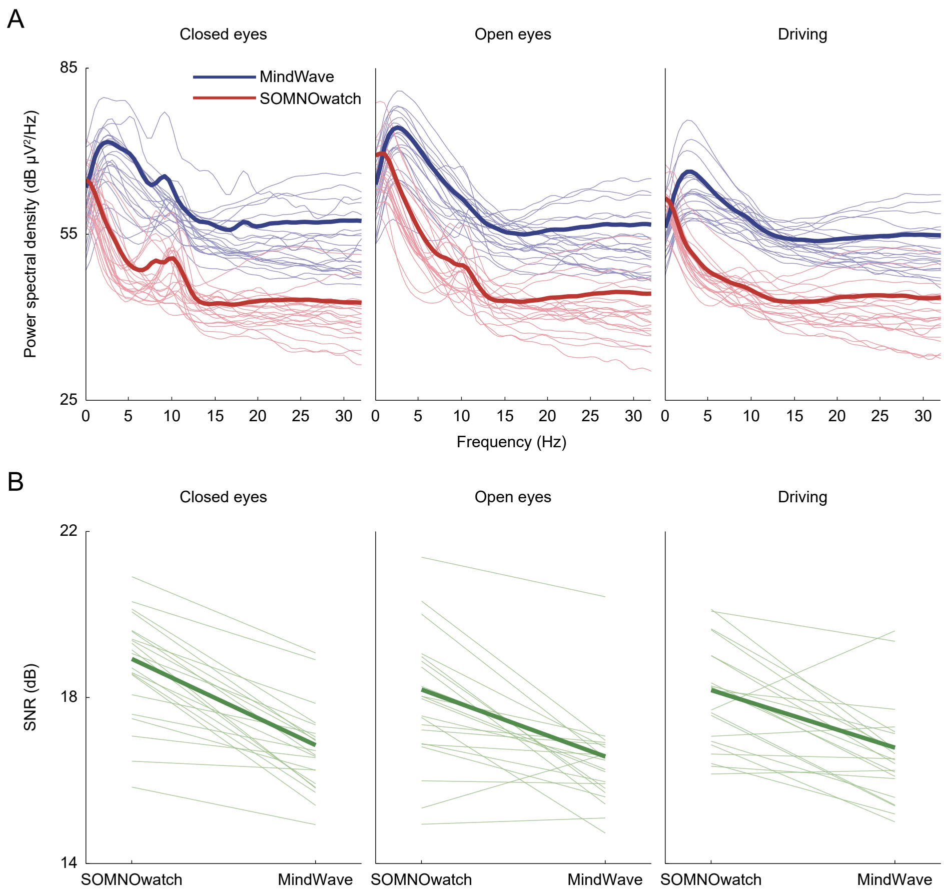


Figure 4.2: Spectral comparison and signal-to-noise ratio (SNR) estimation between both devices. **A)** Power spectral densities for all the tasks (from left to right closed eyes, open eyes and driving tasks). Blue and red thin lines show individual participants and thick lines the average result. **B)** SNR for each participant (green thin lines) and average (green thick line) for the closed eyes (left), open eyes (center), and driving (right) tasks. Image adapted from [89].

fatigue [98], changed across a 2-h monotonous driving. We observed that delta EEG power spectra increased during the first hour and a half and decreased during the last half hour, i.e., an inverted U-shaped quadratic trend, and beta EEG power spectra increased describing a linear trend across the experimental session (Figure 4.3A), which is coherent with the linear decreasing trend of the saccadic eye movements (Figure 4.3B). Therefore, our combined results show that EEG-metrics recorded by this low-cost device can detect driver fatigue levels online. Detailed information can be found in the article preprint (Appendix B) or in the original article [31].

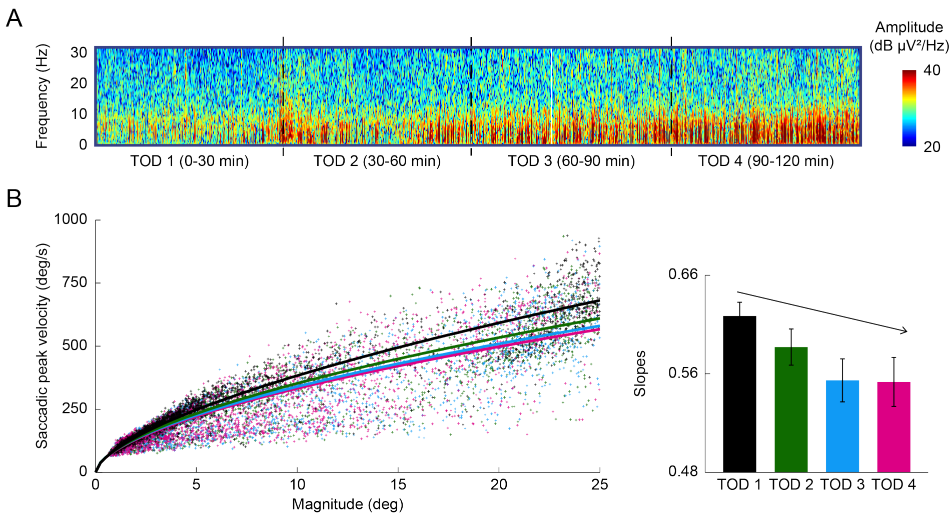


Figure 4.3: Effect of Time-On-Driving (TOD) on the EEG power spectrum of one participant and the saccadic peak velocity. **A)** Spectrogram for participant 14 which shows the EEG power spectrum across the entire driving session (2-h). The dB scale is relative to 1 $\mu V^2/Hz$. **B)** Saccadic main sequence (peak velocity/magnitude relationship) for participant 14 across the four consecutive TOD blocks (1: black, 2: green, 3: light blue, 4: magenta; 30-min per block). Each dot represents a saccade. The curves are power-law fits to the data for each TOD block. Right panel: Average saccadic peak velocity across all participants for each TOD. Error bars represent the standard error of the mean across participants (n=12). Image adapted from [31].

### 4.2.2 Detecting mental workload in surgical teams using a wearable single-channel electroencephalographic device

The main finding of this work was to examine how surgical complexity affects brain activity during realistic exercises. We proved the feasibility of a low-cost wearable EEG device (MindWave) to gather unbiased information about surgeons' mental workload. Our results show the sensitivity of an EEG-based index (prefrontal beta EEG power) to detect variations in surgeons' mental workload. Data show that highly demanding procedures (i.e., sutures performed with LESS) induced higher prefrontal beta EEG power activity, whereas less demanding procedures (i.e., sutures performed with MPS) induced lower beta EEG power activity (Figure 4.4). Another important finding showed that beta-activity was similar for primary surgeons and assistant surgeons when they were performing the same surgical exercises, suggesting synchronized brain activity between surgical teams during operations [19, 99]. Detailed information can be found in the article preprint

(Appendix C) or in the original article [32].

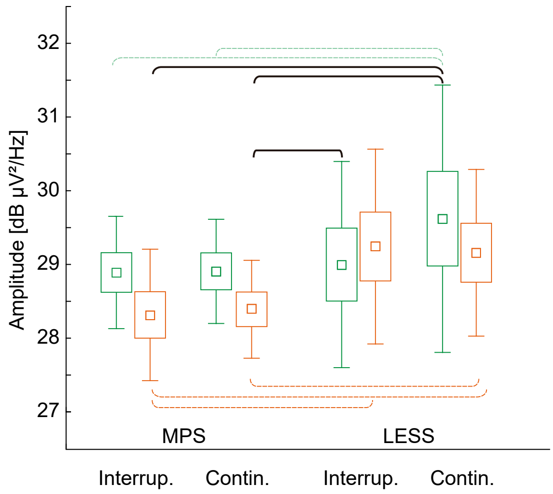


Figure 4.4: The effects of task complexity on beta EEG power activity. Green color represents the results for primary surgeon and orange color represents the results for the assistant surgeon. Differences within the same surgical role are indicated with dotted square brackets. Differences between surgical roles are indicated with solid square brackets. For each experimental condition, the inner boxes represent the mean (M) and the external ones the standard error of the mean (±SE). The error bars represent the standard deviation (±SD). All values are calculated across all the participants (n=8). Interrup., interrupted suture; Contin., continuous suture. Image adapted from [32].

## 4.3 NeuroSafety

NeuroSafety is a low cost portable and wireless system for real-time acquisition and display of biosignals. In this thesis, we present the first prototype which includes a sensor to measure the eye movements that was validated by different preliminary studies.

### 4.3.1 Hardware

The hardware development of NeuroSafety has been carried out through several design-prototype-evaluation phases (Figure 4.5). The aim of this technique is to develop a minimally invasive prototype at the lowest possible cost. In this first development, NeuroSafety is a wearable prototype capable of collecting eye movements data mounted on safety glasses, which allow the operator to be protected during the tasks they perform without their field of view being reduced.

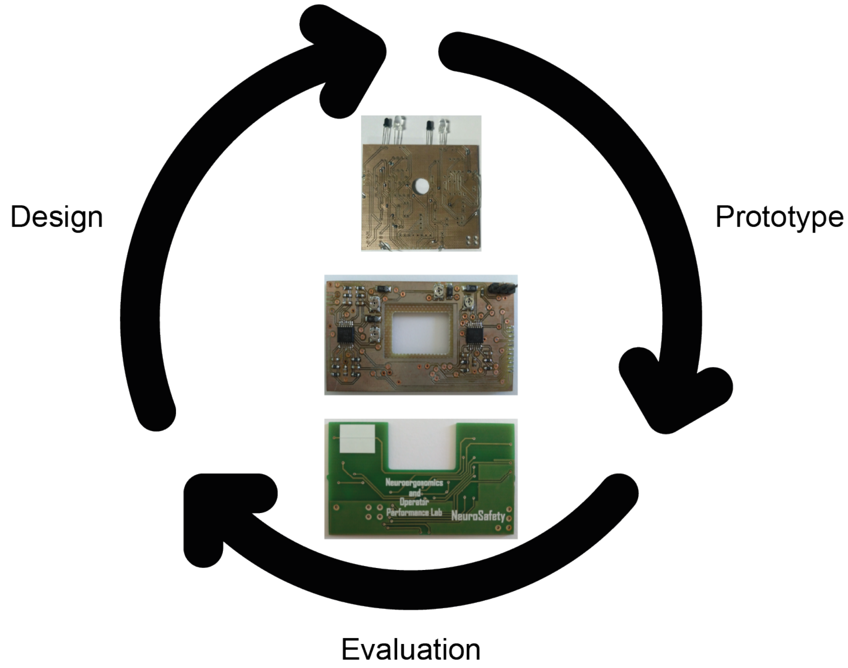


Figure 4.5: Development carried out for NeuroSafety based on an iterative design (design-prototype-evaluation). Each of the images that appears within the design cycle corresponds to one of the versions of the prototype that have been developed through the iterative design.

We decided to use an assembly based on two PCBs, so one of them could be used to collect EEG (this sensor has not been included yet in the current version of the prototype) and the other one could be used to gather eye movement information. To gather such eye movement information emitters and photoreceptors are placed/located on the nose and direct infrared oculography is used to detect the position of each eye. With this eye movement detection method, an infrared light beam is triggered throughout a very short pulse to the eye by the infrared emitters and the light reflected by the eye is collected by the photoreceptor. It is impossible to know the position of the eye at any time using only one pair emitter-photoreceptor. However, its position can be obtained using the triangulation method if two pairs emitter-photoreceptor are used and one of them is placed on the top part of the eye and the other one on the bottom. In the current version of the prototype two pairs emitter-photoreceptor are included for each eye so the position of both eyes at any time can be known. Table 4.1 shows the size of different PCBs that have been used during the development process of the prototype.

Table 4.1: Dimensions of the two printed circuit boards contained in the NeuroSafety prototype in the different versions that have been made. It is possible to observe the decrease in size of both printed circuit boards according to the creation of the different versions of the prototype.

| Version of printed circuit board | Eye movement printed circuit board | | EEG printed circuit board | |
|---|---|---|---|---|
| | Width (mm) | Height (mm) | Width (mm) | Height (mm) |
| v1 | 60,52 | 63,97 | 66,8 | 73,78 |
| v2 | 46 | 42 | 60 | 32 |
| v3 | 46 | 42 | 50 | 30 |

The electronic design of NeuroSafety is formed of two main blocks (Figure 4.6). The first block (acquisition block) is composed of an ADS1015-ADC from Texas Instruments (Dallas, TX, USA). The ADS1015 is an analog-to-digital converter (ADC) that can be configured to as a four-channel single-ended device or as a two-channel differential device, both with 12-bit resolution at a sampling rate of up to 500 samples per second (the number of samples per second can be modified by software). In NeuroSafety, the ADC is configured as a four-channel single-ended device. Of these four channels, two are set to obtain the position of the right eye and the remaining two to obtain the position of the left eye. It allows transforming the values of the photoreceptors into digital values for easy processing. Afterwards, the data acquisition block communicates with the second block (control block) via an I2C communication bus. This block consisted on a System on Chip (SoC) Intel Edison developed by Intel (Santa Clara, CA, USA) which receives data from each photoreceptor of each eye in a synchronized way. Later, the SoC creates data packets and sent via UDP protocol through a WiFi network point. This network point is created every time the device is started and allows the creation of an access point to which a user, with the appropriate software can connect to the device and visualize the data in real-time from the eye movement sensor. Finally, the entire prototype is encapsulated in a printed black PLA plastic, to protect the printed board circuits from external agents such as bumps or dust. At the moment, we are developing a new version of NeuroSafety which includes the MindWave EEG sensor.

### 4.3.2 Software

Two versions of the software have been developed for the first prototype of NeuroSafety. The first version of the GUI has been developed using LabVIEW software and has a simple and clear interface to visualize and record data (Figure 4.7A). This interface connects to the access point created by Intel Edison SoC (see Section 4.3.1) to receive data packets from the eye movement sensor in order to visualize and save the data in files in real-time.

The second version of the GUI has been developed using MATLAB®

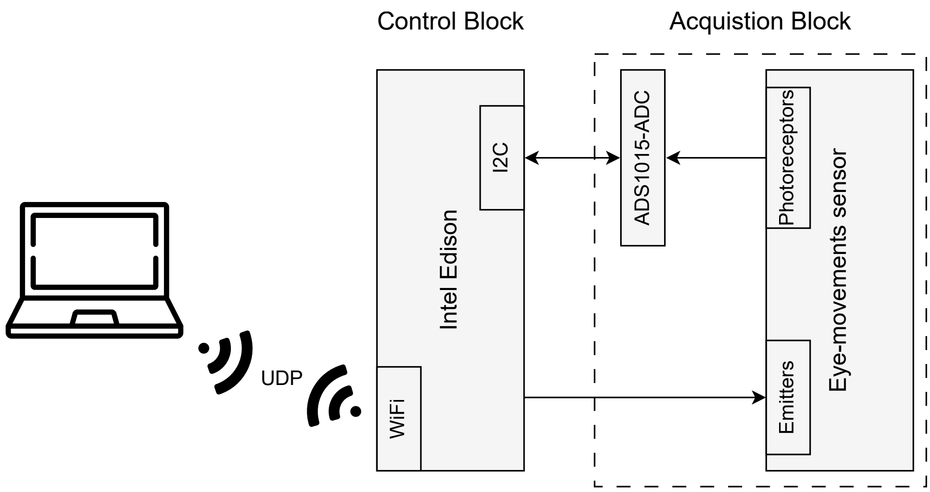


Figure 4.6: Electronic block diagram of NeuroSafety. The acquisition block is composed of the eye movement sensor and the ADS1015-ADC. The ADC reads the data from the infrared photoreceptors and transmits them via the I2C bus to the control block which is made up of the Intel Edison SoC. Once the control block receives the data from the ADC, the WiFi module integrates in the SoC sends the data to a PC using the UDP protocol to real-time data visualization.

software. This version of the interface is intended for an end user and is responsible for real-time data acquisition and processing (Figure 4.7B). Both data acquisition and processing are performed in Java and C/C++. Data acquisition is done in the same way as for the first version of the GUI. The only difference is the incorporation of software to do the data processing of the eye movement sensor in real-time. This processing is based on the use of the saccadic eye movements to monitor the operator's psychophysical state, similar to the work presented in [31].

### 4.3.3 Studies based on NeuroSafety

In this section we present a brief summary of the main results that have been taken for the validation of the first version of the NeuroSafety prototype.

#### Validation of the NeuroSafety prototype (eye movement sensor) with standard calibration measurements

The main contribution of this work was to determine the error level of the eye movement sensor incorporated in NeuroSafety. We performed a standard calibration test of eye movement devices [97] at a distance with the participant of 60 cm and 120 cm respectively. The recorded positions of the gaze points along with the corresponding reference point positions displayed on the screen were transformed from digital values obtained through the ADC of Intel Edison (see Section 4.2.1) to degrees of visual angle (dva) [100]. We used the geometric dimensions of the configuration screen-participant environment to calculate the transformation of the digital values of the ADC, assuming that the direction of the participant's gaze was perpendicular to the middle of the screen in a horizontal and vertical direction. In this way the reference point shown in the center of the screen was the origin of the coordinates (0,0) with which the rest of the angles could be calculated. Subsequently, the error angle in the direction of the gaze was calculated as the difference between the direction to the target point and the direction to the gaze point recorded during the participant's fixation on the target point. The results obtained show that the average errors at 60 cm and 120 cm (Figure 4.8) are 1.8953 dva and 0.9548 dva respectively, which when compared to a commercial eye movement device [97], demonstrate that the sensor we have been developed and integrated into NeuroSafety can be used as a low-cost eye movement sensor bearing in mind that there are assumed errors that may be due to the design of the device itself or the movement of the participant.

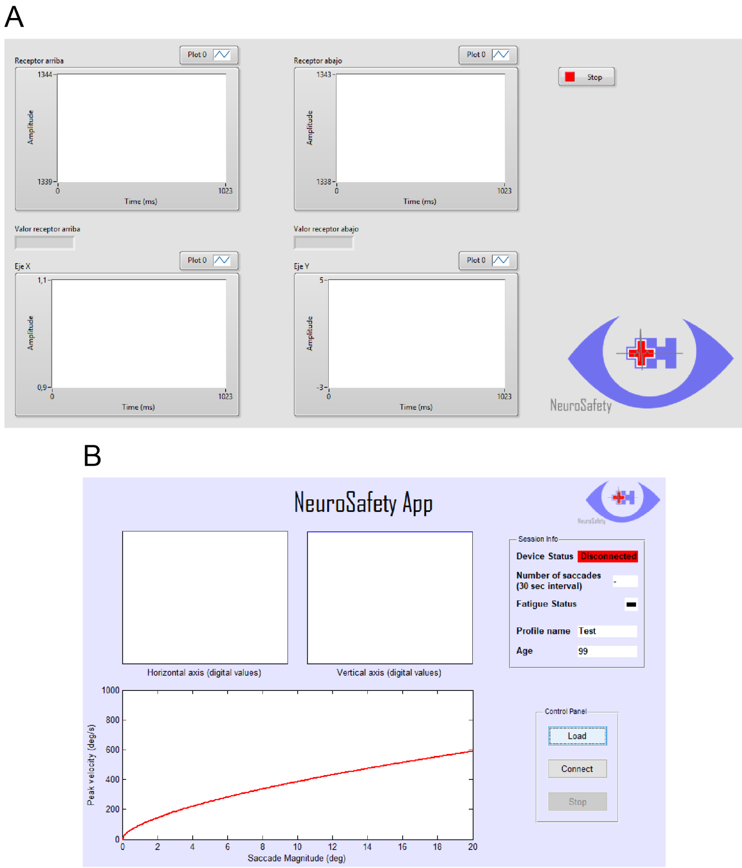


Figure 4.7: Software developed for real-time data visualization of eye movement signals of NeuroSafety. **A)** Application developed using LabVIEW software. The two upper graphs (receptor arriba y receptor abajo) show the raw value from the ADS1015 (digital value). The two lower graphs (eje x, eje y) show the calculated x and y-value of the eye in digital values. **B)** Application developed using MATLAB® software. The two upper graphs (horizontal axis y vertical axis) show the average position of the horizontal and vertical values in digital values. The graph at the bottom shows an eye movement main sequence [31] which is calculated every 30 seconds to obtain the psychophysical state of the operator. Finally, the boxes on the right show information associated with the session (device on/off, number of saccadic movements detected in the 30-second interval, name of the operator and age).

