THE DEVELOPMENT OF OPTALERT

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Optalert grew out of my research and clinical practice of sleep medicine which began in 1969 at Monash University Medical School, Alfred Hospital, Melbourne. The background to that was my interest in the psychophysiology of behavioural states, particularly sleep and wakefulness. This led me in 1969-1972 to do a PhD in sleep medicine, the first in Australia. Apart from enabling me gain detailed knowledge of the newly expanding physiology of sleep, I developed expertise in the measurement and conceptual analysis of excessive daytime sleepiness (EDS) in patients suffering from a variety of sleep disorders. However, many of those disorders were not widely recognized then and remain so today. One such disorder that is common, obstructive sleep apnea, became treatable only after 1981 when CPAP treatment was developed at Sydney University. I recognized, as did others, that EDS in patients had dire consequences, including an increased risk of car accidents.

I developed the Epworth Sleepiness Scale (ESS) in 1990, and validated it in a series of investigations and publications over several years. The ESS had become a world standard method for measuring a person's general level of sleepiness (average sleep propensity) in daily life by the mid 1990's.

I had established the Epworth Sleep Centre in 1988 and nurtured its national and international reputation as a centre of excellence. As part of my clinical practice I monitored the sleep of many thousands of patients by overnight polysomnography, an essential step in the diagnosis and treatment of their sleep disorders. A mainstay of polysomnography is the monitoring of (among other things) the electroencephalogram (EEG), the electrooculogram(EOG) and the electromyogram(EMG) in the sleep laboratory to distinguish sleep stages from each other and from wakefulness. I had designed the digital polysomnography equipment that was used at Epworth and manufactured by Compumedics Pty Ltd, and which was later sold around the world to equip other sleep laboratories. However, I realized that those methods and technologies were not appropriate for monitoring the alertness/drowsiness of active people, for theoretical, technical and practical reasons. In 2001 I wrote a detailed report, commissioned by VicRoads, about the whole range of methods that could be considered for monitoring the alertness/drowsiness of drivers.

As early as1994 I had begun to develop a new infrared reflectance method for monitoring eye and eyelid movements which I recognized were to play a critical role in the study of active people. I made the first, very simple version of the new device myself in June 1994, and in July 1994 I called it Optalert.

The following are some highlights in the history of Optalert's subsequent development:

February 1995. I contracted Robert Accardi, of Priority 1 Design, to make an analogue system with 2 infrared emitters and 2 phototransistor sensors, one for monitoring the eye and eyelid movements of each eye by reflectance. Initially this had 100microsec pulses of IR light every 1600 microsec, but this was soon changed to 20 microsec pulses every 500 microsec. There were analogue filters to reduce the effect of environmental IR. The user manual and circuitry for this device is attached. This was relatively successful and led to the finding that binocular coordination of eye and eyelid movements was an important new variable that had not been considered previously.

July 1995: I made the decision to change from analogue to digital methods for monitoring IR reflectance, with sensors on both eyes. Because of other important developments with my practice and because I did not have ready access to the necessary hardware and software engineering skills at the time, the planned developments with Optalert were put on hold until 1998.

February 1998: I recognized the need to measure the velocities of eye and eyelid movements, the duration of eyelid closures, and the presence of slow eye movements while removing the effects of smooth pursuit and vestibulo-ocular movements from the proposed digital measurements. At this stage, I proposed to calibrate the velocities of saccadic eye movements by timing the duration of purposeful 10 degree saccades. I also proposed to use an accelerometer to measure the position and tilt of the head. I first developed the idea then of a device for warning drivers of the onset of drowsiness while they were driving.

March 1998: I made my first plans to avoid the use of a calibration procedure for assessing the velocity of eye and eyelid movements by using a ratio, at this stage, of

maximum acceleration / maximum velocity x duration

of individual movements. This idea was not developed much until it was changed to the amplitude/velocity ratio in mid 2001.

