Evaluation of a Prototype Driver Impairment Device in Volunteers: A Double Blind Placebo Controlled Crossover Study with Alcohol.

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Background
Driving performance is easily disrupted as a direct consequence of the use of alcohol, licit and illicit drugs. Epidemiological research suggests that a blood alcohol level of 80mg/100ml (the UK legal limit) is associated with an approximate doubling of the risk of a driver becoming involved in a collision. This legal BAC limit is used as a reference point to indicate the impaired and non-impaired performance of a driver. For many years alcohol has been the drug of greatest concern since it is one of the most commonly used psychoactive substances and the most frequently recognised cause of drug induced driver impairment. However, psychoactive drugs both medicinal and illegal can have an equally impairing effect on driving performance. Psychoactive substances can cause impairment of attention, information processing, memory, and divided attention, the disruption of which will have a direct consequence on an individual's ability to drive. Sedative drugs have been shown to impair car handling ability and other drugs especially tricyclic antidepressants and benzodiazepines have been shown to play an important role in accident causality. In addition, research has shown antihistamines to cause driving related impairment. These drugs continue to be heavily prescribed to patients who are likely to drive, with some impairing antihistamines available over the counter without prescription. Research relating to illegal drugs and their ability to impair driving is also prevalent. Cannabis, heroin, methadone and ecstasy all have detrimental effects on an individual's ability to attend to the complexities of driving. Epidemiological data of fatal accident victims showed that there was a presence of illegal drugs in 18% of cases and of medicinal drugs in 6% of cases and whilst there is an annual average of 75000 convictions for driving above the prescribed legal limit of alcohol in England and Wales, there are fewer than 2000 convictions for driving whilst unfit through drink or drugs. There is not at present any objective test available in line with the breathalyser that can be used at the roadside to determine impairment due to drugs, whether impairment is brought about through prescription medication, OTC medication or illegal substances.

The measurement of drug-induced impairment using psychometric test batteries has been shown to be a reliable and valid measure of assessing a wide range of psychoactive compounds. These tests assess many aspects of information processing, sensori motor coordination, reaction time, short term memory and other psychomotor functions related to skilled behaviour. The most sensitive, commonly used, and reliable tests for assessing driving ability are tracking tasks and reaction time tasks, as they have been shown to be good models of the perceptual cognitive demands placed on the individual. Attentional performance is also one of the most important information processing abilities related to driving behaviour. Past research has yielded high correlations between vehicle speed, accident rates and driver attention. The Sustained Attention to Response Task (SART) has been shown to be a good predictor of every-day attentional failures, and action slips.
Through the use of psychometric tests it is possible to show cognitive and psychomotor impairment of skills relevant to driving in scientific conditions. However, these tests may not be directly transferable for use in the field. The global hypothesis is whether psychometric tests which correlate with driving performance can be presented on portable devices in the uncontrolled environment of the roadside. Furthermore, can a device be sensitive enough to determine impairment of an individual considering the variability of scores expected across the general population? Also, in the absence of a baseline can these results be considered reliable.

**Objectives**

This study reports data from the effects of two known doses of alcohol used to investigate the validity and sensitivity of this prototype psychometric impairment device.

**Methodology**

The study was a randomised, double blind placebo controlled, crossover design. Volunteers received 50mg/100ml and 80mg/100ml of alcohol and alcohol placebo as a single dose. The alcohol dose was calculated using a formula based on the Adjusted Widmark Scale with an additional adjustment based on iterative data from the Transport Research Laboratory (Crowthorne, Berkshire, UK). This study was approved by the Quorn Research Review Ethics Committee.

Psychometrics were presented on a compact, ruggedised handheld computing device. The two tests were: Critical Tracking Task (CTT) - an integrative task of cognitive and psychomotor function, comprising of tracking ability, divided attention and reaction time. The task required the user to track a moving target with a PDA stylus whilst responding to a peripheral awareness task. The Sustained Attention to Response Task (SART) assessed sustained attentional performance. Continuous stimulus in the form of road sign images were presented on the hand held device. Volunteers were required to respond to the presentation of every stimulus with a key press unless presented with the target stimulus in which case they were required to withhold response. Each subject initially took part in a familiarisation session where each test was carried out three times.

