

Following is a collection of Studies of the
Eyecheck™ Pupillometer



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Illinois State Police



EyeCheck™ Study



ILLINOIS STATE POLICE
Office of the Director

George H. Ryan
Governor

May 28, 2002

Sam W. Nolen
Director

The Honorable George H. Ryan
Governor
207 Statehouse
Springfield, Illinois 62706

Dear Governor Ryan:

I respectfully submit a report on the Use of Pupillometry Used in Law Enforcement, pursuant to Public Act 91-881. This law amends the Illinois Vehicle Code Section 11-501.5, directing the Illinois State Police to create a pilot program to establish the effectiveness of the pupillometry technology.

Very respectfully

A handwritten signature in black ink, appearing to read "Sam W. Nolen".

Sam W. Nolen

Director

Enclosures
cc: Honorable James "Pate" Philip
Honorable Michael J. Madigan
Honorable Emil Jones, Jr.
Honorable Lee A. Daniels

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AT SPRINGFIELD

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Division of Academic Affairs
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June 4, 1999

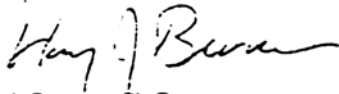
Dr. Patricia Rushing
Illinois State Police Academy
3700 East Lake Shore Drive
Springfield, IL 62707

Dear Dr. Rushing:

The Institutional Review Board met recently to review the protocol for your project, "Fatigue and Pupii Response Measurement Assessment." Approval of your project was given pending several changes and clarifications. I have received and reviewed your revised materials, and am writing to inform you that you may now proceed with your study. We expect all participating organizations to adhere to the procedures and guidelines of the protocol.

I appreciate the attention you have given to the issue of the protection of human subjects and I wish you success in your research.

Sincerely,



Harry J. Berman, Ph.D.
Human Subjects Review Officer

Illinois State Police

Study of Pupillometry used in Law Enforcement

Executive Summary

In 1996 the Illinois State Police (ISP) began measuring pupillary response with the EyeCheck™ instrument. The EyeCheck™ instrument was developed by MCJ Inc., Rockford, Illinois. MCJ Inc. is a research and development company, which investigates non-invasive technologies for determining impairment with biometrics. EyeCheck™ is a non-invasive instrument, which introduces a light stimulus to a subject's pupil and measures the subsequent pupillary reaction or pupillary dynamic. Pupillary movement provides indications of activity within the body's central nervous system. Interpretation of pupillary reaction has assisted in determining possible impairment caused by alcohol, drugs, or fatigue.

On July 1, 2000, Public Act 91-881 was passed and amended 625 ILCS 5/11-501.5 by adding paragraph (b) to the section. The added paragraph states, "The Department of State Police shall create a pilot program to establish the effectiveness of pupillometer technology..." The bill mandated an 18-month pilot program utilizing 15 instruments. The purpose of the project was to determine if pupillometer technology could detect motor vehicle drivers' impairment caused by alcohol and/or drugs. In addition, the amendment specified the measurement of fatigue levels in commercial motor vehicle drivers. A training curriculum was developed by the ISP Academy staff and MCJ Inc. to accomplish the mandate set by Public Act 91-881.

The pilot involved collecting data for 18-months and on November 15, 2002, data was forwarded to the New England College of Optometry for analysis. Upon analysis, it was concluded pupillometry can be used as an objective measure to screen and identify reduced alertness as a result of sleepiness or fatigue. It was also determined pupillometry can be used to screen and identify subjects potentially under the influence of drugs.

Pupillometry has proven, through empirical testing, to be an effective tool, which can assist in the detection, confirmation, and ultimate prosecution of impaired drivers. Impairment not involving alcohol can be difficult to identify and even more difficult to confirm and prove. The use of a pupillometer as a screening instrument would aid in identifying impairment and expedite roadside evaluation of a suspected impaired driver.

Illinois State Police

Study of Pupillometry used in Law Enforcement

Pupillary reaction of the human eye has been studied for more than 800 years. These reactions have been measured by medical professionals since the 18th century, to determine physiological and psychological conditions affecting the human body. Law enforcement officers have been examining pupillary reaction to detect alcohol and/or drug impaired drivers since the late 1970s. Officers have been trained to make observations regarding the size and movement of a subject's pupils. Pupillary movement provides indications of activity within the body's central nervous system. Interpretation of pupillary reaction has assisted in determining possible impairment caused by alcohol, drugs, or fatigue.