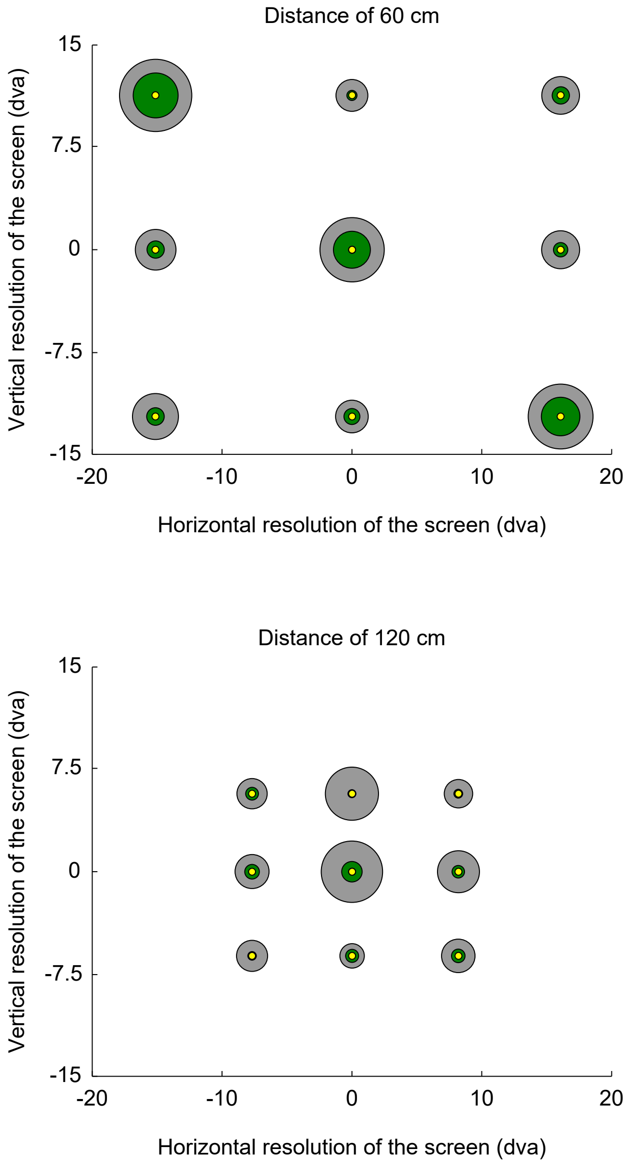


Figure 4.8: Fixation error calculated for 11 points (the central point appeared 3 times) which are displayed on screen at a distance of 60 cm (upper part) and 120 cm (lower part) from the participant eyes. Yellow dots indicate the position where the fixation point were shown. Green circles show (calculated individually for each fixation point) the average of the fixation error. Grey circles represent the maximum value of fixation error (after outliers filtering).

# Chapter 5

# Conclusions

This chapter offers a summary of the main contributions, application fields and future work of the thesis. This multidisciplinary thesis, which has mainly covered two fields of study related to information and communication technologies and ergonomics and human factor, has been written as an article-thesis. It proposes the use of low-cost devices based on realistic measures (EEG and eye movements) to monitor the psychophysical state of the operator (mental under/overload situations), a problem present in many facets of our daily life and in the environment of any worker and that can cause accidents of varying severity, even fatal (see Chapter 1). After studying the state of the art (see Chapter 2), we were able to identify important limitations of the existing commercial devices, such as lack of scientific validation or too high prices. Hence, this work presents both the previous laboratory and real environment studies needed to ensure scientific evidence of the effectiveness of sensors and measures, and the development of the prototype of a device based on the previously validated aspects.

The main contributions of the works included in this thesis are four. Of these four contributions, three are related to the first objective of the thesis and one to the second objective:

- Firstly, the MindWave was compared under simple conditions which are prototypical of the research settings. The MindWave obtained good qualitative results, and acceptable quantitative results. In spite of the noise limitation of the device, it offered stable recordings even over long periods of time. The results obtained by the MindWave are comparable to those obtained with a medical-grade ambulatory device, except for a potential calibration error and spectral differences at low frequencies. Nevertheless, since the recordings are stable, the device is suitable for self-controlled experiments. Hence, the feasibility of using a low-cost, single dry electrode EEG wearable device to collect quality information is demonstrated. These measures can be used to assess the cognitive state of the operator.

- Moreover, we tested the validity of EEG-based technology as a measure of the cognitive state in applied settings. According to the results, the tested technology (MindWave) meet several neuroergonomics criteria to be considered as an ideal measure. Concretely, it met two of the main requirements: (i) sensitivity: it was sufficiently sensitive to reveal significant variations in the cognitive state; and (ii) non-invasiveness: the EEG recordings did not interfere with task performance, not even when several devices were being used simultaneously to study the interconnectivity between different operators. Two main test environments were used to obtain these results: monitoring changes in mental state (from alertness to fatigue) during simulated driving, and quantifying mental workload in surgeons in real scenarios. Furthermore, we used the saccadic velocity, which is a common index to monitor fatigue at the wheel, as a standard reference measure in the simulated driving environment. This allowed us to corroborate the coherency of the EEG measures with the saccadic eye movements. To sum up, our results suggest that the MindWave device can provide a sensitive real-time non-invasive measure of variations of the psychophysical state.

- In addition, a significant amount of valuable scientific findings (validation of brain activity and eye movements as measures to evaluate the mental state of the operator, verification of the measurements of a low-cost EEG device against a gold standard, fatigue monitoring in drivers in a simulated environment and monitoring of mental overload in surgeons in a real environment) has been obtained and published in JCR international journals and conferences. Thus, providing the relevance of the conducted researches and of the outcomes and conclusions derived from them.

- Finally, these results support the usefulness of the development of a low-cost non-invasive wearable device prototype (NeuroSafety, see Section 4.2), based on commercial-off-the-shelf sensors, to gather different psychophysiological measures and, therefore, allow monitoring the operators' cognitive state, detecting risky situations in real-time, in an attempt to reduce accidental rate.

## 5.1 Applications fields

Some fields in which all the work done throughout the thesis could be applied are the following:

- Road safety. Fatigue detection as a way to prevent road accidents in order to improve drivers' security.
- Patient safety. Mental overload detection in the operating room to avoid possible accidents.

## 5.2 Future work

In this section we propose future lines of research based on the work developed in this thesis and on the limitations that we have been discovering throughout such development:

- Further work is needed on the development of quality dry electrodes to restrict the signal noise. Although current technology allows data to be obtained with sufficient quality to be studied, it is important to make progress in reducing the noise from this type of electrode in order to lessen the signal processing required, which would help to lose as little information as possible by making the most of the signal.
- Currently, there are no standard methods for signal processing on low-cost devices applied to neuroergonomics. The development of a validated standard method for the processing of these signals would be a great advance that would ease the creation of commercial devices of low-cost and high quality.

In addition to these two future lines of research, we propose the following lines of development to improve NeuroSafety:

- Integration of the MindWave EEG sensor in NeuroSafety. In addition, the possibility of connecting other sensors belonging to the operator's environment (e.g., movements of a driver's steering wheel) to create a complete operator-environment system is currently being studied.
- Due to the rapid development of electronic components, which increasingly reduce their size, a smaller version of NeuroSafety could be developed using, for example, components such as flexible circuits to obtain an ergonomic device which does not disturb the operators while they perform their tasks.
- Given the recent implementation of technologies such as 5G that promises a bandwidth of up to 20Gbps and a latency between 1 and 2 milliseconds, the device could be connected to the cloud to be able to analyze NeuroSafety data in real-time, with the consequent reduction of the

device final size since it would only be necessary to incorporate a microcontroller to manage the data collection from the different sensors and a 5G module to send the data to the network.

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# Appendix A

Rieiro, H., Diaz-Piedra, C., **Morales, J. M.**, Catena, A., Romero, S., Roca-Gonzalez, J., Fuentes, L. J. & Di Stasi, L. L. (2019). Validation of Electroencephalographic Recordings Obtained with a Consumer-Grade, Single Dry Electrode, Low-Cost Device: A Comparative Study. *Sensors*, 19(12), 2808. `https://doi.org/10.3390/s19122808`

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sensors

MDPI

*Article*

# Validation of Electroencephalographic Recordings Obtained with a Consumer-Grade, Single Dry Electrode, Low-Cost Device: A Comparative Study

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**Abstract:** The functional validity of the signal obtained with low-cost electroencephalography (EEG) devices is still under debate. Here, we have conducted an in-depth comparison of the EEG-recordings obtained with a medical-grade golden-cup electrodes ambulatory device, the SOMNOwatch + EEG-6, vs those obtained with a consumer-grade, single dry electrode low-cost device, the NeuroSky MindWave, one of the most affordable devices currently available. We recorded EEG signals at Fp1 using the two different devices simultaneously on 21 participants who underwent two experimental phases: a 12-minute resting state task (alternating two cycles of closed/open eyes periods), followed by 60-minute virtual-driving task. We evaluated the EEG recording quality by comparing the similarity between the temporal data series, their spectra, their signal-to-noise ratio, the reliability of EEG measurements (comparing the closed eyes periods), as well as their blink detection rate. We found substantial agreement between signals: whereas, qualitatively, the NeuroSky MindWave presented higher levels of noise and a biphasic shape of blinks, the similarity metric indicated that signals from both recording devices were significantly correlated. While the NeuroSky MindWave was less reliable, both devices had a similar blink detection rate. Overall, the NeuroSky MindWave is noise-limited, but provides stable recordings even through long periods of time. Furthermore, its data would be of adequate quality compared to that of conventional wet electrode EEG devices, except for a potential calibration error and spectral differences at low frequencies.

**Keywords:** brain activity; electroencephalography; driving simulator; low-cost wearables; NeuroSky® MindWave Mobile headset

## 1. Introduction

Electroencephalography (EEG), since its invention in the early 1900s [1], has been one of the most commonly used techniques for neurological and psychological assessments. Traditionally, EEG measurements have been performed with highly sensitive electronic devices in an attempt to maximize the signal-to-noise ratio, and using multiple electrodes (32, 64, 128, or more—usually reusable—embedded in a stretch-lycra electrode cap or pasted to the scalp). Typically, these expensive devices (with prices ranging from $5,000 to $50,000) restrict data collection to controlled laboratory environments, requiring participants to be physically tethered to them. Furthermore, they involve extensive training and experience for experimental setup and data collection [2,3].

Starting in the seventies, neuroscientists and neural/biomedical engineers have leveraged the potential of this technique in more applied settings, including brain computer interface (BCI) applications [4,5]. However, despite early interest to explore brain activity in more realistic contexts, for example to improve workplace safety [6] or to assess sleepiness during day and night work [7], EEG has only slowly gained traction in real-world settings [8,9], mainly due to the bulkiness and cost of the equipment. Nevertheless, in the past ten years new EEG devices [10] and processing algorithms [11] have appeared that overcome many of these barriers (for a recent review on this topic, see [12]). Their improved design offers simple arrangements that do not limit participants' behavior and are easy to set up by researchers and general public, as they require little to no training [13–15]. Recent advances in dry electrodes technology have facilitated the recording of EEG in situations not previously possible [16,17]. Finally, their cost (from $99 to $500) has also become highly competitive, which makes these new EEG devices easily accessible to a wide commercial market, pushing BCI towards mass consumer adoption [18]. However, the functional validity of the EEG signal acquired with low-cost neurotechnologies is still under debate [19], and the quality (accuracy and reliability) of the data acquired with most of these low-cost EEG devices have not been fully proved yet [20].

The NeuroSky® MindWave Mobile headset (NeuroSky Inc., San Jose, CA, USA, henceforth MindWave) is one of the most popular and affordable (about $99) low-cost EEG devices. Furthermore, the current adoption trend for this device [21–28] makes it imperative to help researchers and final users understand its validity. MindWave's developers claim [29] it is able to measure cognitive functions, such as attentional and relaxation states, with only one passive dry electrode on the forehead, located at Fp1 (left frontal pole). However, quantitative studies of its actual validity for sensitively measuring EEG signals are limited to a manufacturer-provided white paper [29], the assessments carried out by Johnstone and colleagues of the previous version of this device [30,31], and another two works that compared the MindWave with wireless wearable EEG devices [32,33]. Differences in experimental methodology, such as the analysis of raw vs MindWave's processed data, size of the study population (5 vs 20), as well as in recording techniques (simultaneously vs consecutively testing), make a direct comparison of these findings difficult [10]. Thus, results on the functional validity of the MindWave are not conclusive and the question of whether MindWave might be reliable enough to track overall EEG signal remains open (e.g., [32], but see [33]).

Here, we carried out the first, in-depth study of the EEG recording quality of the MindWave device by performing simultaneous recordings with a medical-grade ambulatory electroencephalograph (SOMNOwatch + EEG-6, SOMNOmedics GmbH, Randersacker, Germany). Under well-controlled experimental conditions, we compared EEG signals acquired from virtually the same scalp place (Fp1 vs AF3) while participants performed laboratory tasks (e.g., a resting state task, alternating closed and open eyes). Furthermore, considering the growing interest for implementing tools to monitor cognitive performance in naturalistic environments [9], EEG signals were acquired also during a 1-hour long every-day activity (i.e., a simulated driving task).

The results presented here give an accurate representation of the strengths and limits of the MindWave recording device, and delineate the most appropriate scenarios for its use in scientific applications.

## 2. Methods

### 2.1. Participants

In conformity with the Code of Ethics of the World Medical Association [34] and under the guidelines of the University of Granada's Institutional Review Board (IRB approval #24/CEIH/2015), we recruited 21 active drivers (ten females) between the ages of 20 and 40 (mean age ± standard deviation [SD] = 25.14 ± 4.69 years). All participants were volunteers, had normal or corrected-to-normal vision, and held a valid driver's license. We used medical history of significant head injury or neurological disorder as exclusion criteria. Furthermore, to reduce the influence of other potential confounder variables (e.g., participants not fully rested taking part in the study), we also considered low levels of arousal before the driving task (a score greater than 3 on the Stanford Sleepiness Scale, SSS [35]) as an exclusion criterion. No participants were excluded based on these criteria.

### 2.2. Instruments and Materials

Neurosky® MindWave (NeuroSky Inc., San Jose, CA, USA). This device consists of a single dry electrode (12 mm × 16 mm) placed on Fp1, according to the international 10-20 system [36], which inputs data to a TGAM1 (ThinkGear ASIC Module) integrated circuit. These two elements are mounted on a light headset (90 g). The device uses a monopolar montage with one active site, and employs a pea-sized (~0.8 mm diameter) electrode clipped to the left earlobe as reference. The device samples data at 512 Hz. The MindWave electrodes are made of stainless steel and all connections use shielded cables. Energy is supplied by a single 1.5 V AAA battery (for more details, see Table S1). The manufacturer has rated the device for continuous 8-hour operation on a single battery. Nevertheless, we took the precaution of changing the batteries after every 2 hours of use [37]. The headset uses a wireless Bluetooth connection to send EEG raw data to a recorder platform. We collected the raw EEG data into EDF+ (European Data Format) files using ad hoc LabVIEW (National Instruments Co., Austin, TX, USA) software.

SOMNOwatch + EEG-6 (SOMNOmedics GmbH, Randersacker, Germany). For a fair comparison between devices, we selected the SOMNOwatch + EEG-6 acquisition device (hereafter, SOMNOwatch). Both the MindWave and the SOMNOwatch devices are small, wearable devices, reasonably affordable, intended for applied (clinical or research) studies, and require a short setup time. The SOMNOwatch is generally used to perform ambulatory polysomnography [38] (i.e., to record EEG during sleep at home), and its reliability for sleep staging has been confirmed [39]. It has been used for research purposes as well (e.g., to record EEG in real-life settings [8,40]). Thus, it is robust to movements and noise, as well as artifacts from electrode movement that lead to changes in contact impedance, or even the generation of a triboelectric response on the wires.

This device consists of two small thin boxes (SOMNOwatch and EEG headbox with ten wired electrodes) fastened to the chest with flexible belts. In this setup, it can record EEG, electrooculographic (EOG), and electromiographic data, as well as the position of the body. The device samples data at 256 Hz applying a band pass filter (0.1–80 Hz) (for more details, see Table S1). Impedance was kept below 5 kΩ for all electrodes. We used a monopolar montage with gold cup electrodes (Natus Neurology Incorporated—Grass Products Warwick, Pleasanton, CA, USA) at five active scalp sites: AF3 (right above Fp1), Fpz, C3, C4, and Cz (online reference) placed according to the international 10/20 system [36], and using the left mastoid (A1) as the offline reference. Ground was placed at Fp2. We analyzed the EEG activity of the channel AF3, which is the closest channel to Fp1 (localization of the MindWave electrode, see Figure 1). We recorded vertical and horizontal EOG from the outer canthus of the right eye and below the left eye using a bipolar configuration. The device collects internally the raw EEG data. We used the DOMINO Light software (version 14.0, SOMNOmedics GmbH, Randersacker, Germany) to export raw signals to EDF+ files.

Resting state EEG (no-task condition). We used a resting-state EEG experimental paradigm to analyze brain activity in the absence of any specific task. Thus, we designed a no-task closed eyes/open eyes resting state session: four periods of three minutes each in which participants alternated two closed eyes and two open eyes periods (12 min total). The first period (with the eyes open or closed) was randomly assigned to participants. The participants had to blink rapidly for 5 seconds to signal the start/end of both tasks (the whole eyes open/eyes closed task and the driving task). We used the blinks bouts as biological triggers. A researcher (author C.D.-P.), seating behind the participants, was in charge of giving participants instructions about the changes in periods. The resting state was always performed under no light/sound stimulation. Participants were asked to hold still with their hands resting on their legs and to direct their gaze toward infinity in the direction of a blank wall during the open eyes session.