July 1998: I first contracted Jeff Harcourt to work on a new digital eye and eyelid monitoring system on a glasses frame that also had an accelerometer attached for the measurement of head tilt and movements. There was one IR emitter and one phototransistor sensor in a single housing, held in place by Blu-tack, pointing at each eye. The frame was connected by cable to an 8-channel analogue to digital converter with 8-bit accuracy and circuitry for control of the IR pulses in a box that was about 1.5 metres from the glasses. This was used with a laptop PC to display the signals. Pulses of IR 50 microsec long were repeated 2000 times per sec, ie every 500 microsec. The incidental IR light was removed by subtracting the IR light detected immediately before each pulse from that at the height of the pulse. This can be called Optalert-1.0 even though there had been an earlier prototype device.

December 1998 to August 1999: By this time it was clear that 50Hz noise that was both optical and electrical in nature was a problem with the recorded signals from Optalert because of the inductance of the cable between the pulse-controlling circuits and the transducers on the glasses. However, for the first time, zero-crossing intervals in the position and velocity signals recorded by Optalert could be measured manually by using two time cursors on the laptop screen to give accurate measurements of the duration of eyelid closure and reopening, etc. The IR transducers were successfully changed to much smaller surface-mount devices, and the pulse frequency was reduced to 1000 per sec. A small DC accelerometer attached to the glasses frame gave a measure of head tilt. This version of Optalert is now referred to as Optalert-1.1. Its success encouraged me to continue investing my own money for further development of Optalert.

June 2000: The first driving simulator experiments with Optalert-1.1 were carried out at Monash University Department of Psychology. Four volunteer subjects drove the relatively unsophisticated simulator with STISIM software for 30-min periods when alert and repeatedly during the night with progressive sleep deprivation. The nature of the software was such that it was difficult to relate changes in performance to the eye movement recordings on the same time scale. However, these early experiments showed the potential promise of Optalert for monitoring drowsiness in drivers.

I decided to develop my own visual psychomotor performance task that could be selected to be used either as a simple reaction-time test or a choice reaction-time test, and which would also record the subject's eye and eyelid movements on the same laptop screen and time scale. I called this the Johns Test of Vigilance (JTV). Specifications and user instructions for the JTV are attached.

October 2000: The JTV was working well as a reaction timer with Optalert-1.1 recording eye movement data, but neither reaction times nor eye movements were measured automatically. The JTV gave 'yes-no' answers in relation to errors of omission in the subject's performance that could be readily correlated with changes in eye movements with sleep deprivation that caused drowsiness. Optalert now had two sensors and one emitter for each eye and various alternative positions for those transducers were tried.

February 2001: It was decided on the basis of advice from Jeff Harcourt to redesign the data acquisition system using a faster processor and Ethernet instead of the serial port that had been used previously because it could not always cope with the amount of data required to be recorded. Optalert-2 was to have 16-bit accuracy with 8 sensors, four on each eye. This took more than a year to implement and was not finished until September 2002.

July 2001: I wrote a detailed report on the various ~~of~~ methods that had either been tried or could be considered for monitoring alertness/drowsiness in drivers. This was commissioned by VicRoads.

November 2001: A provisional patent was filed that described the use of the IR reflectance method for measuring several characteristics of eye and eyelid movements such as the presence of slow eye movements, long eyelid closures etc, that could be used to monitor alertness/drowsiness in active people. The IR sensors were now placed below the cornea, looking up at the upper eyelid with Optalert-1.1. This was found to be the best position for monitoring eyelid movements which were becoming more important than saccades. The time taken for the eyelids to close during blinks (eyelid closure) was confirmed as a very useful measure of drowsiness, predicting subsequent performance failure in the JTV. The first normative data were produced for Optalert-1.1s measurements of eyelid closure, eyelids remaining closed and eyelids reopening during JTVs, all measured manually from the laptop screen. The velocity of movements was calculated as the change in position per 10 msec.

February 2002: I proposed to use two different velocity measurements, with the change in position per 10 msec for detecting and quantifying saccades and normal blinks, and per 100 msec for detecting slower blinks and other movements.

May 2002: Sleep Diagnostics Pty Ltd was formed to own the IP associated with Optalert and to facilitate and fund its further development. Crantock Investments, my family trust, was its only shareholder then.

September-October 2002: First use of the amplitude-velocity ratio (AVR-10msec) as a measure of the relative velocity of eyelid movements during blinks and saccades. This had the great advantage that it did not require calibration for each user or setup. The AVR of eyelid closure was shown to be a good predictor of performance failure involving errors of omission in the JTV when drowsy. Grimaces could then be distinguished from blinks. The first experiments were conducted on changes in AVR with increasing blood alcohol concentrations.

