SMART THINKING

Haldor Sjaaheim discusses how Smartbrain is developing the EmerEEG neurostimulation and diagnostic device for personalised telemedicine and its future benefits for patients

Smartbrain has, together with a consortium of industry leading partners and universities, received funding through the FP7 'Research for the Benefits of SMEs' programme to develop: 'A portable device for early detection and treatment of Traumatic Brain Injury based on advanced qEEG and HD-TES to prevent major health problems and especially for use in emergencies and telemedicine.'

Traumatic Brain Injury (TBI) is defined as damage to the brain resulting from an external force with the result of a temporary or permanent impairment of the brain function. It is one of the leading causes of disability worldwide and constitutes a major health problem with devastating consequences and an enormous socioeconomic burden on individuals and their families. The severity of TBI is divided into mild, moderate and severe, and mild TBI (mTBI (concussion)) represents 70-90% of all known TBI incidences. The overall incidence of hospitalised and fatal TBI ranges from 100 to 300 per 100,000 inhabitants per year, with an average of 235 per 100,000 per year. This accounts annually for more than 1.2 million citizens in the EU countries plus Norway, Iceland, and Switzerland, of which nearly 80,000 die.

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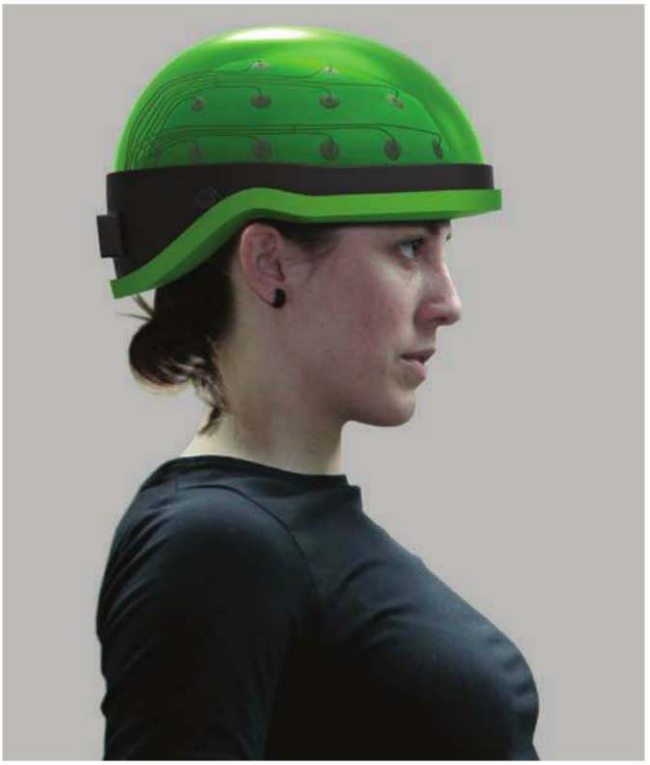
It is estimated that eight million people in Europe experience some level of disability caused by TBI. The total economic burden caused by TBI of all documented incidences was estimated to be €33bn in 2010. However, a large number of mTBI cases are not hospitalised or documented and the total number of mTBI incidences in adults is conservatively estimated to be more than 600 per 100,000, per year.

In the last decade, mTBI has been recognised as a major public health concern, especially for teenagers and young adults, because it can potentially lead to significant disruptions in education, working, and quality of life (QOL) in general. Most mTBI patients recover within three to 12 months, however a considerable share continues to report persisting distressing physical, emotional and cognitive symptoms (post-concussion syndrome (PCS)) including headache, balance problems, dizziness, fatigue, depression, anxiety, irritability, and memory and



attention difficulties. In addition, mTBI may be associated with an increased risk for certain neurological and psychiatric disorders, including Parkinson's disease, early onset dementia, chronic traumatic encephalopathy, and schizophrenia (reviewed in Cancelliere *et al.*, 2012).