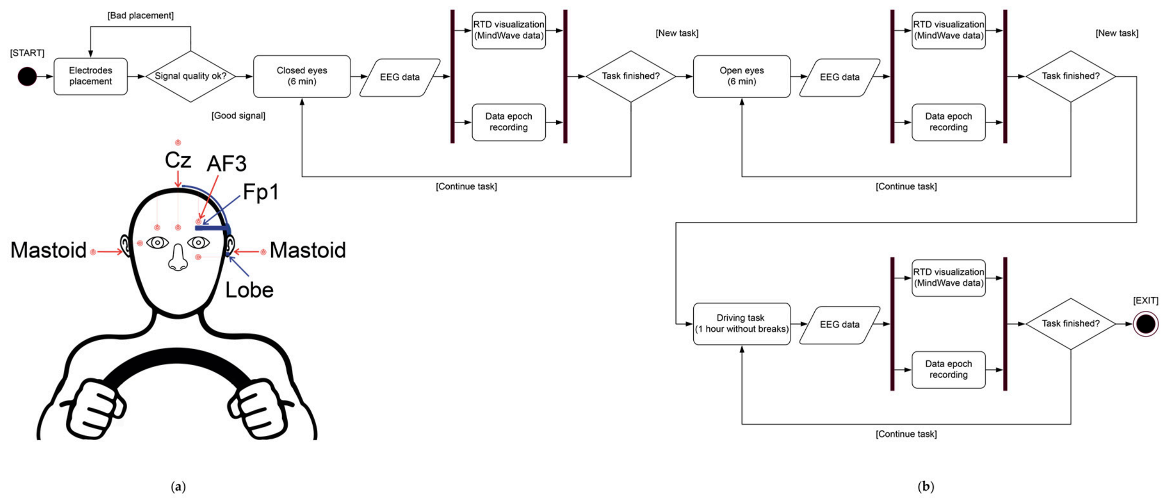



**Figure 1.** Experiment structure. (**a**) EEG recording configuration. Red elements and arrows indicate the electrodes used by the SOMNOwatch device. Blue elements and arrows indicate electrodes used by the MindWave device. (**b**) UML (Unified Modeling Language) activity diagram for the implementation and data acquisition of the experiment. The session started with the placement of the electrodes. After checking the signal quality, EEG data collection started. The experiment started with the resting state task (~15 min) structured as two cycles of task 1 (closed eyes, 3 min each) and task 2 (open eyes, 3 min each). The experiment started with either task 1 or task 2, as the order was random for each participant. Afterwards, the driving task (task 3) started (a 60-minute driving session without breaks). MindWave data was visualized in real time (RTD visualization) for all tasks. Once the three tasks finished, the session ended.

Driving simulator task. We used a 60-minute driving session to analyze brain activity while participants were performing an ecological and dynamic task requiring controlled attention but not excessive mental effort [21]. We developed a two-lane rounded rectangle virtual circuit using the OpenDS 2.5 software (OpenDS, Saarbrücken, Germany). Participants, seating on a car seat (PlaySeat®, Almere, The Netherlands), drove a middle-sized car for one hour without breaks around the circuit in sunny conditions and without any other traffic present. The absence of traffic or intersections minimizes motion artifacts due to head movements, especially in a head-unrestrained condition. To control the car, participants used a Logitech G27 steering wheel (steering wheel with active dual-motor force feedback, gas and brake pedals; Logitech International S.A., Lausanne, Switzerland). Six loudspeakers located around the driver, at about ground level, provided the simulated surround sound of the engine. Speedometer and tachometer gauges were shown in the bottom right of the screen. A speed limit of 60 km/h was set. Each simulation included approximately thirty full laps around the simulated circuit (average number of laps ± SD = 32 ± 3); thus, all subjects saw/heard approximately the same visual/auditory stimuli during the task. We used a video projector (EB-410W, EPSON, Suwa, Japan) to display the virtual circuit on a 1.32 m × 1.63 m screen, about 2.5 m from the driver's eyes (resulting in a view angle of ~30° vertically and ~36° horizontally). During the driving period, the projected image on the wall provided the only light inside the simulation laboratory.

## 2.3. Procedure

The experiment took place in a simulation laboratory (for more details see [41]), located at the Mind, Brain, and Behavior Research Center (Granada, Spain). First, the participant signed the informed consent form. We performed an initial screening to assess inclusion and exclusion criteria and to collect information about sociodemographic characteristics and driving experience. Then, while the participant was seating in a comfortable chair, the pertinent areas of skin were cleaned up with a slightly abrasive paste and alcohol before we placed the electrodes on his/her scalp. Gold electrodes were filled with conductive paste and pasted with collodion. Due to the instability of the MindWave EEG headset, the dry electrode was placed and secured with surgical tape to facilitate the adherence with the forehead skin. To reduce the impedance between skin and electrodes, to the extent possible, we ensured that hairs were put away [42]. Once participants were fitted with the devices and seated in the car seat, they filled in the SSS scale and drove during five minutes to familiarize themselves with the simulator. After that, they started the resting state EEG. Finally, the 60-minute driving simulation started. All participants were told to follow the usual traffic rules, such as keeping their speed below 60 km/h) and to keep the car in the right lane.

### *2.4. Data Preprocessing*

We imported, preprocessed, and analyzed EDF+ files using MATLAB (Mathworks Inc., Natick, MA, USA) (Figure 2). In order to facilitate the comparison between the waveforms of the recordings, we downsampled the MindWave signal from 512 Hz to 256 Hz (same as the SOMNOwatch device). Both signals were filtered using an order 10 Chebychev type II filter, which provides a sharp transition between passband and stopband without causing rippling in the former, to remove spectral components outside the [0.1 Hz, 45 Hz] interval. The recordings were aligned using an information-theoretic delay criterion [43]. We segmented the five periods including the two cycles of closed eyes and open eyes conditions (a 6-minute cycle), as well as the driving period (a 60-minute session).

Before analyzing the quality of the recording (signal-to-noise ratio [SNR] analysis and spectral estimation, see below), a threshold technique was used to identify and remove high-amplitude artifacts (e.g., blinks, eye movements). The 100 ms previous and the 400 ms following each crossing of the positive amplitude threshold were removed from the analysis (enough to reject the full blink waveform). We set the threshold separately for each subject and recording device to the amplitude value corresponding to the top of the 95% confidence interval for the closed eyes period (i.e., the value that was higher than 97.5% of the samples recorded during the closed eyes periods). The obtained thresholds were validated by visual inspection of the open eyes periods. To avoid excessive trimming of the data, we did not count intervals over the amplitude threshold shorter than ten samples as blinks, and therefore we included them in the analysis. Note that, while this methodology will detect other recording artifacts that are not blinks, visual inspection of the data shows that blinks are in fact the vast majority of detected artifacts and we therefore refer to the detected artifacts as blinks elsewhere in this text.

### *2.5. Time Series Analysis*

We used the metric presented by Darvishi [44] to calculate the similarity between the simultaneous recordings, segmented by the different tasks (closed eyes, open eyes, driving task; for each participant, we averaged the values of the metric for the two periods of closed and open eyes). This metric is similar to a cosine metric [45] in that it estimates similarity by measuring the cosine of the angle between two vectors of an inner product space, with a positive value indicating the vectors point in similar directions and negative values vectors in opposite directions. Values close to zero mean near-orthogonality of the signals. This metric adds to the standard cosine metric invariance against phase shifts, making it robust against residual alignment errors either due to imperfections in the alignment algorithm. This invariance also reduces the effect of time-variant misalignments caused by lost data in the RF channel.

Considering two sequences $X = (x_1,x_2, \ldots ,xn)$ and $Y = (y_1,y_2, \ldots ,ym)$, where generally $n \neq m$. Assuming, without loss of generality, $m \leq n$ the Darvishi algorithm takes the following steps to measure the similarity [44] (Equations (1) to (4)):

$$\mu_y = \frac{1}{m}\sum_{i=1}^{m} Y_i, \tag{1}$$

$$X_k = Circshift(X,(-k+1)),\ \mu_{X_k} = \frac{1}{m}\sum_{i=1}^{m} X_{k_i},\ k = 1,2,\ldots,n \tag{2}$$

$$S_k = \frac{\sum_{i=1}^{m}\left(X_{k_i} - \mu_{X_k}\right)(Y_i - \mu_Y)}{\sqrt{\sum_{i=1}^{m}\left(X_{K_i} - \mu_{X_k}\right)^2 \sum_{i=1}^{m}(Y_i - \mu_Y)^2}} \tag{3}$$

$$Sim(X,Y) = \max_{1\leq i\leq n}[S(i)] \tag{4}$$

where $\mu_y$ is the mean of $Y$, $X_k$ is the result of a circular shift operator which circulary shifts $X$ by shiftsize samples, $\mu_{X_k}$ is the mean of $X_k$, $S_k$ is the covariance between $X_k$ and Y, and $Sim(X,Y)$ is the max between the values of $S_k$.

We calculated baseline levels for the similarity metric to approximate the expected metric values for a pair of unrelated but spectrally similar signals. These baseline values allowed us to test the statistical significance of the similarity between the recordings (see Statistical Analysis and Results sections). We estimated the baselines by comparing the SOMNOwatch recording to a random sequence with similar spectral composition, as obtained by the use of autoregressive signal modelling techniques [46].

### 2.6. Spectral Analysis

Power spectrum estimations were performed using the Welch method [47]. For quantitative analysis, we used a Hamming window of 256 samples (1 s), with a 128 sample overlap between segments. Spectrograms were plotted using a 1024 sample (4 s) window with 512 sample overlap.

### 2.7. Signal-to-Noise Ratio Estimation

We quantified the difference in noise levels between the recording devices using an approach based on linear prediction coding, as in Kamel and Jeoti [48] (Equation (5)).

Find $a_0$, $a_1$, $a_p$ such that they minimize

$$e(n) = -\sum_{i=0}^{p} a_i x(n-i),\ a_0 = -1,\ p = 255 \tag{5}$$

Linear prediction coding determines the coefficients of a forward linear predictor by minimizing the prediction error in the least squares sense. $p$ is the order of the prediction filter polynomial, $a = [1, a_{(1)}, \ldots a_{(p)}]$. $x$ is the data of the signal to analyze (SOMNOwatch or MindWave).

We modelled the noise as additive and white, and used linear prediction to separate the flat spectral components from the "shaped" components and estimated the signal-to-noise ratio (SNR) on each second of the recording, and averaging the results across tasks. For the driving task, we also compared the SNRs for the first and second halves of the task, in order to detect any possible degradation of the signal-to-noise ratio during the recordings [17] (see Supplementary Materials).

### 2.8. Blink Recognition

Wearable EEG devices are often used to generate control commands that trigger predefined actions (e.g., mouse clicks) based on easy recognizable signals (i.e., the eye blinks, [49]). Thus, blinking behavior might be used to compare the devices' performance [32,50]. We calculated and compared the blink detection rates among devices and tasks. To recognize blinks, we used the detection algorithm described above.

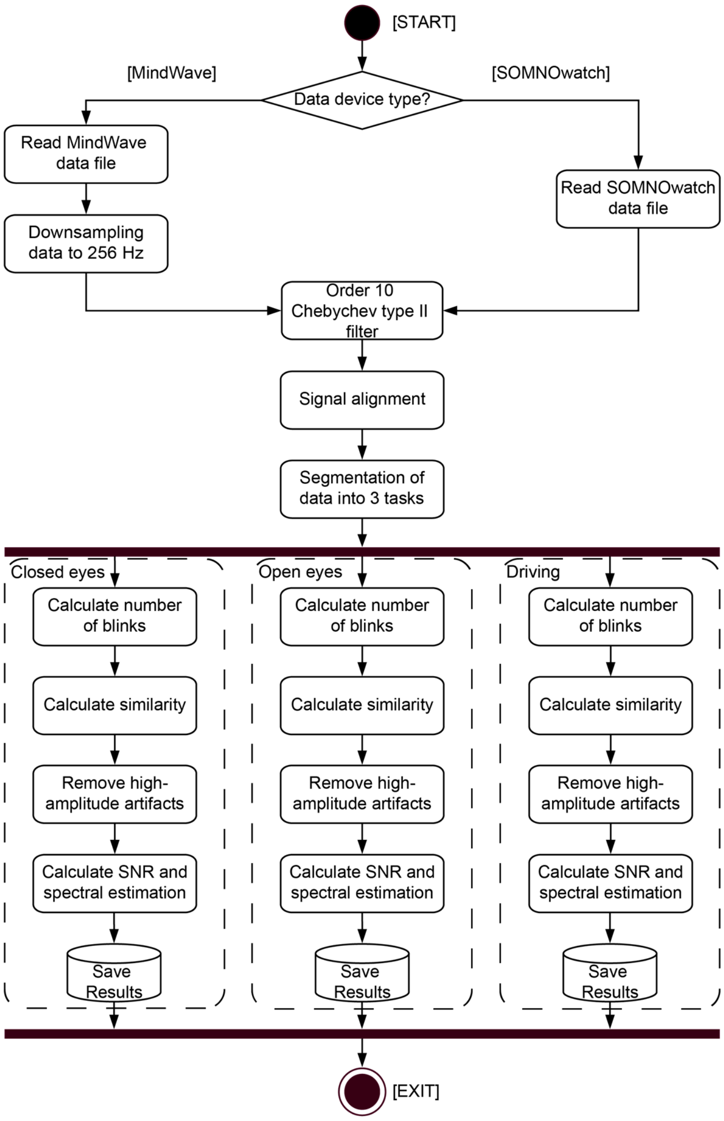



**Figure 2.** Data processing. UML (Unified Modeling Language) activity diagram for the experimental data processing. The process started by checking the device type. For the MindWave, we read the data file and downsampled it to 256 Hz; for the SOMNOwatch, we just read the data file (already at 256 Hz). Next, we applied an Order 10 Chebychev type II filter, followed by a signal alignment. We segmented the data into the three tasks (closed eyes, open eyes, and driving tasks). For each task, we detected blink artifacts, calculated the similarity measure, and removed high-amplitude artifacts, to finally compute the signal-to-noise ratio (SNR) and to perform the spectral estimation. Note that rectangles indicate processes, diamonds indicate decisions, and parallelograms indicate output data.

*2.9. Baseline Comparisons between Recording and Reference Sites*

To exclude the possibility that the above described comparative analyses might be compromised by differences related to (a) recording sites (Fp1 when using the MindWave vs AF3 when using the SOMNOwatch), or to (b) reference sites (the ear lobe when using the MindWave vs the left mastoid when using the SOMNOwatch, Figure 1), we conducted an additional experiment. Five subjects (mean age ± SD = 23.2 ± 1.8 years; three males; no overlap with previous participants) ran a reduced experimental session, which only included the 12-minute resting state task. We performed these new comparisons with the SOMNOwatch.

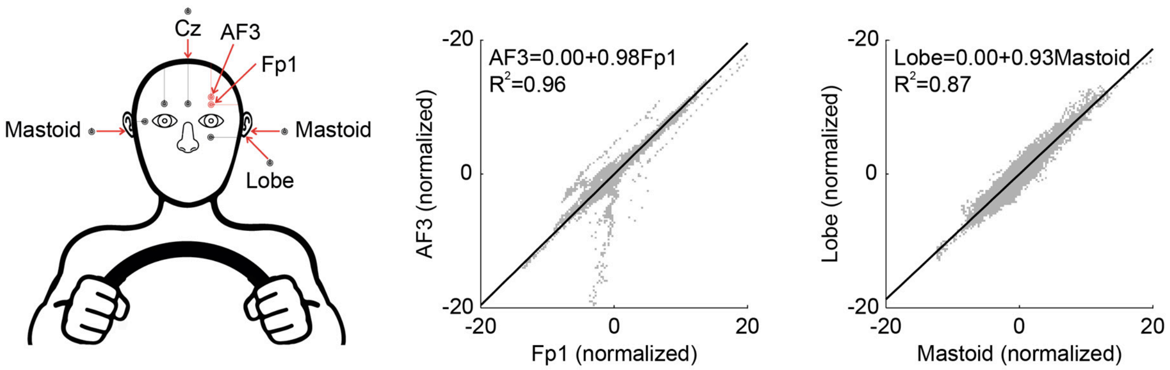
### 2.10. Statistical Analyses

We tested our results using standard statistical techniques, with the alpha level set at 0.05. First, we tested the existence of a significant similarity between the recorded signals with both devices using a repeated measures 2 × 3 analysis of variance (ANOVA). The first factor was the *metric estimated*, with two levels: real (SOMNOwatch vs. MindWave), and baseline (SOMNOwatch vs. a random sequence) (see Section 2.5 for details on the calculation). The second factor was the *tasks* tested with three levels: closed eyes and open eyes conditions, and the driving task. Second, we compared estimated values of the SNR between the two recording devices and between the first and second half of the driving task, using a factorial 2 (*recording device*: SOMNOwatch vs. MindWave) × 2 (*recording period*: first 30 min vs. last 30 min of recording) repeated measures ANOVA. Third, we compared the blink detection rate between the two recording devices and among the three tasks, using a factorial 2 (*recording device*: SOMNOwatch vs. MindWave) × 3 (*tasks*: closed eyes, open eyes, and driving task) repeated measures ANOVA. In both cases, we studied the effects of both main factors and their interactions, and used a Bonferroni correction on the obtained *p*-values to control for multiple comparisons. Fourth, to estimate the reliability of EEG measurements during the two closed eyes periods for each device, we calculated the Spearman correlation coefficients. Finally, we tested the effect of the different SNRs obtained in real measures by studying the discriminability of the Berger effect (the activation of alpha waves during periods with closed eyes [51]) using two-tailed paired *t*-tests. To compare between recording and reference sites, we calculated linear regression models.

## 3. Results

### 3.1. Comparisons between Recording and Reference Sites

Data obtained using different recordings sites ($R^2$ = 0.96; Figure 3b) and different reference sites ($R^2$ = 0.87; Figure 3) were almost identical (for the individual participant data, see Figures S1 and S2). Therefore, in light of these complementary analyses, the possibility that the results described below might have been compromised by the different recording or reference sites seems highly unlikely.




(a) (b) (c)

**Figure 3.** Differences between recording sites (Fp1 and AF3) and reference sites (mastoid and lobe) when recorded with the SOMNOwatch. (**a**) EEG recording configuration. Red arrows indicate the four electrodes' placements of the SOMNOwatch used to compare the data. (**b**) Linear regression model for Fp1 and AF3 when recorded with the SOMNOwatch for five participants. The cloud of points shows the data for each subject first centered (by subtracting the average) and divided by its standard deviation, while the solid line represents the result of a linear regression of the form AF3 = b + g × Fp1. The numerical results for the regression and the correspondent determination coefficient are shown in the graph inset. (**c**) Linear regression model for Mastoid and Lobe references when recorded with the SOMNOwatch for five participants. In this case, the solid line represents the result of a linear regression of the form Lobe = b + g × Mastoid.

### 3.2. Comparisons of Temporal Data Series

In a visual inspection of graphed data, the main differences along the time series resided in the higher noise levels found in the MindWave trace when compared to that obtained with the SOMNOwatch. Additionally, the shape of the blinks was very different, with blinks recorded with the MindWave showing a characteristic biphasic shape. The left panel of Figure 4 shows an example of simultaneous recording in a single participant. Note that while the SOMNOwatch output is calibrated to a microvolt scale, the output from the MindWave is subject to large calibration variations for each individual device, as per manufacturer specifications [52]. The right panel of Figure 4 shows the similarity metric over the recording for the three different tasks. This similarity metric is robust against small residual misalignments, such as the one observable on the left panel of Figure 4 (see Methods section). The values of the similarity metric were consistently above 0.1, indicating a positive correlation between the signals.