November 2002: The final patent application was filed that included descriptions of the AVR and of the Optalert technology, changes with drowsiness, and their relationship to increasing blood alcohol concentrations.

May 2003: Exto Partners were contracted to develop a business plan and a project plan for Optalert, to manage the project from day to day and to suggest, then implement ways of raising funds for the further development of Optalert. I had retired from my role as Director of Epworth Sleep Centre in March 2002 and realized that the future success of Optalert could not be acheived without a lot more help from people with a variety of skills that I did not have.

July 2003: I instigated the formation of the Drowsiness and Fatigue Research Group at Swinburne University of Technology, School of Biophysical Sciences and Electrical Engineering, where I had been an Adjunct Professor (Psychophysiology) since 1998. Optalert has subsequently been included in several experiments there.

November 2003: Optalert-2.0 was developed based on plastic safety glasses with four sensors and one emitter on each eye. These were still held in place by Blu-tack. The microprocessor controlling the timing and duration of IR pulses and the analogue-to-digital conversion of the data from each sensor was placed on the side of the glasses. This virtually eliminated the problems we had in relation to 50 Hz noise in the recorded signals. A USB connection was now used instead of Ethernet between the glasses and the laptop, which made a big improvement. A log-file analyzer was now available in software for the automatic calculation of eye movement parameters, including the AVR and the duration of each component of eyelid movements during blinks. I found that, rather than use two different velocity measurements, with 10 and 100 msec periods over which changes in position were calculated, it was sufficient to use one such measurement with a 50 msec interval. It was decided to use 500 pulses of IR light per second as the optimal frequency of sampling with 12-bit accuracy.

February- June 2004: Optalert-3.1 was developed, replacing the plastic safety glasses with a metal frame taken from commercially available sunglasses, and reverting to two sensors and one emitter for each eye. There had been no advantage in having four sensors for each eye, as in Optalert-2.0. A flexible circuit board was used to connect the transducers to the microprocessor board on the glasses fame with version 3.0. A mechanism was then developed for changing the position of the frame in relation to the eyes by using an adjustable nose-piece. The idea was good, but this first implementation failed because it was too unstable laterally. This was Optalert-3.1.

July-November 2004: Optalert-4.0 was developed from 3.1 by re-designing and miniaturizing the microprocessor board and flexible circuit board, using plastic glasses frames designed and hand-made for us by Roger Henley in Adelaide, designing a new method for housing the transducers in the frame and a new method for adjusting the nose-piece that was much improved. However, this initial frame design was soon found to be unacceptable when tried by volunteer divers from Linfox. Optalert-4.1 had a more open aperture and a lighter frame, in looks and in weight, than 4.0 and has proven to be much more acceptable. Optalert-4.1 is currently being used by Linfox drivers. So far, recordings have been made by only a few drivers, but this has already shown that it is possible to record eye and eyelid movements in truck divers that can form the basis of a measure of their drowsiness continuously in an acceptable way.

However, for some time now we have recognized a problem that has made recordings from drivers more difficult to analyze than those from people doing the JTV while sitting at a desk. The problem arises mainly because there are vestibulo-ocular movements associated with the movements of the vehicle, not present in the JTV situation, that share some characteristics with slow eye movements and blinks in drowsy people. However, we have recently developed a measure of the relative amplitude of all movements and the relative position of the eyes and lids at any time, a measure that is self-calibrating and which distinguishes most blinks from other movements, including most vestibulo-ocular movements. Initial results suggest that using this amplitude criterion to select which events to include in the measurement of drowsiness will solve this problem.

A composite measure of drowsiness, The Johns Drowsiness Index (JDI), is now in development. This will be calibrated against the equivalent changes seen with increasing blood alcohol concentrations in experiments using the JTV that have already begun at Swinburne University. It is also planned to show how the JDI is related to changes in driving performance on the advanced driving simulator at Monash University Accident Research Centre. This is one of the 10 best simulators in the world that includes a method for moving the vehicle, as if on the road, that should reproduce the vestibulo-ocular eye movements seen in actual driving conditions.

Although we have not yet completed our development of the JDI, I can see no major impediments to the successful further development of Optalert-5, the proposed first version to be available commercially.

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