In 1996, the Illinois State Police (ISP) began measuring pupillary response with the EyeCheck™ instrument. The EyeCheck™ instrument was developed by MCJ Inc., Rockford, Illinois. MCJ Inc. is a research and development company, which investigates non-invasive technologies for determining impairment with biometrics. EyeCheck™ is a non-invasive instrument, which introduces a light stimulus to a subject's pupil and measures the subsequent pupillary reaction or pupillary dynamic. Initially, the investigation intended to measure fatigue levels of commercial motor vehicle drivers. However, testing was expanded in 1998 to include subjects under the influence of alcohol, prescription medication, or sleep deprivation.

On July 1, 2000, Public Act 91-881 was passed and amended 625 ILCS 5/11-501.5 by adding paragraph (b) to the section. The added paragraph states, "The Department of State Police shall create a pilot program to establish the effectiveness of pupillometer technology..." The bill mandated an 18-month pilot program utilizing 15 instruments. A copy of Public Act 91-881 appears in appendix 2. The purpose of the project was to determine if pupillometer technology could detect impairment in motor vehicle drivers caused by alcohol and/or drugs. In addition, the amendment specified the measurement of fatigue levels in commercial motor vehicle drivers. The ISP developed bid specifications for a non-invasive instrument capable of measuring pupillary dynamics. On October 16, 2000, Central Management Services issued an order to purchase 15 EyeCheck™ instruments from MCJ Inc.

A training curriculum was developed by the ISP Academy staff and MCJ Inc. to accomplish the mandate set by Public Act 91-881. The 24-hour course focused on the operation and interpretation of the EyeCheck™ instrument and resulting data. Additional training was provided in pharmacology and physiology of persons suffering from fatigue or persons under the influence of alcohol and/or drugs. The training also included recognizing the signs and symptoms of impaired persons. A total of 19 ISP personnel completed EyeCheck™ training March 7, 2001. Each student was provided with specific protocols for testing subjects under different conditions. They were advised to conduct Standardised Field Sobriety Tests (SFSTs) and Preliminary Breath Tests prior to testing with the EyeCheck™ instrument. Positive test results with the EyeCheck™ instrument were considered presumptive indications of impairment.

Illinois State Police

Study of Pupillometry used in Law Enforcement

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The pilot program was coordinated by Master Sergeant Emanuel A Lebron, Alcohol and Substance Testing Section Supervisor. Data was collected in the following manner:

- The testing of alcohol-dosed subjects was conducted during alcohol workshops. Breath Alcohol Concentrations were confirmed with breath analysis instrumentation;
- The testing of persons suspected of being under the influence of drugs occurred in the correctional facilities of several states. Urine samples were provided by the suspects and sent for toxicological analysis. Toxicology results were confirmed with Gas Chromatography/Mass Spectrum Analysis;
- The testing of persons undergoing 24-hour sleep deprivation studies included computerized testing of cognitive abilities and fine motor skills. These assessments were conducted five times during the 24-hour period. Results were compared with five EyeCheck™ instrument scans;
- The collection of field data was conducted by the 19 ISP Troopers attending the EyeCheck™ training. This data was collected to document normal enforcement activities in a field environment;
- The collection of random data encompassed a diverse population. It included persons suffering from neurobiological disorders, diseases of the eye, those taking medication, and those not under the influence of any substance;
- The collection of normative data was the most significant part of the program. It required the EyeCheck™ instrument scans to be conducted during peak alertness on those individuals not taking medication or drugs. The sampling came from Recruit and Cadet classes at the ISP Academy.

The data was collected and forwarded to Master Sergeant Lebron between March 7 and November 15, 2001. The period between November 15, 2001, and January 30, 2002, was established to provide time for the analysis of collected data by an outside entity. The ISP provided all the data collected to Dr. Jack Richman for analysis.

Dr. Richman, a Professor of Pediatric Optometry and Binocular Vision at the New England College of Optometry, was selected to complete the statistical analysis and narrative summary for the final report. Dr. Richman was chosen because he is a member of the Technical Advisory Panel for the International Association of Chiefs of Police. He is very familiar with law enforcement techniques and various drug recognition tests. This position permits him to be a good resource for law enforcement agencies around the country who perform Standardized Field Sobriety Testing, Horizontal Gaze Nystagmus Testing, and Drug Recognition Evaluation Testing. He provided expert testimony in the Circuit Court of Cook County, Illinois County Department, First Municipal District Traffic Centre on September 10, 2001. His testimony was instrumental during a "Frye" hearing on "State's Motion to Admit Horizontal Gaze Nystagmus

"Evidence, People vs. Johnson No. TO 284-294."