The calculated baseline similarities, obtained by comparing the SOMNOwatch recordings to random sequences with similar spectral composition (see Methods section), were significantly lower than the similarities between devices, indicating an actual correlation between both recording devices. We found no significant effects of *task* in the metric, nor an effect of the interaction between the two factors (repeated measures ANOVA, effect of *metric estimated*: $F(1,20) = 589.35$, $p < 0.05$; effect of *task*: $F(2,40) = 2.59$, $p = 0.09$; first order interaction: $F(2,40) = 3.01$, $p = 0.06$).

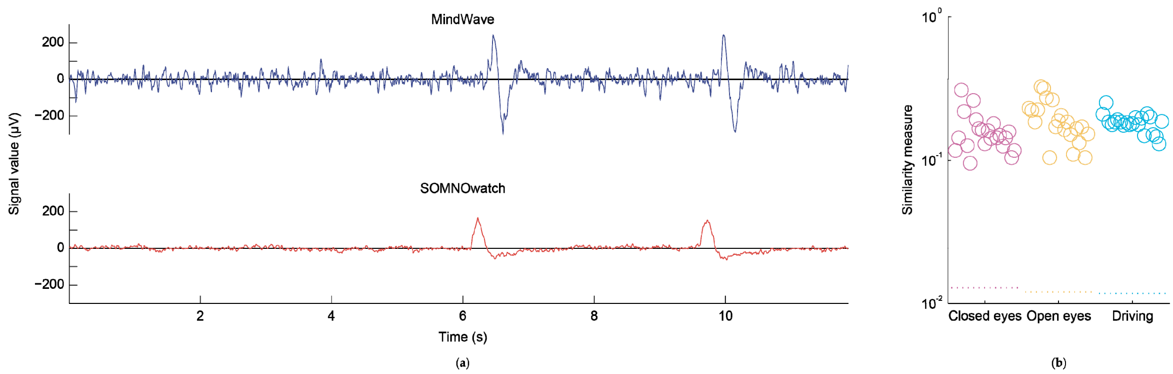



**Figure 4.** Comparison of temporal data series. (**a**) Left panel shows example traces of a simultaneous recording in one participant. The different noise levels and different shape of blinks are easy to observe. (**b**) The right panel shows the similarity measures (open circles) between the recordings for each participant and each of the three separate tasks (closed eyes, open eyes, driving task), as compared to a baseline value (dotted lines at the bottom). The values for each subject are displaced on the horizontal axis for representation purposes.

### 3.3. Comparisons of Spectograms

In a visual inspection of graphed data, spectrograms from both devices were qualitatively similar, although higher noise levels can be observed in the MindWave recording. Figure 5a shows a spectral comparison between the two devices for a random single participant. We also calculated the estimated power spectral density before and after the removal of blinks and artifacts for each task, both for each of the twenty-one participants and on average (Figure 5b). As inferred from the comparison of temporal data series (Figure 4), the SOMNOwatch recordings had generally lower amplitudes. Nevertheless, the curves are fundamentally parallel for frequencies above 4 Hz. For frequencies below 4 Hz, the spectrum is quite different for both devices, with the MindWave showing a peak around 3 Hz. The recorded spectra are identical with or without blinks, except for a difference in total power due to the high amplitude of eye-related artifacts, and for blinks alone (Figure S3). The spectra are also consistent throughout the recording (Figure S4).

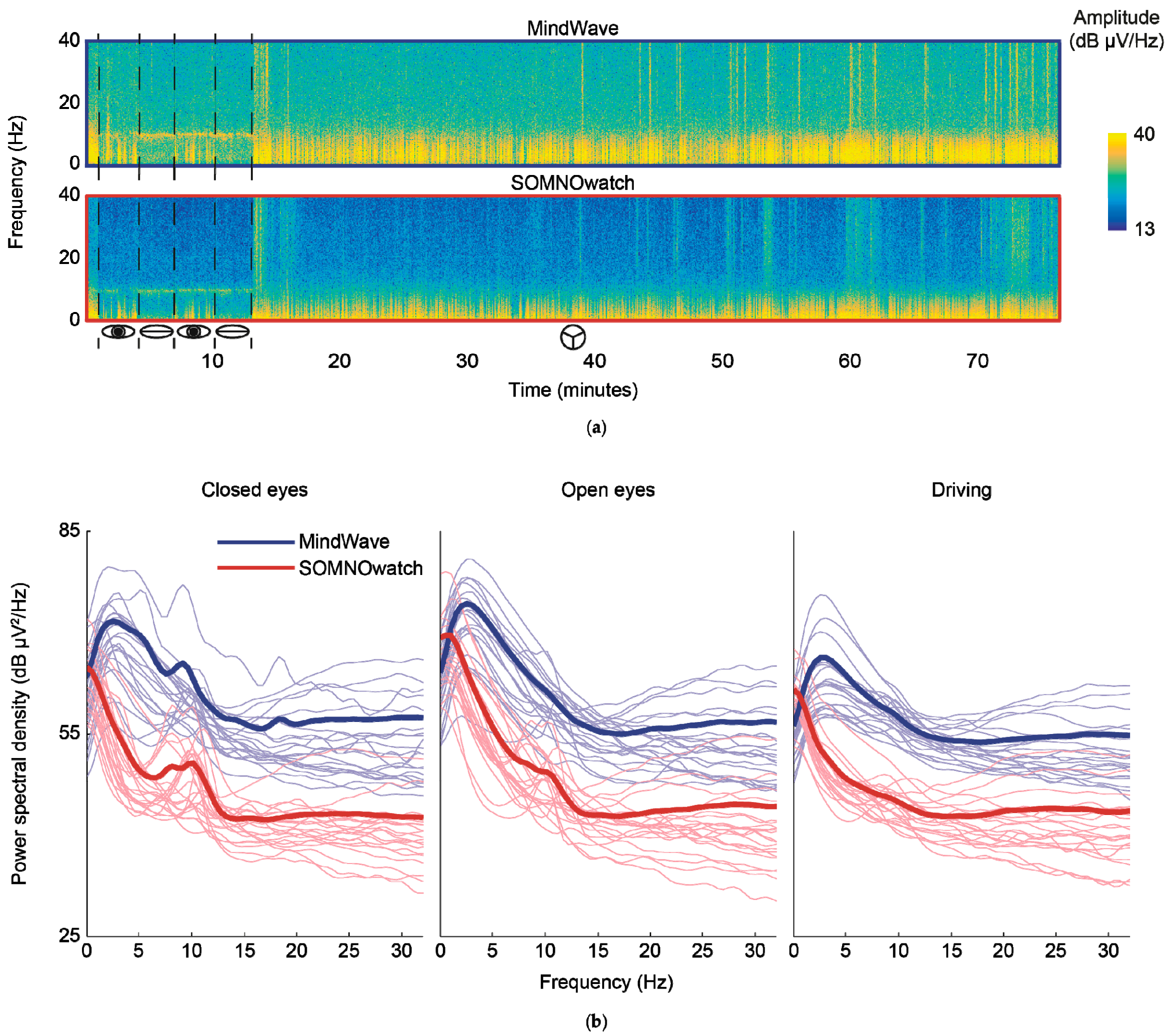



**Figure 5.** Spectral comparison between recording devices. (**a**) Spectrograms of the simultaneous recordings, in a single participant, with the two acquisition devices. The different tasks (open eyes, closed eyes, and the driving task) are delineated in the temporal axis. While the recordings are qualitatively similar, a higher level of noise can be appreciated in the MindWave data. (**b**) Power spectral densities obtained from the closed eyes (**left**), open eyes (**center**), and driving (**right**) tasks. Thin lines show individual participants, thick lines the average result. The devices differed in their response at lower frequencies, as evidenced by the MindWave peak around 3Hz.

### *3.4. Comparisons of the Blink Detection Rate*

To test if the blink detection rate was different between the two recording devices and among the three tasks, we carried out a repeated-measures ANOVA, Bonferroni corrected. The SOMNOwatch detected 6% more blinks than the MindWave, but such difference was not significant, effect of the *recording device*: $F(1,20) = 1.14$, $p = 2.99$. The effect of the *task* was significant, $F(2,40) = 36.60$, $p < 0.001$. As expected, the blink detection rate was statistically lower in the closed eyes task (mean ± SD = 0.15 ± 0.08) than in the open eyes task (mean ± SD = 0.53 ± 0.32), and both detection rates were lower than on the driving task (mean ± SD = 0.87 ± 0.41); all corrected $p$-values <0.05. The interaction between *recording device* and the *task* was also significant, $F(1.23,24.57) = 4.10$, $p = 0.046$. However, post hoc analysis of this interaction were not significant. Figure 6 illustrates the shape of the blinks recorded with both devices, as well as the advantage of the SOMNOwatch in blinking recognition.

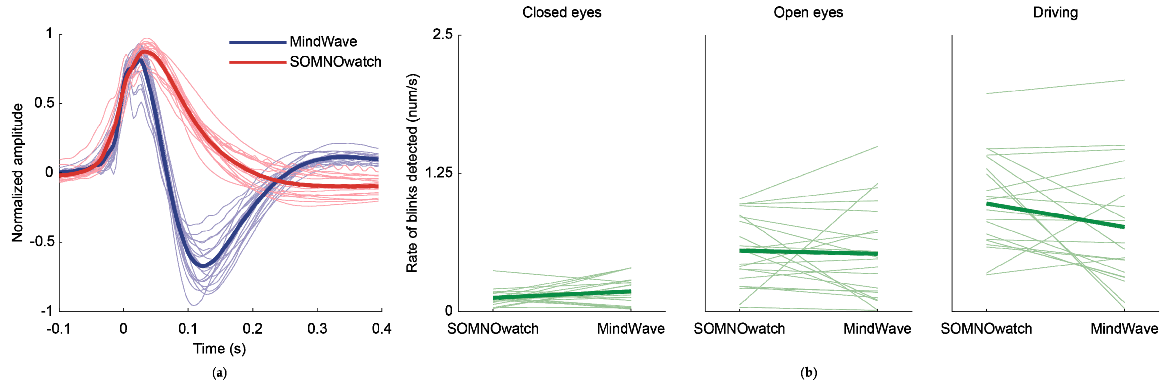



**Figure 6.** Waveform and rate of detected blinks. Average waveforms and blink detection rate for each individual participant ($N = 21$, thin lines) and the population mean (thick lines). (**a**) Average waveform, with the timepoint of crossing the amplitude threshold (see Methods section) aligned to zero. Amplitudes of individual artifacts are normalized to a maximum value of 1. The different shape of blinks is apparent. (**b**) Blink detection rate obtained from the closed eyes (**left**), open eyes (**center**), and driving (**right**) tasks. Thin lines show individual participants and thick lines are the average result.

### 3.5. Comparisons of the Recording Quality

In order to further quantify the differences between the recordings, and specifically the effects of noise in the recorded signals, we estimated and compared the SNRs between both devices (see Methods section, Figure 7). Figure 7b shows a comparison of the estimated SNRs per each participant for both recording devices (thin lines) for each task. There was a loss of 2 dB in SNR on average between the recording devices, as denoted by the thick green line. To test if there was a degradation in recording quality, we also compared the first and second half of the driving (i.e., first 30 min vs. last 30 min of recording) task in both devices, finding no significant differences. We tested both the effect of the *recording device* and the *recording period* using a repeated-measures ANOVA, Bonferroni corrected, effect of the *recording device*: $F(1,20) = 44.35$, $p < 0.05$; effect of the *recording period*: $F(1,20) = 0.54$, $p = 0.47$; first order interaction: $F(1,20) = 0.07$, $p = 0.79$) (see Figure S4).

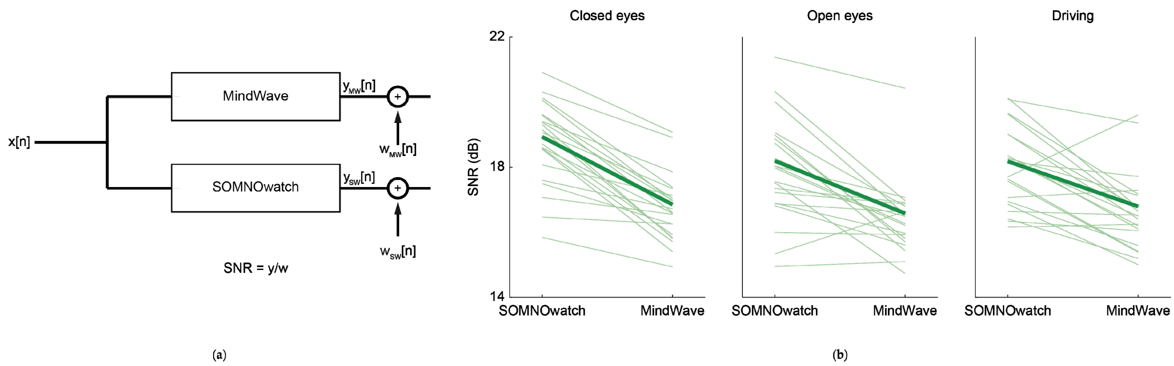



**Figure 7.** Signal-to-noise ratio (SNR) estimation. (**a**) Additive white noise model employed for the estimation of the SNR. The physiological signal $x$ is filtered by the impulse response, resulting in filtered signal $y$, of both recording devices, at which point white noise ($w$) is added, resulting in the recorded signals. The SNR is defined as the ratio between the power of the filtered signal and the power of noise. (**b**) Results for each participant (thin lines) and average (thick line) the closed eyes (**left**), open eyes (**center**), and driving (**right**) tasks. SNR for the SOMNOwatch is on average 2 dB above that of the MindWave.

Furthermore, we analyzed how this difference in SNR affected a simple, standard EEG analysis such as differentiating between open and closed eyes states [51]. We calculated the power on the alpha band (8–12 Hz) for both periods and compared the results using a paired $t$-test. Both differences were significant. For the MindWave, $t(17) = 2.11$, $p = 0.049$, and for the SOMNOwatch, $t(17) = 3.49$, $p = 0.002$. Figure 8 shows normalized alpha waves for both devices during the periods of closed and open eyes. For a summary of results, see Table 1.

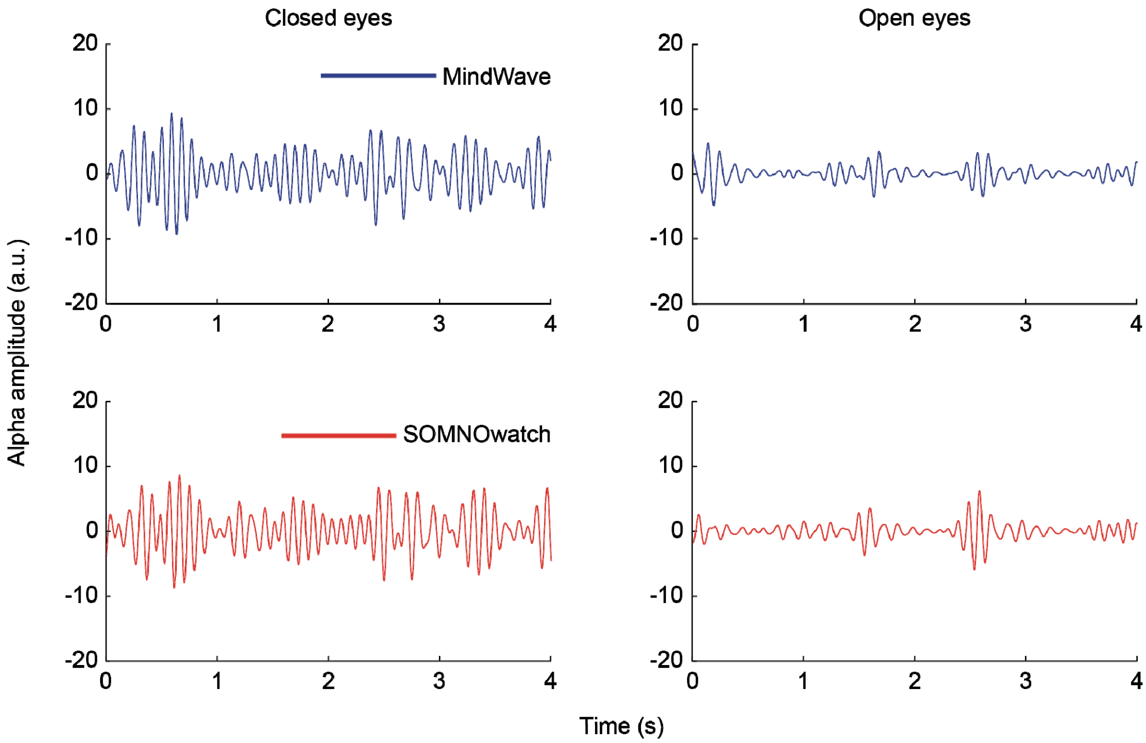



**Figure 8.** Normalized alpha waves as simultaneously captured by both devices during periods of closed eyes and open eyes. Alpha waves were separated from the rest of the signal using a 10th-order Chebychev filter. The alpha amplitude is clearly increased in closed eyes periods.

**Table 1.** A summary of statistical results comparing recording and reference sites (1), similarity (2), signal-to-noise ratio (SNR) (3), blink detection (4), reliability (5), and spectral analysis (6).

| | |
|---|---|
| **1. Similarity between the recording and reference sites** | |
| Are Fp1 and AF3 as recording sites analogous? | Yes, $R^2$ (AF3 = b + g × Fp1) = 0.96 ($p < 0.001$) |
| Are the left mastoid and the left lobe as reference sites analogous? | Yes, $R^2$ (Lobe = b + g × Mastoid) = 0.87 ($p < 0.001$) |
| **2. Similarity between the recordings** | |
| Are similarities between devices greater than similarities between the SOMNOwatch recording and a random sequence? | Yes, $F(1,20) = 589.35$, $p < 0.05$ |
| Do similarities between devices depend on the tasks? | No, $F(2,40) = 2.59$, $p = 0.09$ |
| **3. SNR: Degradation in recording quality** | |
| Is SNR different between the two recording devices? | Yes, $F(1,20) = 44.35$, $p < 0.05$ |
| Is SNR different between the first and the second period? | No, $F(1,20) = 0.54$, $p = 0.47$ |
| **4. Blink detection rate** | |
| Does blink detection rate differ between the two recording devices? | No, $F(1,20) = 1.14$, $p = 2.99$ |
| Does blink detection rate differ depending on the tasks? | Yes, $F(2,40) = 36.60$, $p < 0.001$ |
| **5. Signal reliability: closed eyes periods** | |
| Is the EEG signal from the MindWave reliable? | Yes, $r_s = 0.71$ |
| Is the EEG signal from the SOMNOwatch reliable? | Yes, $r_s = 0.95$ |
| **6. Spectral analysis: Berger effect** | |
| Does the amplitude of EEG oscillations in the alpha band differ between open and closed eyes tasks for the MindWave? | Yes, $t(17) = 2.11$, $p = 0.049$ |
| Does the amplitude of EEG oscillations in the alpha band differ between open and closed eyes tasks for the SOMNOwatch? | Yes, $t(17) = 3.49$, $p = 0.002$ |

## 4. Discussion

We assessed the recording quality of the MindWave by performing simultaneous recordings with the SOMNOwatch, a traditional, medical-grade ambulatory device, and comparing the signals acquired with both devices during the performance of laboratory tasks. In a single assessment session, we recorded participants' brain activity at Fp1 (AF3 in the case of the SOMNOwatch, see Figure 1) during a closed eyes/open eyes task and a driving simulation. We evaluated the recording quality of each device comparing the temporal data series, the spectra, the SNR, the amplitude of EEG oscillations in the alpha band, their reliability, and the blink detection rate. Whereas qualitatively the MindWave signal presents higher levels of noise and a biphasic shape of blinks, the similarity metric indicates that signals from both recording devices are indeed correlated. Moreover, the blink detection rates do not differ between the two recording devices, the amplitude of EEG oscillations in the alpha band are, as expected, different between closed eyes and open eyes for both devices, and signals coming from both devices can be considered reliable (correlating both closed eyes periods), even though reliability is lower for the MindWave. Quantitatively, the main difference between the acquired signals comes from their spectral differences at lower frequencies (<4 Hz) as well as the degradation that MindWave introduces in the SNR.