Despite the short and long-term impact of TBI, the disease has been seriously underrepresented in medical R&D efforts compared to other health problems. It is further well known that sufficient time for rehabilitation following an mTBI event is crucial. Permanent damage from mTBI frequently arises because patients suffer from a second impact to the head before they have been fully recovered. Thus, it is of great value to be able to assess patient condition to evaluate when a patient is ready to enter into normal life activities following an mTBI event, and good diagnostic tools for this assessment are missing.

Smartbrain has recognised the need for a reliable electroencephalography (qEEG) diagnostic device for the early detection of TBI to improve healthcare and first aid care. Further, such a device can reduce the socioeconomic burden in healthcare costs and strengthen neuroscience research.

Our proposed solution to detect and reduce the short and long-term symptoms of TBI is the development of a medical head device for acute and reliable diagnosis of TBI, of all severities, based on advanced quantitative qEEG providing at the same time a treatment intervention (if it is necessary) based on real-time monitored and personalised high definition Transcranial Electrical Stimulation (HD-TES). This novel one-size-fits-all EmerEEG solution will detect TBI focal areas and make it possible to initiate spatial targeted HD-TES to prevent secondary molecular damages to the brain and, putatively, reversal of the initial impact damage. HD-TES is an emerging, safe, non-invasive technology for focal targeting of cortical structures with DC currents below 5mAh.

The head device will be developed for applications in emergency departments, healthcare centres, general practices, ambulances, high risk TBI locations (sport arenas, off-shore industry etc.), and rehabilitation centres.

'Our innovation will increase quality of life, improve first aid care, and healthcare in remote and rural areas. Moreover, society will benefit from sustainable savings in costs for healthcare and for work disability.'

The EmerEEG equipment will be safe and easy to use by a trained operator and the project will contribute to establishing the first reliable platform for telemedicine support on qEEG output analysis and HD-TES treatment progression. Importantly, we will encourage the use of the EmerEEG solution in research and science projects to approve and improve medical qEEG/HD-TES applications. The system design will have an inherently unique and predictable performance, thus making scientific results from different research groups directly comparable. This new medical innovation for simultaneous diagnosis and treatment of TBI could indubitably be a milestone for medical research and stimulation of various brain disorders and trauma.

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The project is targeting one of the many neurological conditions that would greatly benefit from advances in qEEG/HD-TES diagnostic and stimulation devices. The EmerEEG device is trying to bridge the gap between research and clinical application and provide an easy and unified platform that can be operated by emergency and hospital staff with the specialist aid of telemedicine centres.

In the development of EEG-systems there is a compromise between the time used for application, i.e. the time it takes to apply and prepare the electrodes onto the scalp of a subject, and

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the quality of the obtained measurements. The preferred electrodes are the so called 'wet electrodes', since these provide the best signal to noise ratio. In stimulation of the brain, it is only possible to use wet electrodes.

The current state-of-the-art connection quality for both dry and wet electrodes is heavily dependent on the operator skills and technique. Even if two different montages seem similar at a glance, they can change unpredictably because of differences in gel volume, surface area, dispersion and electrode/skin pressure. This problem can arise between individual electrodes in one subject, due to movement and uneven drying of the gel. This also imposes a problem when the same subject is recorded in multiple sessions, making the recording of biopotential more unpredictable than necessary.

Smartbrain has a unique solution that is easy to use and maintain without compromising quality and usability: the EmerEEG device combines many benefits over the current state-of-the-art system:

- Industry's first head device with combined qEEG and HD-TES;
- 'One min prep & clean' with novel automatic fluidic system;
- Patented positioning system with predictable behaviour;
- Laboratory EEG-quality available anywhere;
- No need for supporting infrastructure; and
- A portable and comfortable design.

The system, as well as the protective shield, are comfortable for patients and will also be a viable method for long-term monitoring of epilepsy patients and polysomnography.

Both these platforms are designed to enable researchers and healthcare professionals to engage in a community of expertise and build-up of a new dynamic database that, in the future, will increase the accuracy of both diagnosis and stimulation and bring huge savings for the healthcare system.

Smartbrain

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