**Results & Analysis**

A paired-samples t-test was conducted to evaluate the effect of practice on the main response measures of each test, no practice effects were observed on any test variable. Analysis of Variance (SAS, PROC, GLM) was applied to each response variable in the three treatment periods. Due to the unique nature of the use of this test battery, analysis did not include baseline data to validate and replicate possible use at the roadside. A probability value of less than 0.05 was considered to be significant.

**CTT**

There were no statistically significant differences observed on OA (average tracking deviation), OART (average reaction time) or OA post peripheral stimulus presentation following treatment with placebo, low or high dose alcohol. However, a clear impairment
trend is observable from the mean scores as is presented in Figures 1 & 2.

Figure 1 - Mean (± SEM) average tracking deviation for the CTT

Figure 2 Mean (± SEM) average reaction time for the CTT

Significance was observed for the test variable OA_10 (average tracking deviation at the end of the task) between those on high dose alcohol and those on placebo (p=0.0456), the mean scores of which are presented in Figure 3.
Analysis was also carried out on the results of the same test which had been carried out on an IBM compatible laptop. A significant difference in performance was observed for: average tracking error, between placebo and high dose alcohol (p=0.0069). Similarly reaction time to the peripheral stimuli was significantly increased for both high (p=0.0148) and low (p=0.0236) dose alcohol compared with placebo. Further significance was observed for the average tracking deviation in the end of the test between placebo and high dose alcohol (p=0.0017) and between high dose and low dose (p=0.0140).

**SART**

There were no significant difference observed for the following response measures: correct SART responses, reaction time to correct SART responses, reaction time to incorrect SART responses. Significance was observed for incorrect SART responses, i.e. when subjects were instructed to withhold a response to the target symbol between high dose and placebo (p=0.0174) and low dose and placebo (p=0.0489). Mean incorrect responses are presented in Figure 4. There was also a significant difference between placebo and high dose alcohol for incorrect responses when presented on the laptop.

![Figure 3](image1.png)  
**Figure 3** – Mean (± SEM) average tracking deviation at the end of the CTT

![Figure 4](image2.png)  
**Figure 4** Mean (± SEM) scores for incorrect SART presses
Discussion
The Critical Tracking Task (CTT) was capable of detecting the impairing effects of 80mg/100ml of alcohol when presented on the PDA. However, when presented on the IBM laptop the test appeared more sensitive. The motor control element (tracking error), and the reaction time element of the test significantly differentiated between those on the high dose of alcohol, and those on the low dose. Due to the performance differences observed on the PDA and the laptop it seemed possible that the functionality of the PDA was making the tracking task easier to execute and was therefore not instigating the same level of breakdown in tracking performance. Mean tracking deviation under placebo conditions on the PDA was 13.6 pixels compared to 32.3 pixels on the laptop. Verster (2002)\(^{17}\) has reported that on average a hard tracking task would be expected to cause a deviation in excess of 20 Root Mean Square deviation compared with an easy tracking task which would usually not exceed 6 Root Mean Square deviation. As a consequence the CTT on the PDA was amended. Data from a further small pilot investigation showed that mean tracking error under placebo conditions had increased to 35.5 pixels. This extended version of the test was carried forward for use in additional validation studies. The SART was capable of significantly detecting the linear impairment relationship induced by 50mg/100ml and 80mg/100ml of alcohol. When presented on the laptop, this significance was paralleled.

Conclusion
At this early stage it is possible to state that the device is sensitive to the impairing effects of alcohol and further trials with various psychoactive compounds are imminent. An obstacle that must be avoided in further developmental stages is the expectation that this device can be directly comparable to the breathalyser. It is not yet clear whether the device will be a suitable objective tool to screen drugged drivers for many reasons that are not considerations when screening for impairment due to alcohol. The consumption of alcohol is legal, and although the dangers of its consumption are recognised, it is an accepted, widely used drug within society. However “drugs” has become a generic term used to include a wide range of psychoactive substances both medicinal and illegal. These drugs are used in various combinations with other drugs and at various doses, so each individual’s psychophysiological response will vary enormously. It is evident then that the development of a device sensitive to drug impairment is not as clear cut a case as when dealing with impairing levels of alcohol and use of the breathalyser.

Future Development
A discussed above further validation of the utility of the device needs to be carried out together with a method of combining the most sensitive response measures of the two tests into a global impairment ratio. The development of an impairment ratio is dependent on the collection of an extensive amount of normative data to ascertain the variability of scores that are to be expected in a non-impaired sample.

References