The most salient difference is the attenuation that the MindWave device introduces at the low frequency components (<4 Hz). This power reduction is identical when considering the full recording, the recording without blinks, and the spectrum of blinks alone. This fact suggests that this is caused by the spectral (linear) properties of the combination of sensor and electronics used in the MindWave device, and not due to nonlinear effects, as would have been the case if the power reduction was different with changes in the signal amplitude, such as the ones present in blinks and artifacts. Since eye blinks have spectra with high-amplitude components into the 0.5–3 Hz band [53], we can conclude that this spectral difference is the reason for the different shape of artifacts found (Figure 6a).

Previous validations of the MindWave include a manufacturer whitepaper in which the MindWave is compared to an unspecified Biopac device (BIOPAC Systems, Inc., Goleta, CA, USA), using an unspecified methodology [29]. This whitepaper shows the spectrum acquired with the MindWave having a similar shape to that described here, but it claims that this is due to low levels of low frequency noise and attributes it to the shorter, fixed wiring present on the MindWave. However, the manufacturing company confirmed that the results we were seeing at the low frequency components is due to a high pass filter with a cutoff frequency of 3 Hz, which is embedded in the MindWave device for controlling the low frequency noise (personal communication). Therefore, the MindWave does not actually have a better than average noise figure in low frequencies, but these frequencies are simply suppressed to avoid distortions in the waveform at the expense of lost information in this spectral band. Here, we show in a replicable manner the effect of this filter and the range of frequencies and waveform modifications it produces. Based on these findings, studies especially interested in assessing the power of the delta band (e.g., [21]) should consider that the MindWave device might not be sensitive enough to obtain reliable spectral values in these frequencies. The spectra of the recordings are otherwise similar to those obtained with the reference SOMNOwatch device, indicating good performance outside the delta band.

Our results also show that the MindWave has a lower SNR than the reference medical-grade ambulatory device used, the SOMNOwatch. The performance of a BCI application—or any EEG configuration for research—depends on its SNR. Thus, the degradation the MindWave device introduces in the SNR is another main limitation. Researchers using the MindWave would need to plan a substantially larger number of trials [54] to counteract this lower SNR in order to obtain valid conclusions and avoid biased interpretations [55]. It is unknown whether this signal degradation occurs because of the device electronics or as a result of the limitations imposed by dry electrodes [17]. Even though dry electrodes simplify the setup procedures, are standard to many BCI applications [56] and have reached a good quality level [17], their performance is still under debate [57] as they might be more susceptible to physiological artifacts, especially due to sweat gland activity or skin stretch affecting impedance [42]. There are several possibilities to address this limitation, such as incorporating improved dry electrodes (e.g., silver plated electrodes) to the MindWave design, or to create a headset able to provide a constant force to press the electrode against the forehead.

The results of blink detection rate show that the levels of detection were similar for both devices. This result might contradict previous works about the inadequateness of the MindWave device for blink-based tasks (e.g., [32]). Differences in MindWave models; for example, the device tested by Maskeliunas and colleagues (2016) [32] had a different sampling rate (128 Hz instead of 512 Hz), might partially explain this apparent incongruence.

Finally, to our knowledge, no previous studies of EEG comparison have been conducted in ecological or naturalistic situations, such as the one employed here (i.e., driving simulation). Thus, a comparison with the few previous works might not be straightforward. However, our results seem to expand the preliminary conclusions on the validity of this device for applied uses found on a reduced sample size ($n$ = 5) [33], and to corroborate the original assessments carried out by Johnstone and colleagues [30,31]. Thus, the MindWave, while limited in terms of recording channels, might have potential value in certain EEG recording situations (e.g., [21,22]). Furthermore, our results support the preliminary observations made by [58] about the stability of the EEG signal over time in ecological everyday activities, such as a driving task.

The presented discussion must be seen in the context of three shortcomings related to the experimental methodology we used to implement the comparison: the improved overall stability of the MindWave headset, the lack of a measure of acceptability by the users, and the reduced set of compared devices. First, to facilitate the adherence between the MindWave headset and the forehead skin, we placed and secured the dry electrode with surgical tape. This solution, obtrusive and not user-friendly, might have improved the performance of the device and the quality of the recorded signals. Thus, our results should be considered in light of this technical adjustment made to ensure a constant pressure of the dry electrode against the forehead. Second, we did not provide a quantification of the overall participants' acceptability of the investigated devices. Although our research questions were not motivated to study the final acceptance of this device, future studies should consider this subjective dimension for a holistic evaluation of the BCI tools [17]. Finally, we did focus only on one BCI device. Nowadays, several (more sophisticated and powerful) wearable EEG headsets have been introduced on the market. Whereas we focused on the MindWave for its specific features (ease-of-use and lower cost), future studies should compare the quality of the EEG signal obtained simultaneously from several devices. Although several technical issues to solve would remain (e.g., recording simultaneously from the same location with more than two devices), it is worth working in this direction.

Overall, despite the limitations presented above, and acknowledging the need for some precautions, the MindWave has great potential that can be exploited with studies conducted in the laboratory as well as in real-world settings. Frontopolar cortex activation (in particular of the Fp1 area) is modulated by a wide range of experimental paradigms related to memory, perception (somesthesis), and motor learning [59,60]. Some practical advantages include the possibility of simultaneous recordings and a simple setup procedure for patients and other special populations (e.g., children, e.g., [23]). The stability of the recordings and the fact that the device has good linearity makes it an appropriate device for within-subjects comparisons, and for experiments in which controlled measurements are acquired with a MindWave as well (e.g., [21]). On the other hand, spectral limitations, together with the lack of precise calibration, may cause problems when comparing absolute results obtained with a MindWave with other studies in the literature, especially if comparing the power across different power bands. Additionally, the MindWave's low signal-to-noise ratio needs to be taken into account when designing experiments and measurements employing this device, since this reduced SNR will affect the effect size and therefore statistical power.

## 5. Conclusions

Wearable EEG-based BCI devices, thanks to technological developments in dry electrodes and lowering prices, are now receiving considerable attention as potential research tools inside and outside the laboratory setting [16,17], especially in the gaming industry (e.g., [61]). Furthermore, their cost might enable a wide range of studies (e.g., involving low-income countries as well) that were not previously possible. Motivated by these considerations, we conducted a concise comparison under simple conditions that are prototypical of the basic and applied research settings in which the MindWave tends to be primarily used (e.g., [21]). The MindWave, with specific technical adjustments (see Procedure section), provides good qualitative results, and acceptable quantitative results, especially when the cost of the device is taken into account. The device is noise-limited, but provides stable recordings even over long periods of time. The results obtained are comparable to those obtained with a medical-grade ambulatory device, except for a potential calibration error and spectral differences at low frequencies. Still, since the recordings are stable, the device is valid for self-controlled experiments.

**Supplementary Materials:** The following are available online at http://www.mdpi.com/1424-8220/19/12/2808/s1, Figure S1: Differences between Fp1 and AF3 when recorded with the SOMNOwatch. Dummy in the left upper corner represents the electrode placement used. The scatter plots show samples acquired using Fp1 and AF3 on the SOMNOwatch. The data is presented for each subject individually. The cloud of points shows the individual samples, while the solid lines represent the result of a linear regression of the form AF3 = b + g × Fp1. The numerical results for the regression and the correspondent determination coefficient are shown in the graphs insets. Figure S2: Differences between references (mastoid and lobe) when recorded with the SOMNOwatch. Dummy in the left upper corner represents the electrode placement used. The scatter plots show Fp1 signals referenced to the left mastoid (A1, the reference used by the SOMNOwatch) and the ear lobe (the reference used by the MindWave). The data is for each subject individually. The cloud of points shows the individual samples, while the solid lines represent the result of a linear regression of the form Lobe = b +g × Mastoids. The numerical results for the regression and the correspondent determination coefficient are shown in the graphs insets, Figure S3: Waveform and spectra of detected blink artifacts. Average waveforms and power spectra for each individual participant (N = 21, thin lines) and the population mean (thick lines). (a) Average waveform, with the timepoint of crossing the amplitude threshold aligned to zero (see Methods section). Amplitudes of individual artifacts are normalized to a maximum value of 1. The different shape of blinks is apparent. (b) Power spectral density of detected artifacts. The shape of artifacts recorded on both devices matches that found on the full recordings, Figure S4: Spectra and signal-to-noise ratio (SNR) for the first and second half of each recording (one-hour driving task). Each period has a length of approximately 30 min. (a) Power spectral density, after blink removal, obtained with both recording devices. (b) Estimated SNRs for each participant (N = 21, thin lines) and on average (thick lines). Both measurements are stable between recordings, Table S1, Technical specifications of the MindWave and the SOMNOwatch + EEG-6 systems.

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# Appendix B

**Morales, J. M.**, Diaz-Piedra, C., Rieiro, H., Roca-González, J., Romero, S., Catena, A., Fuentes, L. J. & Di Stasi, L. L. (2017). Monitoring driver fatigue using a single-channel electroencephalographic device: A validation study by gaze-based, driving performance, and subjective data. *Accident Analysis & Prevention*, 109, 62-69. `https://doi.org/10.1016/j.aap.2017.09.025`

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**Title:** Monitoring driver fatigue using a single-channel electroencephalographic device: A validation study by gaze-based, driving performance, and subjective data

**Running head**: Detecting driver fatigue using a single-channel EEG device

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**Abstract**

Driver fatigue can impair performance as much as alcohol does. It is the most important road safety concern, causing thousands of accidents and fatalities every year. Thanks to technological developments, wearable, single-channel EEG devices are now getting considerable attention as fatigue monitors, as they could help drivers to assess their own levels of fatigue and, therefore, prevent the deterioration of performance. However, the few studies that have used single-channel EEG devices to investigate the physiological effects of driver fatigue have had inconsistent results, and the question of whether we can monitor driver fatigue reliably with these EEG devices remains open. Here, we assessed the validity of a single-channel EEG device (TGAM-based chip) to monitor changes in mental state (from alertness to fatigue). Fifteen drivers performed a 2-hour simulated driving task while we recorded, simultaneously, their prefrontal brain activity and saccadic velocity. We used saccadic velocity as the reference index of fatigue. We also collected subjective ratings of alertness and fatigue, as well as driving performance. We found that the power spectra of the delta EEG band showed an inverted U-shaped quadratic trend (EEG power spectra increased for the first hour and half, and decreased during the last thirty minutes), while the power spectra of the beta band linearly increased as the driving session progressed. Coherently, saccadic velocity linearly decreased and speeding time increased, suggesting a clear effect of fatigue. Subjective data corroborated these conclusions. Overall, our results suggest that the TGAM-based chip EEG device is able to detect changes in mental state while performing a complex and dynamic everyday task as driving.

*Keywords*: Brain activity; Driving simulation; Eye movements; Fatigue detector; Low-cost technology; Wearable technology

## 1. Introduction

Electroencephalography (EEG)-metrics are among the most reliable contemporary methods to assess cognitive states (Di Stasi, Díaz-Piedra, et al., 2015). EEG recording devices have dramatically developed in the last ten years thanks to technological progress (Minguillon, Lopez-Gordo, & Pelayo, 2017), making ubiquitous acquisition of brain activity not only possible, but inexpensive (Borghini, Astolfi, Vecchiato, Mattia, & Babiloni, 2014; Picot, Charbonnier, & Caplier, 2008; Wang, Zhang, Shi, Wang, & Ma, 2015). These new devices, which are user-friendly, portable, and low-cost, have increased the use of EEG-metrics in daily-life situations (for a review, see Minguillon et al., 2017), such as driving a car (Morales et al., 2015).

The EEG recording device “TGAM headset” (ThinkGear ASIC module NeuroSky Inc., San Jose, CA, USA) is a single-channel, dry electrode, wireless signal transfer system (see **Figure 1B)** that has received considerable attention from the general public (Dance, 2012; Bilton, 2013) and the neuroscientific community (e. g. Johnstone, Blackman, & Bruggemann, 2012; Rogers, Johnstone, Aminov, Donnelly, & Wilson, 2016) because of its set of features that make it an ideal wearable EEG system: the low intrusiveness of the equipment, the robustness of the sensor technology, and the wireless measurement solution (Gramann et al., 2011). Furthermore, since it has been validated for scientific use for assessing variations in the cognitive state (Johnstone et al., 2012), neural-engineering researchers have started developing EEG-based applications for daily-life (Minguillon et al., 2017), including for road safety (Morales et al., 2015).

Driver fatigue (i.e., under-aroused) is the most critical issue for transportation safety (National Transportation Safety Board, 2017), representing the main cause of motor vehicle crashes and traffic-related deaths (Touryan, Lance, Kerick, Ries, & McDowell, 2016). Wearable EEG-based fatigue monitors have the potential to help drivers to assess their own levels of fatigue (Ko, Lai, Yang, & Lin, 2015) and, therefore, to prevent the deterioration of driving performance (Dawson, Searle, & Paterson, 2014). Given its features, the TGAM headset should be suitable for use as a driver fatigue monitor. Unfortunately, since the pioneer case study by Yasui (2009), the question of whether the TGAM headset can monitor driver fatigue remains open. The few reports that have investigated this issue have not obtained conclusive results (see below), due to the inconsistencies and/or limitations in their methods/research designs. Examples of these limitations include 1) the *use of unfiltered/unprocessed EEG data* (Wan, He, & Voisine, 2013; Lin, Ding, Liu, & Liu, 2015; He, Zhou, Hu, & Wang, 2015; Hsiao, Kitagawa, & Watada, 2015; He, Zhang, Zhang, Zhou, & Han, 2016; Abdel-Rahman, Seddik, & Shawky, 2015; He, Liu, Wan, & Hu, 2014; Lim, Chia, & Chin, 2014), 2) the *use of an imprecise operationalization of the construct* of *fatigue* – often confused with postprandial somnolence –

(He et al., 2014, 2015), and 3) the *absence of (comparative) gold standard indices of fatigue* (Lim et al., 2014). All these limitations have compromised the potential utility of this wearable single-channel EEG device as a fatigue monitor.

Here, we present the first conclusive evidence about the sensitivity and validity of a single electrode EEG device (TGAM-based) as a driver fatigue monitor. We investigated the effects of a 2-hour driving time – a common inducer of fatigue at the wheel (Wijesuriya, Tran, & Craig, 2007; Di Stasi et al., 2012, 2016) – while we continuously monitored drivers' brain activity as well as their saccadic velocity. As saccadic velocity is a well-known fatigue index (Schmidt, Abel, DellOsso, & Daroff, 1979; Galley & Andres, 1996; Schleicher, Galley, Briest, & Galley, 2008; Hirvonen et al., 2010; Di Stasi et al., 2016), we used it as a standard reference measure for fatigue. We also collected driver performance and subjective ratings of alertness and fatigue. We hypothesized that, during the 2-hour driving session, participants would gradually experience higher levels of fatigue. EEG activity, recorded at the prefrontal cortex, as well as saccadic velocity, would reflect this phenomenon. Furthermore, we expected that participants would show poorer driving performance (i.e., increased speeding behavior) as the driving session progressed.

## 2. Material and methods

### *2.1 Ethical Approval*

We conducted the study in conformity with the Code of Ethics of the World Medical Association (WMA, Declaration of Helsinki) (WMA, 1964). The experiment was carried out under the guidelines of the University of Granada´s Institutional Review Board (IRB approval #24/CEIH/2015).

### *2.2 Participants*

Seventeen active drivers (mean age [± standard deviation, SD] = 25 ± 3.45 years, range 22-34; 12 men) volunteered to participate in this study. All participants had normal or corrected-to-normal vision and held a valid driver license (average number years of driving experience [±SD] = 5.94 ± 2.74 years). We asked participants to abstain from alcohol and caffeine-based beverages 24 and 12 hours, respectively, before the driving session. Additionally, they had to get at least 7 hours of sleep the night prior to the study. Thus, for screening purposes, we measured subjective levels of arousal using the Stanford Sleepiness Scale before the driving session (Hoddes, Dement, & Zarcone, 1972) (see below): no participants scored more than 3, had they done so they would have been excluded from further testing (Connor et al., 2002;

Morad et al., 2009; Di Stasi, Díaz-Piedra, et al., 2015). No participants were excluded based on this criterion. Two participants suffered from simulator sickness and did not finish the driving session. Therefore, we finally analyzed data from 15 out of 17 participants (mean age ± SD = 24.33± 2.69 years, range 22-31; 10 men). From three of them, due to log system failures during the recording, we only analyzed performance and subjective data.

### *2.3 Experimental design*

The study followed a within-subjects design with the Time-On-Driving (TOD) as the independent variable. Each experimental session consisted of four consecutive 30-minute TOD blocks (TOD1, TOD2, TOD3, and TOD4) (Di Stasi et al., 2012; Di Stasi, McCamy, et al., 2015). Participants did not rest between TOD blocks. We chose this temporal window to be close to the maximum TOD that professional drivers are allowed before a mandatory break (VOSA, 2009). As dependent variables, we considered several psychophysiological (the EEG power spectra, as well as the saccadic peak velocity while driving), driving performance (the percentage of speeding time), and subjective indices (the perceived alertness and fatigue before and after the driving session).

### *2.4 Driving Simulation and performance*

We used the OpenDS 2.5 software (OpenDS, Saarbrücken, Germany) to create the virtual environment. We developed a two-lane, rounded rectangle (curvature angle of $\pi/2$ rad) road scenario. The road was ~1.5 km long with a width of 8 m, and it was surrounded by an empty and monotonous grassy meadow (see **Figure 1A**). Participants drove a middle-sized car for 2 hours without breaks (i.e. without stopping the vehicle or restarting the engine) around the same road in sunny conditions and without any other traffic present (average number of laps ± SD = 62.2 ± 2.39). A speed limit of 60 km/h was set up (average speed ± SD = 53.37 ± 2.25 km/h).

The interaction with the virtual car took place via devices typically present in an automatic transmission vehicle; accordingly, the primary controls of the simulator were physical. To control the car, participants used a Logitech G27 steering wheel (steering wheel, gas and brake pedals; Logitech International S.A., Lausanne, Switzerland) while seating on an adjustable car seat (PlaySeat®, Doetinchem, The Netherlands). Speedometer and tachometer gauges were shown in the bottom right of the screen. Six loudspeakers located around the driver, about the ground level, provided the simulated surround sound of the engine.

We used a video projector (EB-410W, EPSON Pty Ltd., Australia) to display the virtual circuit on a 1.32 x 1.63 m screen, about 2.5 m from the driver´s eyes (resulting in a view angle of ~26° vertically and ~33° horizontally). The experiment took place in a dimly lit laboratory.

Similar experimental settings have been successfully used to investigate drowsy driving (Isnainiyah, Samopa, Suryotrisongko, & Riksakomara, 2014; Lawoyin, Fei, Bai, & Liu, 2015). During the entire experimental session, we controlled for room illumination and temperature, as well as for background noise (~24 lux [Iluminance meter T-10, Konica Minolta, Inc., Japan], ~25°C [Arduino controlled LM35 wire Digital Thermometer], and ~52 dB [Sound Level Meter DSL-330, Tecpel Co Ltd., Australia]).

The driving simulator recorded the car speed automatically (sample rate 20 Hz). We calculated the time spent speeding for each participant and TOD block, defined as the amount of time driving at a speed 10% or more above the speed limit.

*2.5 EEG recordings and analyses*

We collected EEG activity (at 512 Hz) using the TGAM headset (ThinkGear ASIC module TGAM1_R2V2.4A, NeuroSky Inc., San Jose, CA, USA). The device uses a monopolar montage with a single frontal dry stainless steel electrode (TGAM) placed at (approximately) Fp1 (contact area 12 x 16mm), according to the International 10/20 system (Jasper, 1958) (see **Figure 1B, C**). The ear clip (left *ear*-lobe) acts as both ground and reference, which allows the TGAM chip to filter out the electrical noise from the body and the ambient environment. Before electrode placement, the pertinent areas of the skin were cleaned with a slightly abrasive paste and alcohol. Then, the dry electrode/ear clip were placed and secured with surgical tape.

The TGAM headset sends EEG raw data to a recorder unit via a Bluetooth connection. We collected the raw EEG data into EDF+ files using an ad-hoc LabVIEW software script (National Instruments Co., USA). Then, we imported the EDF+ files, preprocessed and analyzed them using Matlab (Mathworks Inc., USA). To remove physiological artifacts from eye activity, we filtered the signal using an order 10 Chebyshev type II filter, with a flat pass band between 0.1 Hz and 45 Hz, and an independent customized algorithm to remove blinks (Rieiro et al., submitted).

We segmented the whole EEG 2-hour recording in four consecutive non-overlapped epochs of 30 min each (one for each TOD): TOD1 (0-30 min), TOD2 (30-60 min), TOD3 (60-90 min), and TOD4 (90-120 min). We divided data from each TOD into segments of 2 sec in length. We considered artifacts and discarded segments with amplitudes out of the (-100, 100 µV) range. Then, we used the fast Fourier transform (window size of 512 samples and overlapping of 256 samples) – implemented in the EEGLAB Matlab toolbox – to perform spectral analysis and to calculate power spectra for the bands: delta (0.5-4 Hz), theta (4-8 Hz), alpha (8-13 Hz), and beta (13-30 Hz) frequency bands  (Di Stasi, Díaz-Piedra, et al., 2015). Finally, we computed the average power for each frequency band and TOD. The power spectra were expressed as $\mu V^2/Hz$. We used the 10 logarithmic scale ($\log_{10}$) transformation to improve normality of data.

*2.6 Eye movement recordings and analyses*

We sampled eye movements binocularly at 1 KHz using infrared oculography (JAZZ-*novo*, Ober Consulting, Poznan, Poland). The JAZZ-*novo* is a portable and lightweight, head-mounted system (see **Figure 1B**) that records the positions of both eyes to compute the position of the cyclopean eye. The eye-tracker uses a radio frequency connection to send raw data to a recorder platform. We collected the raw eye-movements data into EDF+ files using an ad hoc LabVIEW software script (National Instruments Co., USA).

We detected and analyzed saccadic movements as in Di Stasi, McCamy, and colleagues (Di Stasi, McCamy, et al., 2013). Briefly, we identified saccades with a modified version of the algorithm developed by Engbert & Kliegl (2003). This algorithm bases saccade identification on a velocity threshold that adapts to the level of noise in the data (see Engbert & Kliegl [2003] for a detailed description). Here, we used $\lambda = 10$ (to obtain the velocity threshold) and a minimum saccadic duration of 10 ms. To reduce the amount of potential noise, we imposed a minimum intersaccadic interval of 20 ms so that potential overshoot corrections are not categorized as new saccades (Møller, Laursen, Tygesen, & Sjølie, 2002). Because the magnitude of a saccade is related to both the velocity and the duration of the movements (Gruart, Blázquez, & Delgado-García, 1995), we studied the effects of TOD on the saccadic peak velocity/magnitude relationship (Becker & Fuchs, 1969; Evinger, Manning, & Sibony, 1991). We assumed a power fit relationship between saccadic magnitude and peak velocity (Di Stasi, McCamy, et al., 2013). Thus, we performed robust linear regressions (using the robust fit function in MATLAB [Mathworks Inc., USA]) on the raw data for each participant for each TOD block. We did a robust linear regression on $\ln(\mathrm{PV}) = m\ln(\mathrm{MAG}) + b$, which assumes the power-law $\mathrm{PV} = e^b\mathrm{MAG}^m$.. Here and throughout, *b* is the *y*-intercept and *m* is the slope. Thus, for each participant, we obtained four slope values of the saccadic peak velocity/magnitude relationship – one for each TOD – (hereafter, saccadic peak velocity).

*2.7 Questionnaires*

To evaluate the effectiveness of the fatigue-inducing manipulation, we asked participants to fill in the Stanford Sleepiness Scale (SSS) and an adapted version of the Borg rating of perceived exertion (BORG (Borg, 1998). The SSS provides a global measure of how alert a person is feeling, ranging between 1 and 7 (Hoddes, Zarcone, Smythe, Phillips, & Dement, 1973). It contains seven statements ranging from “Feeling active, vital, alert, or wide awake” (score 1) to “No longer fighting sleep, sleep onset soon, having dream-like thoughts” (score 7). The BORG indicated the level of fatigue (i.e., the level of perceived exertion associated with a task). It consists of a numerical scale (ranging from 6 to 20) anchored by “not exertion at all” (score 6) to “maximal exertion” (score 20). Participants filled in the questionnaires – in the same order – in two separate measuring sessions: at the beginning (i.e. Pre-driving), and at the end (i.e. Post-driving) of the driving session. Finally, we used the NASA-Task Load Index (NASA-TLX) (Hart & Staveland, 1988) as a global index of the perceived degree of task complexity (Di Stasi et al., 2009). The NASA-TLX values range between 0 and 100, with higher values indicating higher task complexity.

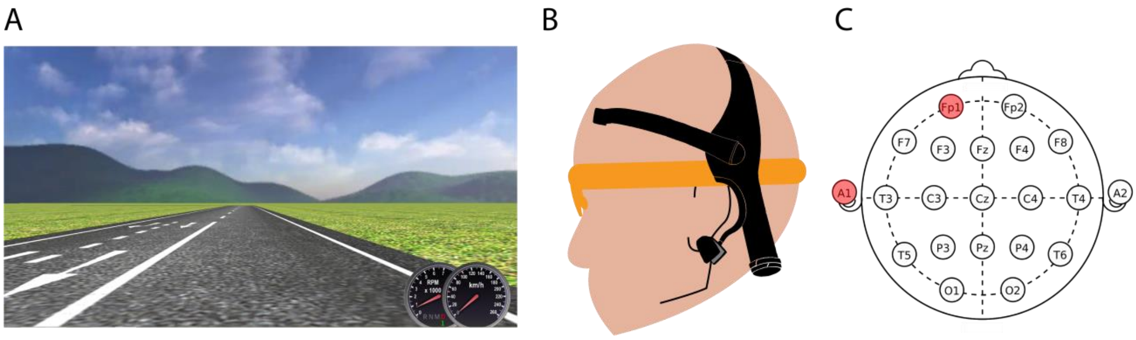


**Figure 1**. **A**) A screenshot taken from the driving simulator. The speedometer gauges were displayed during the simulation. **B**) The configuration used to record EEG (black headset) and eye movements (orange element). **C**) The EEG device uses a monopolar montage with a single frontal dry electrode placed at Fp1, and uses the left *ear*-lobe as the reference/ground.

*2.8 Procedure*

After signing the consent form, participants filled in the SSS and BORG scales. Then, after a five-minute familiarization session, we calibrated the eye tracker and the driving simulation started. We instructed participants to follow the usual traffic rules and to keep the car mostly in the right lane. The speed limit was set up at 60 km/h. During the entire simulation, the experimenter did not communicate with participants, although they were constantly monitored through an observation window behind the car seat. After the simulation, participants filled in the same scales. In order to avoid diurnal fluctuations that affect arousal levels (Río-Bermudez, Díaz-Piedra, Catena, Buela-Casal, & Di Stasi, 2014), we carried out all experimental sessions between 9 a.m. and noon. Thus, we ran only one participant per day. Finally, to avoid an end-spurt effect-reactivation – that occurs when people know they are approaching the end of a task (Bergum & Lehr, 1963) – participants were blind about the duration of the driving simulation.

*2.9 Statistical analysis*

To analyze the effect of TOD (i.e. fatigue), we performed separate repeated-measures ANOVAs on the dependent variables. For the *EEG power spectra*, we performed a two-factor, 4 (TOD) x 4 (Frequency Band), repeated-measures ANOVA. For the *saccadic peak velocity* and the *speeding time*, we performed two one-factor repeated-measures ANOVAs, with TOD as the repeated-measures factor. Effect size was calculated using the partial $\eta^2$ statistic. We also performed separate trend analyses (one for each dependent variable) to identify the existence of significant trends in our data over the four TOD blocks. We used the Bonferroni adjustment to correct for multiple comparisons. If more than one trend was significant, we focused on the trend having the highest effect size. For all dependent variables, we compared each participant to him/herself across the TODs, and, therefore, variability between participants was part of the error terms. For the BORG and SSS scales, we used two separate paired *t*-tests with the two measuring sessions (i.e., Pre vs. Post-driving) as the repeated-measures factor. For all dependent variables, we used the Kolmogorov-Smirnov test and a graphical assessment to verify that both data and residuals were normally distributed. Both assumptions were always confirmed. Significance levels were always set at $\alpha \leq 0.05$.

**3. Results**

During a 2-hour simulated driving session, we continuously recorded drivers' EEG power spectra, saccadic eye movements, and driving performance. For analysis purposes, we divided the driving time in four 30-min blocks: TOD 1, TOD 2, TOD 3 and TOD 4. We also collected subjective ratings of alertness and fatigue at the beginning and at the end of the driving session, and, at the end of the session, the perceived degree of task complexity.

*3.1 Effectiveness of the TOD manipulation*

To examine the effectiveness of the TOD manipulation, we analyzed changes in the saccadic peak velocity, in the percentage of speeding time, and in the SSS and BORG scores depending on the TOD.

Saccadic peak velocity changed across TOD blocks; $F$ (3, 33) = 10.62, $p < 0.001$, partial $\eta^2 = 0.49$ (see **Figure 2A** and **Table 1**). Trend analysis revealed a significant decreasing trend across the four TOD blocks; $F$ (1, 11) = 13.08, corrected $p < 0.05$, partial $\eta^2 = 0.54$. These results confirm that TOD induced higher levels of fatigue as the experiment progressed (Di Stasi et al., 2012; Di Stasi, McCamy, et al., 2015; Hirvonen et al., 2010; Schmidt et al., 1979). In the same line, the driving performance and subjective results were also consistent with an effective fatigue-inducing manipulation. The speeding time changed across TOD blocks; $F$ (3, 42) = 6.95, $p$ = 0.001, partial $\eta^2$ = 0.33 (see **Figure 2B** and **Table 1**). Trend analysis revealed a significant increasing trend across the four TOD blocks; $F$ (1, 14) = 7.84, corrected $p$ < 0.05, partial $\eta^2$ = 0.36. That is, participants exceeded the speed limits more often as the experiment progressed. Participants also experienced increased levels of sleepiness and fatigue at the end of the experiment (average $SSS_{pre}$ ± SD = 2.0 ± 0.7 vs. $SSS_{post}$ ± SD = 3.8 ± 1.0; $t$ (14) = 5.49, $p$ < 0.001; average $BORG_{pre}$ ± SD = 7.7 ± 1.4 vs. $BORG_{post}$ ± SD = 12.6 ± 2.6; $t$ (14) = 7.66, $p$ < 0.001). Finally, after the driving session, participants reported low levels of task complexity (average NASA-TLX ± SD = 44 ± 8.5), probably due to the monotony of the virtual scenario (Grier, 2015).

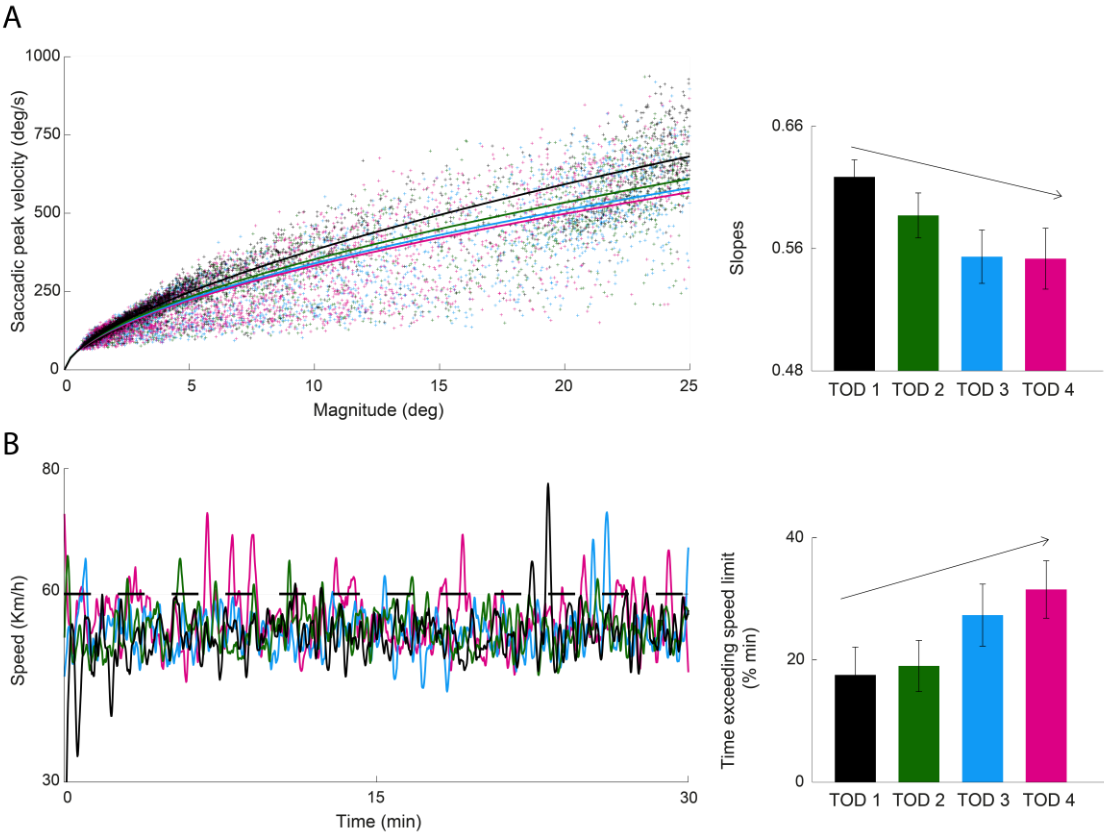


**Figure 2. Effect of Time-On-Driving (TOD) on the saccadic peak velocity and driving performance**. **A)** Saccadic main sequence (peak velocity/magnitude relationship) for participant #14 across the four consecutive TOD blocks (1: black, 2: green, 3: light blue, 4: magenta; 30-min per block). Each dot represents a saccade. The curves are power-law fits to the data for each TOD block. Right panel: Average saccadic peak velocity across all participants for each TOD. The arrow indicates the significant linear trend of the saccadic velocity across TODs. Error bars represent the standard error of the mean across participants ($n$ = 12). **B)** The speed profiles for participant #14 across the four consecutive TOD blocks (colors as in panel A). Right panel: Average number of times (%) of exceeding the speed limit (posted at 60 Km/h) across all participants for each TOD. The arrow indicates the significant linear trend of exceeding the speed limit across TODs. Error bars represent the SEM across participants ($n$ = 15).

*3.2 Effects of TOD on brain activity*

The amplitude of the EEG power spectra was dependent on TOD and the Frequency Band, $F$ (3,33) = 7.16, $p$ = 0.001, partial $\eta^2$ = 0.39; $F$ (3,33) = 28.755, $p$ < 0.001, partial $\eta^2$ = 0.96, respectively. The TOD × Frequency Band interaction was also significant, $F$ (9,99) = 2.51, $p$ = 0.013, partial $\eta^2$ = 0.19 (see **Figure 3** and **Table 1**). We observed an overall inverted U-shaped quadratic trend across the experimental session for the power spectra of the delta, $F$ (1, 11) = 10.22, corrected $p$ < 0.05, partial $\eta^2$ = 0.48. That is, as the experiment progressed, delta EEG power spectra increased for the first hour and half, and, then, slightly decreased throughout the last TOD block (last 30-min). However, the power spectra of the beta band linearly increased across the experimental session, $F$ (1, 11) = 12.82, $p$ = 0.004, corrected $p$ < 0.05, partial $\eta^2$ = 0.54. Finally, alpha and theta EEG power did not show a significant specific trend (corrected $p$-values > 0.05).

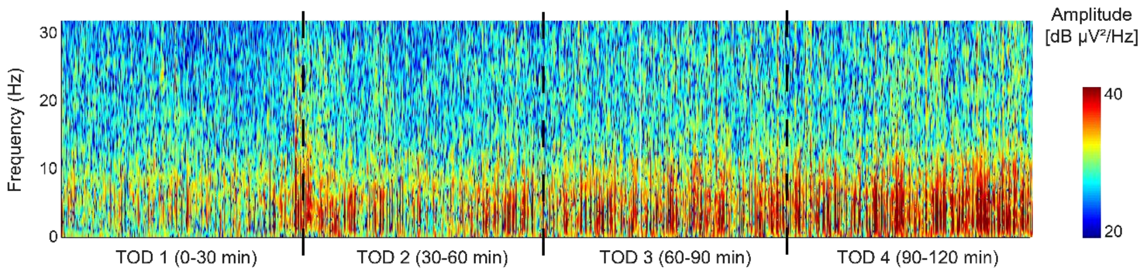


**Figure 3**. **Effect of Time-On-Driving (TOD) on the EEG power spectrum of one driver.** The spectrogram (participant #14) shows the EEG power spectrum for the 2-h driving session. The dB scale is relative to 1 $\mu V^2/Hz$.

**Table 1.** Saccadic peak velocity (slope values of the saccadic peak velocity/magnitude relationship), speeding time, and power of each EEG frequency band for each one of the four Time-On-Driving (TOD) bins (30 minutes each).

| | TOD1 | TOD2 | TOD3 | TOD4 |
|---|---|---|---|---|
| | M±SD | | | |
| Saccadic peak velocity (deg/s)$^{/}$ | 0.63±0.04 | 0.60±0.06 | 0.57±0.07 | 0.56±0.08 |
| Speeding time (% time)$^{/}$ | 17.55±17.5 | 19±16.14 | 27.32±19.65 | 31.5±18.22 |
| Beta ($\mu V^2/Hz$)$^{/}$ | 26.97±0.82 | 27.57±0.84 | 27.82±0.88 | 27.78±0.83 |
| Alpha ($\mu V^2/Hz$) | 29.28±0.83 | 29.70±0.93 | 29.84±1.04 | 29.75±1.12 |
| Theta ($\mu V^2/Hz$) | 31.79±1.24 | 32.29±1.20 | 32.48±1.13 | 32.40±1.36 |
| Delta ($\mu V^2/Hz$)$^{\cap}$ | 32.73±1.39 | 33.53±1.29 | 33.91±1.19 | 33.86±1.43 |

**Note.** Means and standard deviations (M±SD) were calculated from the (mean) values of each participant. "/" denotes a statistically significant linear trend for the driving time manipulation. "∩" denotes a statistically significant quadratic trend for the driving time manipulation.

## 4. Discussion

We aimed to find conclusive evidence about the validity of using a single-channel, dry electrode, wearable TGAM-based chip EEG device to monitor driver fatigue. To obtain a much better understanding of how driver fatigue could be early detected while driving using wearable technologies, we combined this EEG device, for the first time, with high-speed eye tracking technology. Thus, we examined how EEG data (i.e. power spectra density) changed across a 2-hour monotonous driving together with driver's saccadic peak velocity, a well-known index of fatigue (Diaz-Piedra et al., 2016). In addition, we analyzed the driving performance and subjective ratings of alertness and fatigue. We observed an inverted U-shaped quadratic trend for the delta EEG power spectra and an increasing linear trend for the beta EEG power spectra across the experimental session, which is coherent with saccadic eye movements and driving performance data. Thus, our combined results indicate that EEG-metrics recorded by a dry-electrode, single-channel can detect driver fatigue levels online.

### *4.1 The effect of fatigue on ocular, driving performance, and subjective indices.*

We used ocular, driving performance, and subjective indices to validate EEG spectral changes associated with TOD (i.e. fatigue). These validation indices provide unambiguous evidence about our successful manipulation of fatigue (i.e., TOD): participants experienced higher levels of fatigue as the experiment progressed.

Saccadic peak velocity decreased with increased TOD, which is consistent with our previous findings during long driving sessions (Di Stasi et al., 2012; Di Stasi, McCamy, et al., 2015), simulated flying tasks (Di Stasi et al., 2016), and time-on-duty (Di Stasi et al., 2012; Diaz-Piedra et al., 2016), as well as with independent earlier reports (Galley & Andres, 1996; Hirvonen et al., 2010; Ahlstrom et al., 2013). Consistently, driving performance degraded with increased TOD, and perceived levels of alertness decreased and levels of fatigue increased after the two hours driving. Performance degradation and subjective results are in line with earlier studies using similar experimental procedures (e.g., Lal & Craig, 2002).

### *4.2 The effect of fatigue on (pre)frontal EEG spectra*

Spectral measures have repeatedly been reported in the literature to be reliable correlated to mental fatigue (i.e. reduced arousal level) (Wascher et al., 2014). Here, we found that overall EEG power spectrum changed across the 2-h driving session. (Pre)frontal (in our study, Fp1) power spectra for the delta EEG band showed a quadratic trend (power increased during the first hour and half and decreased during the last half hour), while the power spectra of the beta band linearly increased as the driving session progressed. While numerous studies (e.g. Lal & Craig, 2002; Craig, Tran, Wijesuriya, & Nguyen, 2012) have reported increased levels of all EEG-spectral power across the entire scalp due to arousal decrements – including frontal derivations (Kiroy, Warsawskaya, & Voynov, 1996; Cajochen, Wyatt, Czeisler, & Dijk, 2002), this study, for the first time, replicated these differences using a single prefrontal channel. In line with earlier studies, as the cognitive state of the driver shifted from alertness to fatigue, we found an increase of frontal delta (e.g. Kong, Zhou, Jiang, Babiloni, & Borghini, 2017), theta (e.g. Wascher et al., 2014), and alpha (e.g. Simon et al., 2011) bands. Furthermore, as far as the fatigue arose (i.e. with the time-on-driving), there was an increase of frontal fast beta EEG activity, as found by previous studies (Dumont, Macchi, Carrier, Lafrance, & Hébert, 1999; Kiroy et al., 1996; Smit, Droogleever Fortuyn, Eling, & Coenen, 2005). It was suggested that the increase in beta power during sleep deprivation might result from the effort to stay awake (Corsi-Cabrera, Arce, Ramos, Lorenzo, & Guevara, 1996; Lorenzo, Ramos, Arce, Guevara, & Corsi-Cabrera, 1995; Smit et al., 2005). Therefore, the increase in beta power in our study might reflect compensatory mechanisms to deal with the low arousal levels.

### *4.3 An arousal-based explanation*

The results can be interpreted using an arousal-based theoretical approach (Andreassi, 2006): in a condition of a general cognitive deterioration, where the increase of delta EEG activity and the reduction of saccadic velocity occur as the driving session progresses, we observed the adaptive brain mechanisms to provide the proper arousal levels to perform the task (the increase of beta EEG activity) (Kiroy et al., 1996; Craig et al., 2012). Arousal changes could also explain the decrease of delta EEG activity during the last TOD. Even when participants did not know the duration of the driving simulation, after more than 90 minutes of driving, they might have suspected that the session was ending, and the end-spurt effect (Bergum & Lehr, 1963) might have happened. Overall, this compensatory mechanism should, in part, arise at the level of prefrontal areas, which indicate sleep propensity during prolonged wakefulness and are also involved in the control of the saccadic movements (Burke & Coats, 2016; Marzano et al., 2007). In line with this hypothesis, the medial rostral prefrontal cortex (Fp1) has been recently associated with the saccadic programming, including the modulation of the saccadic peak velocity (Burke & Coats, 2016).

Note that we did not differentiate between fatigue and boredom (Lal & Craig, 2001). Thus, our results could be also interpreted as dependent on the reduction in motivation while performing a long monotonous task (for recent reviews on these topics, Borghini et al., 2013; Di Stasi, Marchitto, et al., 2013).

### *4.4 Implications*

Our findings could help to bridge the gap between neural-engineering, basic neuroscience, and road safety by offering valid and conclusive evidence on the sensitivity of a wearable single electrode EEG device to monitor arousal variations while performing an ecological and complex task (i.e. driving). Furthermore, thanks to the possibility of simultaneously recording with other mobile peripheral sensors, this EEG device might make possible a multimodal approach to explore driving behavior. For example, the skin conductance response (SCR) has already been used to study driving behavior (Kinnear, Kelly, Stradling, & Thomson, 2013; Tagliabue & Sarlo, 2015; Tagliabue, Gianfranchi, & Sarlo, 2017), and is also related to physiological arousal due to perceived mental effort (Howells, Stein, & Russell, 2010). As the TGAM headset can be connected to a skin conductance sensor (e.g., [Abdur-Rahim et al., 2016]), the integration of both EEG and SCR would facilitate a more detailed assessment of driving behavior (Gianfranchi, Spoto, & Tagliabue, 2017). Furthermore, the TGAM headset has a reduced cost and a simple setup. Therefore, this comprehensive assessment could be conducted outside a simulation laboratory. For example, the TGAM headset could be easily introduced in several "out of the laboratory" driving training programs (e.g., Tagliabue, Da Pos, Spoto, & Vidotto, 2013) to continuously monitor other arousal-related road safety factors, as for example (driver) mental effort (Di Stasi et al., 2009; Howells et al., 2010).

### *4.5 Conclusions*

The EEG-based technology we tested accomplishes several neuroergonomics criteria to establish an ideal measure of the cognitive state in applied settings (Parasuraman & Rizzo, 2007). Briefly, two of the main requirements of such a measure of the cognitive state are (Luximon & Goonetilleke, 2001): (i) sensitivity: it should detect significant variations in the cognitive state; and (ii) noninvasiveness: it should not interfere with the primary task. In our research, EEG-metrics were sufficiently sensitive to reveal significant differences between varied levels of mental fatigue and noninvasive, that is, the EEG recordings did not interfere with driving task performance. To sum up, our results suggest that the TGAM headset can provide a sensitive, real-time, non-invasive measure of variations of the cognitive state due to driver fatigue.

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# Appendix C

**Morales, J. M.**, Ruiz-Rabelo, J. F., Diaz-Piedra, C., & Di Stasi, L. L. (2019). Detecting mental workload in surgical teams using a wearable single-channel electroencephalographic device. *Journal of Surgical Education*, 76(4), 1107-1115. `https://doi.org/10.1016/j.jsurg.2019.01.005`

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**Title:** Detecting mental overload in surgical teams using a wearable single-channel electroencephalographic device

**Running head:** Prefrontal beta EEG activity reflects surgical task load

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**Abstract**

**Objective:** To assess the sensitivity of an electroencephalographic (EEG)-based index, the prefrontal beta power, to quantify the mental workload in surgeons in real scenarios. Such EEG-based index might offer unique and unbiased measures of overload, a crucial factor when designing learning and training surgical programs.

**Design:** The experiment followed a *2 x 2 x 2* within subjects design with three factors a) *Surgical Role* during the surgery (primary-surgeon vs. assistant-surgeon), b) the *Surgical Procedure* (laparo-endoscopic single-site [LESS] surgery vs. multiport laparoscopic surgery [MPS]), and c) the *Suturing Techniques* (interrupted vs. continuous suture).

**Setting:** The study was carried out at the Advanced Multi-Purpose Simulation and Technological Innovation Complex situated at IAVANTE (Granada, Spain).

**Methods:** Four surgical teams (primary-surgeon and surgeon-assistant, experts in MPS) performed eight surgical exercises on porcine models, under different task complexities. They performed two suturing techniques (continuous and interrupted), employing a low complex procedure (MPS) and a high complex procedure (LESS). Surgeons acted as the primary-surgeon during half of the exercises, and, as the assistant-surgeon, during the rest of them. Simultaneously, we monitored prefrontal beta power spectra of both surgeons, using two synchronized wearable EEG-devices. We also collected performance and subjective data.

**Results:** Prefrontal beta power of the surgical teams was greatly synchronized. Moreover, surgical task complexity modulated prefrontal beta power. LESS surgery caused significant higher prefrontal beta power for both suturing techniques for the primary-surgeon, which indicates higher demands than MPS. Perceived task complexity, overall surgical evaluation, and laparoscopic execution time confirmed EEG-based results.

**Conclusions:** To detect mental overload when surgeons are engaged with complex surgeries, real or simulated, is still guesswork. EEG-based indices have great potential as objective and non-intrusive measures to assess mental overload in surgeons. Furthermore, EEG-based indices might play a relevant role in monitoring surgeons and residents cognitive state during their training.

**Keywords:** Surgical skills assessment, Patient safety, Neuroergonomics, Coordination, Brain synchrony

**ACGME competency:** Practice-Based Learning and Improvement

## Introduction

Surgery is one of the most challenging careers in medicine. It requires both great physical and mental effort, and demands a great level of concentration during long stressful events.[1] Mental overload in surgeons, due to either excessive surgical task demands (i.e., complexity level) or the lack of sufficient physical/mental resources (i.e., fatigue level), is a critical factor in surgery. Mistakes at any point of the surgical process pose a serious threat to patient safety as well as for the wellbeing of the surgeon.[2-4] Providing useful tools for detecting cognitive overload and avoiding such situations is desirable,[5,6] especially for residents. A greater understanding of the mental (over)load imposed by the surgical environment would be particularly helpful to guide the design of learning and training programs.[7] However, measuring mental overload in surgeons, when engaging in high-risk environments such as the operating theatre, is still guesswork. There are few real-time cues available to the mentor (e.g., communication's degradation) to assess how safely the trainee is interacting with the patient and the surgical team.[8] Consequently, effective complementary monitoring aids to assess mental overload are needed.

EEG-based technology offers valid and sensitive research tools to monitor the cognitive state in surgeons, including mental overload. Its use during surgical training might improve the resident's learning curve by enhancing skill assessment methods.[9] Furthermore, thanks to recent technological advances, recording equipment has become increasingly reliable, nonintrusive, and less bulky. These developments have facilitated the surgeon's acceptance and have increased the possibility to collect data during highly engaging tasks.[10,11] Despite all this, collecting EEG data from surgical operations and highly realistic simulations remains a challenge for researchers (for a recent review, see [12]). Thus, research in this filed is limited.

EEG-based research in non-surgical scenarios has largely proven the sensitivity of the (frontal) beta EEG power spectrum (hereafter, β-activity) in detecting variations in operator's arousal[13] due to task demands.[14–16] As the task demands increase, the level of engagement increases,[17] and mental stress intensifies,[18] there is a concomitant increase in β-activity.[19–21] Hence, it seems plausible to assume that β-activity may also reflect nonspecific cognitive states such as mental overload.

In this study, we investigated whether prefrontal β-activity could differentiate the levels of task demands imposed by different surgical procedures of different complexity (high complexity: laparo-endoscopic single-site [LESS] surgery vs. low complexity: multiport laparoscopic surgery [MPS]) while using two suturing techniques (interrupted vs. continuous suture). Furthermore, we wonder if prefrontal β-activity could also differentiate between the roles played in the surgical team (primary-surgeon vs. assistant-surgeon). That is, we wanted to answer the question if prefrontal β-activity could act as a useful cue to indicate surgeon's cognitive state during a realistic training session.

## Material and methods

### *Ethical Approval*

We conducted the study in conformity with the Code of Ethics of the World Medical Association (WMA, Declaration of Helsinki).[22] The experiment was carried out under the guidelines of the University of Granada´s Institutional Review Board (IRB approval #899). Written informed consent was obtained from each surgeon prior to the study.

### *Participants*

Four pairs of board certified surgeons (6 females and 2 males) participated in the study (mean age ± standard deviation [SD]: 31.37 ± 2.2 years; average number years of experience ± SD: 6.62 ± 1.78 years). They attended IAVANTE (Andalusian Public Foundation for Progress and Health), in Granada (Spain), for the experiment. Surgical specialties included general surgery (7) and urology (1). All participants had normal or corrected to-normal vision, and were right handed. Overall, participants' average working day length was between 9 and 12 hours (with workweek durations ranging from 41 to 60 hours). They reported an average of 5.8 hours of sleep (SD = 0.99) the night before the experiment. For screening purposes, at the begin of the experimental session participants filled in the Stanford Sleepiness Scale (SSS) (see *Questionnaires* section).[23] Average SSS score was lower than 3 (SD = ± 1.06), indicating an optimal quality of alertness at the beginning of the study.[24]

### *Experimental design*

The experiment followed a *2 x 2 x 2* within subjects design with three factors a) *Surgical Role* during the surgery (primary-surgeon vs. assistant-surgeon), b) the *Surgical Procedure* (LESS vs. MPS), and c) the *Suturing Techniques* (interrupted vs. continuous suture). Thus, each surgeon underwent eight experimental conditions. Potential learning, practice, and time-on-task effects on the surgical procedures were controlled by a Latin square design across the experimental conditions.

*Apparatus and tasks*

Four Spanish domestic pigs (Sus scrofa domestica), one for each surgical team, were used as a model to perform the surgical exercises. Before starting each experimental session, an expert surgeon (author: J.R.R.) prepared the anesthetized pig introducing four trocars for the experiment (including the TriPort+ for the LESS procedures [Olympus America INC, USA], see **Figure 1**). Then he made eight longitudinal incisions on the surface of the urinary bladder. During the experiment, the surgical team closed these incisions with stitches using a single, running 6-0 polypropylene suture (interrupted and continuous suturing, see **Figure 1C**). The primary-surgeon used two pairs of Maryland Graspers and suture material, and the assistant-surgeon was responsible of the telescope (Hopkins II Autoclavable Laparoscope [10 mm, 0°, 31 cm] with a Telecam One-chip Camera Hed). Once the sutures were completed, the primary surgeon and assistant-surgeon exchanged roles and the tasks were performed again.

*Surgical Performance*

We allowed a maximum time of 1,800 seconds (30 minutes) for each surgical exercise. Then, we used the time to complete each of them (execution time) as an indicator of the effect of task complexity on performance. However, as per the adage ‘a fast surgeon is not always a good surgeon’, the performance of each surgical team was also evaluated by an expert surgeon (author: J.R.R.) using a modified version of the rating scale for operative performance.[25]

*Questionnaires*

All surgeons filled in The Stanford Sleepiness Scale (SSS) before starting the experimental session. This provides a global measure of how alert someone is feeling.[23]

After each surgical exercise, surgeons also filled in the NASA-Task Load Index (NASA-TLX) questionnaire, as an indicator of the degree of complexity that they experienced while performing each surgical exercise. NASA-TLX has a score ranging from 0 (minimum task load) to 100 (maximum task load).[26] A modified version of the rating scale was used to evaluate operative performance, with scores ranging from 1 (better performance) to 5 (worse performance).[25] This questionnaire was adapted to only focus on the self-assessment of psychomotor skills demonstrated during the surgical exercise.

*EEG recordings and analyses*

We performed simultaneous recordings of the surgical team's EEG activity (at 512 Hz) using two NeuroSky MindWave Mobile headsets (NeuroSky Inc., San Jose, CA, USA). These devices use a monopolar montage with a single dry electrode placed at Fp1, according to the International 10/20 system [27], referenced to the left earlobe (for a detailed description, see [28]). Before electrode placement, the pertinent area of the surgeons' skin was cleaned with a slightly abrasive paste and alcohol. Then, the dry electrode was placed and secured with surgical tape. Both devices sent EEG raw data to two recorder units via Bluetooth connections. We collected the raw EEG data into two synchronized EDF+ files using an ad-hoc LabVIEW software script (National Instruments Co., USA). Then, we imported the EDF+ files, preprocessed and analyzed them using Matlab (Mathworks Inc., USA). To remove physiological artifacts from eye activity, we filtered the signal using an order 10 Chebyshev type II filter, with a flat pass band between 0.1 Hz and 45 Hz, and an independent customized algorithm to remove blinks. After that, data from each surgical exercise (and surgeon) were divided into 2-sec segments. We considered artifacts and discarded segments with amplitudes out of the (-100, 100 µV) range. Then, we used the fast Fourier transform (window size of 512 samples and overlapping of 256 samples) implemented in the EEGLAB Matlab toolbox to perform spectral analysis and to calculate power spectra of the beta frequency band (13-30 Hz).[29] Finally, we computed the average β-activity for each of the eight experimental conditions.

*Procedure*

The experiment was carried out at the Advanced Multi-Purpose Simulation and Technological Innovation Complex situated at IAVANTE. This complex houses several operating rooms and laparoscopic/robotic simulators, which provide health professionals with general clinical skills and specific surgical training.

Before starting the experiment, each surgical team signed the consent forms, and filled in the SSS. Then, we recorded date of birth, sex, hand dominance, average daily shift length and weekly worktime, as well as hours of sleep the night before. Afterwards, the surgical team received a demonstration on how to perform the surgical exercises. An expert surgeon (author: J.R.R.) with expertise in both surgical procedures (LESS and MPS) performed this demonstration. Then, the surgical team began to operate. After each exercise, surgeons filled in NASA-TLX and the rating scale for operative performance. Expert surgeon (author: J.R.R.) also filled in the rating scale for operative performance, for an external evaluation of the surgical team performance. The surgical team took a short break in the middle of the study. During the break, surgeons could go out from the operating room without leaving the building.

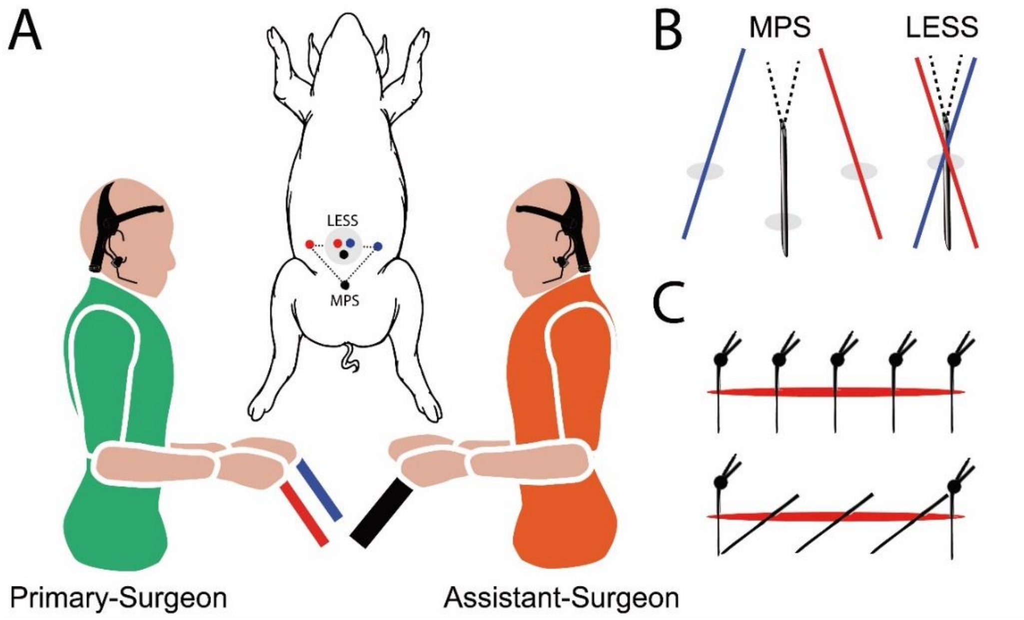


**Figure 1. A)** A surgical team wearing the mobile EEG-devices while performing the surgical exercises. The green figure denotes the primary-surgeon and the orange figure denotes the assistant-surgeon. Real porcine models were used for the experiment. **B)** The multiport laparoscopic surgery (MPS) triangulated work-configuration is represented (on the porcine model) by the three small dots connected by a dotted line. The hand-instruments are directed from two points of entry (colored points) and the telescope is placed just apart from them (black dot). The images were displayed on a 15" LCD TFT monitor facing the surgical team (element not shown). The laparo-endoscopic single-site (LESS) surgery triangulated laparoscopic work-configuration is represented (on the porcine model) by the big grey dot. The hand-instruments, as well as the telescope, are directed from a single point of entry. Furthermore, at the point of entry, the hand-instrument cross like a chopstick: the surgeon´s right-hand controls the left instrument (and vice-versa). **C)** The surgical exercises. Two suturing techniques were demonstrated: interrupted suture (upper-figure) and continuous suture (lower-figure).

*Statistical analyses*

To analyze the overall effect of our manipulation, we performed separate 2 (*Surgical Role*) x 2 (*Surgical Procedure*) x 2 (*Suturing Techniques)* repeated-measures ANOVAs on the main dependent variables (i.e., β-activity, NASA-TLX score, and operative performance score). We analyzed the external expert evaluation of the surgical team, as well as the execution time following a 2 (*Surgical Procedure*) x 2 (*Suturing Techniques*) repeated-measures ANOVAs. For all dependent variables, we compared each surgeon/surgical team to him/herself/itself across the surgical exercises, and, therefore, variability between surgeons/surgical teams was part of the error terms. We used the Bonferroni adjustment to correct for multiple comparisons. Finally, Kolmogorov-Smirnov test and graphical assessment were used to verify that both data and residuals were normally distributed. Both assumptions were confirmed in all cases. Significance levels were always set at $\alpha \leq 0.05$.

## 3. Results

### *3.1 Effectiveness of the surgical complexity manipulation*

Surgeons' perceived task complexity (NASA-TLX scores) changed accordingly to our manipulation: the task load experienced by the primary-surgeons was higher than the assistant-surgeons, $F(1, 7) = 43.31$, $p < 0.001$, and sutures (continuous and interrupted) executed using LESS procedure were perceived as more demanding than the ones executed using MPS procedure, $F(1, 7) = 43.84$, $p < 0.001$. However, interrupted and continuous sutures were perceived as having the same task complexity ($F$-value < 2.3) (see **Table 1**). Furthermore, participants perceived their operative performance being worse during LESS procedures than during the MPS ones, $F(1, 7) = 23.56$, $p < 0.05$, and while they acted as the primary-surgeon than as an assistant-surgeon, $F(1, 7) = 10.13$, $p < 0.05$.

The surgical teams needed more time to perform the sutures (continuous and interrupted) utilizing the LESS procedure than the MPS procedure, $F(1, 7) = 9.20$, $p < 0.05$ (average execution time ± SD: LESS = 1512 ± 375 sec. vs. MPS = 1126 ± 387 sec.) . Based on external evaluation, performance was less accurate utilizing the LESS procedure, $F(1, 7) = 51.33$, $p < 0.001$ (average external evaluation ±SD: LESS = 4.27 ± 0.36 vs MPS = 2.89 ± 0.52). No other main or interaction effects were significant (all $F$-values < 3.1).

### *3.2 Effects of the surgical complexity on β-activity*

Task complexity modulated β-activity, overall interaction: $F(1, 7) = 8.41$, $p < 0.05$ (see **Figure 2** and **Table 1**). Within the same surgical role, we observed higher β-activity when participants performed either suture (interrupted and continuous) using the more complex surgical procedure (LESS) (all corrected $p$-values < 0.05). These results seem to confirm previous findings on the (extra) cognitive cost associated to LESS procedures when compared to the MPS ones.[30] Furthermore, within the same surgical exercise, β-activity did not differentiate between the surgical roles, suggesting that the surgical team was mostly synchronized across the operations.[31,32] Note: We obtained similar results performing non-parametric statistics (repeated-measures Friedman [ANOVAs (8, 7) = 12.3 $p = 0.090$] and Wilcoxon Matched Pairs Tests [all $p$-values < 0.05]).

**Table 1. The effects of task complexity on β-activity, subjective ratings of complexity, and operative performance.** Average values and, in brackets, standard deviations calculated from all participants (n = 8). For the NASA-Task Load Index (NASA-TLX), higher scores indicate higher perceived levels of complexity. Operative performance scores range from 1 to 5, with values closer to 1 indicating better performance.

| | **Primary-Surgeon** | | | | **Assistant-Surgeon** | | | |
|---|---|---|---|---|---|---|---|---|
| | **MPS** | | **LESS** | | **MPS** | | **LESS** | |
| | **Contin.** | **Interrup.** | **Contin.** | **Interrup.** | **Contin.** | **Interrup.** | **Contin.** | **Interrup.** |
| β-activity (μV2/Hz) | 28.91 (0.71) | 28.89 (0.76) | 29.62 (1.81) | 29.00 (1.40) | 28.39 (0.66) | 28.32 (0.89) | 29.16 (1.13) | 29.24 (1.32) |
| NASA-TLX [0-100] | 45.42 (14.32) | 50.52 (19.85) | 64.27 (14.25) | 75.00 (17.47) | 22.81 (12.57) | 29.58 (17.47) | 49.27 (20.18) | 49.79 (13.63) |
| Operative performance | 2.5 (0.57) | 2.25 (0.55) | 3.47 (0.39) | 3.72 (0.93) | 1.78 (0.45) | 2.28 (0.49) | 2.93 (0.65) | 2.97 (0.82) |

*Note.* Contin. = Continuous Suture; Interrup. = Interrupted Suture; LESS = laparo-endoscopic single-site; MPS = multiport laparoscopic surgery.

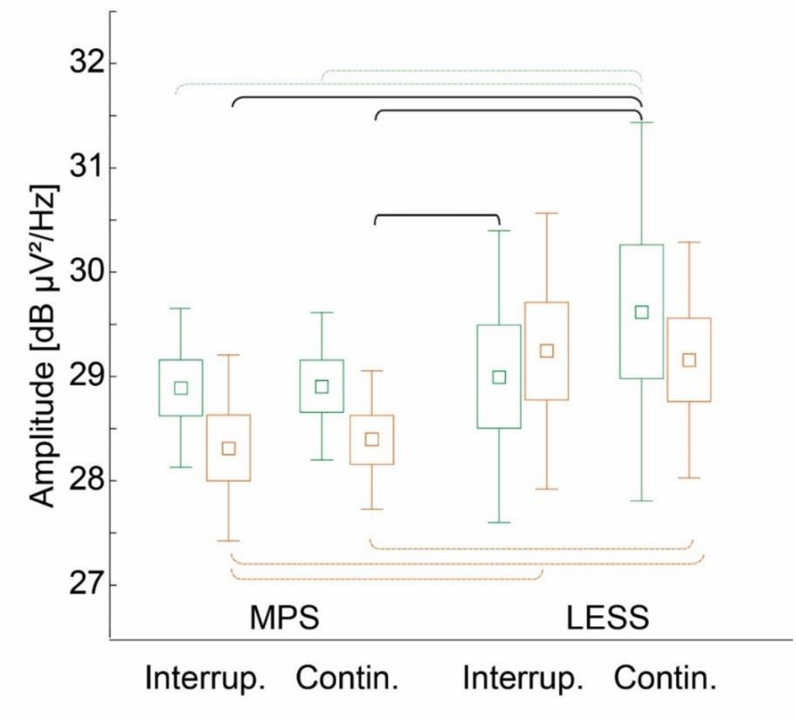


**Figure 2) The effects of task complexity on β-activity**. Primary-surgeon data are represented in green, assistant-surgeon in orange. Differences within the same surgical role are indicated with dotted square brackets. Differences between surgical roles are indicated with solid square brackets. For each experimental condition, the inner boxes represent the mean (M) and the external ones the standard error of the mean (±SE). The error bars represent the standard deviation (±SD). All values are calculated across participants (*n* = 8). Interrup. = Interrupted suture; Contin. = Continuous Suture.

**Discussion**

In healthcare settings, as in any safety-critical system, an optimal operator cognitive state is the key element to learn, develop, and refine fundamental skills that ensure high levels of performance. Good performance should lead to greater patient safety. Nowadays, successful surgical performance relies not only on the physical conditions of the surgeon (e.g., getting sufficient rest between shifts), but also on his/her ability to cope with arduous and mentally overloading situations (for a recent review, see [1]). Thus, the operator's mental overload has long been recognized as an important factor to consider to enhance patient safety and quality of care.[33]

Here, we examined how surgical complexity affects brain activity during realistic exercises. Our results show the sensitivity of an EEG-based index, the prefrontal β-activity, in detecting mental load variations in surgeons. Additionally, we demonstrated the feasibility of using a wearable EEG-device to collect unbiased measures of surgeons' mental overload. Data indicate that highly demanding procedures (i.e., sutures performed with LESS) induced higher prefrontal β-activity, whereas less demanding procedures (i.e. sutures performed with MPS) induced lower β-activity.

EEG power reflects the amount of neurons that discharge at the same time.[34] This discharge generates oscillatory activities that are task dependent; that is, oscillations occur more frequently during more demanding tasks.[35] Thus, EEG power is thought to be related to the cortical resources employed for information processing.[36] Here, we recorded EEG activity from the prefrontal cortex. This area plays an important role in attention, concentration, and executive functions (including planning, selecting, and ongoing regulation of goal-directed behaviors).[37,38] Variations in this area, associated with a task complexity modulation, provide quantitative evidence of compensatory strategies used to deal with different task loads imposed by the environment. Our results confirm recent investigations in surgical scenarios using the fNIRS technique that showed that prefrontal excitation is subject to task difficulty modulations.[39–41] Furthermore, our results are in line with those obtained in non-surgical scenarios: increase in β-activity has been associated with increased task demands[19–21,29,42] and mental stress,[18] which may also be due to the importance of the task at hand.[43] Finally, considering that task complexity is also a modulator of arousal[44–46] and arousal influences EEG power, it is plausible to assume that changes in β-activity actually reflect a surgeon's mental overload due to task complexity.

Previous studies have measured mental load on surgical teams using subjective measures. For example, the NASA-TLX could differentiate between the primary and the assistant-surgeon.[47,48] However it does not reflect differences between the procedures,[49] despite the fact MPS and LESS have considerable different levels of difficulty[47–49] and, consequently, are expected to induce different levels of mental load.

Furthermore, comparisons are often drawn between the operating room and the aircraft cockpit.[50] Indeed our data suggests a similar synchronicity effect between the members of the surgical team as to that previously observed inside the cockpit between pilots.[31,51] That is, β-activity was similar for primary-surgeons and assistant-surgeons performing the same surgical exercises, suggesting a possible synchronization between the surgical team members. It has been shown, that enhancing performance requires the team to be highly concentrated (EEG-synchronized) over specific periods of time.[52,53]

Finally, because the EEG signal is considered to be too noise-prone to allow the recording of the brain dynamics during normal working interactions, and, considering that the physical nature of the surgeon’s tasks implied constant movements, one might wonder if the EEG-based indices are inappropriate to monitor surgeon’s task load in real working conditions. This possibility seems unlikely in light of the new artefact removal procedures that allows analysis of EEG signals recorded during walking and running.[54] In this-vein, future studies are needed to examine the plausibility of reliable EEG recordings outside of surgical settings, where the surgical team members will be moving.

**Conclusion**

Despite early interest in the 1990s in the application of the EEG technology to the surgical field,[55] studies are still rare (for a recent review, see [12]). Here, we monitored the surgical team’s cognitive state during realistic surgical procedures. Real-time EEG monitoring not only would allow instantaneous detection of overload situations. Additionally it could provide real-time feedback to the team allowing time to introduce countermeasures to prevent a sentinel event (perhaps even by automated equipment). Furthermore, the application of these tools will help to create effective learning experiences, making surgical simulations appropriately difficult so that they will be sufficiently challenging but not so difficult that learning cannot happen. Finally, for future work we are taking into consideration the option of monitoring the whole surgical team[48,49] to get a fuller picture of the mental and physical demands, as well as the use of briefing sessions[56] as a way to improve the rapport between surgical team members and, consequently, the learning experience.

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# Appendix D

System classification according to the State-of-the-art. The table have been split into two pages due to the size.

| Name | Release Date | Monitoring systems using physiological variable | | | | | | | Behavioral variable monitoring systems | | | | TSLB | BL | ES | LC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | HRV | GSR | OM | HM | Act | EEG | BT | SWM | LD | EV | RT | | | | |
| **Driver monitoring system** | - | | | | | | | | | | | | | | | |
| **Optical Cabin Control** | - | | | | | | | | | | | | | | | |
| **Guardian** | - | | | | | | | | | | | | | | | |
| **WARDEN™** | - | | | | | | | | | | | | | | | |
| **Engine driver VTCS** | 2002 | | | | | | | | | | | | | | | |
| **Nap Zapper** | 2004 | | | | | | | | | | | | | | | |
| **Driving Monitoring System** | 2006 | | | | | | | | | | | | | | | |
| **Driver Alert Control** | 2007 | | | | | | | | | | | | | | | |
| **Attention Assist** | 2009 | | | | | | | | | | | | | | | |
| **Anti Sleep Pilot** | 2011 | | | | | | | | | | | | | | | |
| **Ford Driver Alert** | 2012 | | | | | | | | | | | | | | | |
| **Readiband** | 2013 | | | | | | | | | | | | | | | |
| **Active Driving Assistant** | 2013 | | | | | | | | | | | | | | | |
| **iBuzz Fatigue Alert** | 2013 | | | | | | | | | | | | | | | |
| **Smart Eye's Driver Monitoring System** | 2014 | | | | | | | | | | | | | | | |
| **Fatigue Detection System** | 2014 | | | | | | | | | | | | | | | |
| **Vigo** | 2015 | | | | | | | | | | | | | | | |
| **SmartCap** | 2015 | | | | | | | | | | | | | | | |
| **Driver Monitoring** | 2015 | | | | | | | | | | | | | | | |
| **Driver Attention Alert System** | 2015 | | | | | | | | | | | | | | | |
| **Optalert** | 2015 | | | | | | | | | | | | | | | |
| **Cat Driver Safety System** | 2015 | | | | | | | | | | | | | | | |

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|---|---|---|---|---|---|
| HRV | Heart Rate Variability | EEG | Electroencephalography | RT | Reaction Time |
| GSR | Galvanic Skin Resistance | BT | Body Temperature | TSLB | Time Since Last Brake |
| OM | Oculomotor Measurements | SWM | Steering Wheel Movements | BL | Baseline |
| HM | Head Movements | LD | Lane Deviation | ES | Embedded System |
| Act | Actigraphy | EV | Environmental Variables | LC | Low-Cost System |

| Name | Release Date | Monitoring systems using physiological variable | | | | | | | Behavioral variable monitoring systems | | | | TSLB | BL | ES | LC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | HRV | GSR | OM | HM | Act | EEG | BT | SWM | LD | EV | RT | | | | |
| **DriverMate** | 2016 | | | | | | | | | | | | | | | |
| **ActiveVision Service** | 2016 | | | | | | | | | | | | | | | |
| **StopSleep** | 2016 | | | | | | | | | | | | | | | |
| **CAT Smartband** | 2016 | | | | | | | | | | | | | | | |
| **Driver Fatigue Alert** | 2016 | | | | | | | | | | | | | | | |
| **Fatigue Detection Warning** | 2016 | | | | | | | | | | | | | | | |
| **Drowsiness-Control Technology** | 2017 | | | | | | | | | | | | | | | |
| **DS Driver Attention Monitoring** | 2017 | | | | | | | | | | | | | | | |
| **Driver Attention Monitoring System** | 2017 | | | | | | | | | | | | | | | |
| **Driver Attention Alert** | 2017 | | | | | | | | | | | | | | | |
| **i-ACTIVE SENSE: Driver Attention Alert** | 2017 | | | | | | | | | | | | | | | |
| **Driver Drowsiness Alert** | 2017 | | | | | | | | | | | | | | | |
| **Toucango** | 2018 | | | | | | | | | | | | | | | |
| **Driver Status Monitor** | 2018 | | | | | | | | | | | | | | | |
| **Driver Drowsiness Detection** | 2018 | | | | | | | | | | | | | | | |
| **Cadillac CT6 Super Cruise System** | 2018 | | | | | | | | | | | | | | | |
| **Driver Attention Warning** | 2018 | | | | | | | | | | | | | | | |
| **Peugeot Driver Attention Alert** | 2018 | | | | | | | | | | | | | | | |
| **Driver Monitoring System with WAC** | 2018 | | | | | | | | | | | | | | | |
| **Datik** | 2018 | | | | | | | | | | | | | | | |
| **Driver Monitoring System – Driver Focus** | 2019 | | | | | | | | | | | | | | | |
| **OpGuard** | 2019 | | | | | | | | | | | | | | | |

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|---|---|---|---|---|---|
| HRV | Heart Rate Variability | EEG | Electroencephalography | RT | Reaction Time |
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| OM | Oculomotor Measurements | SWM | Steering Wheel Movements | BL | Baseline |
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