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The attached report provided by Dr. Richman, in appendix 4, indicates his methodology for analysing the effectiveness of pupillometry. The analysis was conducted in the following four phases:

- Phase One: To determine the characteristics and reactions of pupils in normal (non-impaired) subjects with the EyeCheck™ instrument;
- Phase Two: To determine the capability of the EyeCheck™ instrument to discriminate and identify fatigue and sleep deprived impaired subjects from normal (non-impaired);
- Phase Three: To determine the capability of the EyeCheck™ instrument to discriminate and identify drug impaired subjects from normal (non-impaired);
- Phase Four: To determine the capability of the EyeCheck™ instrument to discriminate and identify alcohol intoxicated subjects from normal (non-impaired).

Dr. Richman's conclusions indicate pupillometry can be used as an objective measure to screen and identify reduced alertness as a result of sleepiness or fatigue. He also believes pupillometry can be used to screen and identify subjects potentially under the influence of drugs. However, he is not as confident in the instrument's ability to screen and identify intoxicated subjects.

On November 14, 2001, two EyeCheck™ instrument surveys were sent to 22 personnel involved in the pilot program. Results indicate field personnel encountered problems integrating the EyeCheck™ instrument with existing computer hardware in their squad cars. Others expressed their concerns regarding officer safety issues such as the officer's attention focused on the operation of the instrument and not the actions of the test subject. However, all respondents felt the EyeCheck™ instrument has the ability to detect impairment. Many of them expressed a desire for the ISP to continue the program.

Pupillometry has proven, through testing, to be an effective tool, which can assist in the detection, confirmation, and ultimate prosecution of impaired drivers. Impairment not involving alcohol can be difficult to identify and even more difficult to confirm and prove. The use of a pupillometer as a screening instrument would aid in identifying impairment and expedite roadside evaluation of a suspected impaired driver. A pupillometer can simplify toxicology testing by specifying the type of drug to test for when impairment due to drugs is suspected. Law enforcement personnel have considered fatigued commercial drivers as a public safety concern, nationwide, for years. The use of a pupillometer by regular Patrol Officers and Commercial Vehicle Enforcement Officers could have a positive impact on highway safety. The instrument, in addition to observations, could provide an officer with evidence to justify placing a fatigued driver out-of-service.

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The ISP could improve their drug/alcohol testing procedures by utilizing this instrument on incumbent officers, as well as, new employees. The benefits of such utilisation could result in stronger compliance to drug and alcohol policies. Additionally, it could reduce the cost of initial testing by eliminating current urine/blood tests, which are negative. The time involved in collecting and preserving the chain of custody will have an impact on the administrative procedures, potentially reducing employee time spent on such testing, paperwork, and associated cost. This too may have a further impact on state laboratories and their screening backlog.

The utility of pupillometry appears to be substantiated through the testing and analysis conducted. The full potential of this technology as a screening and diagnostic tool has yet to be determined. At a minimum, it can provide cost savings to a variety of state agencies involved in chemical testing. The savings would incur when using the instrument as a pre-screening device before paying for an unneeded toxicology test. There are clearly some potential benefits to pupillometry; therefore, following is a list of recommendations for future consideration:

1. Expand the testing to include other state agencies and individual ISP districts;
2. Install new Pupillometry software as it is made available to the market;
3. Configure computer hardware in patrol vehicles, which will permit the use of peripheral devices;
4. Provide preliminary training to officers regarding the detection driver of the drug or fatigue-impaired driver.

PUBLIC ACT 91-881

An act to amend the Illinois Vehicle Code by changing Section 11-501.5 to direct the Department of State Police to create a pilot program to establish the effectiveness of the pupillometer technology (the measurement of the pupil's reaction to light) as a non-invasive technique to detect and measure possible impairment of any person who drives or is in actual physical control of a motor vehicle resulting from the suspected usage of alcohol, other drug or drugs, intoxicating compound or compounds or any combination thereof. This technology shall also be used to detect fatigue levels of the operator of a Commercial Motor Vehicle as defined in Section 6-500 (6), pursuant to Section 18b-105 of the Illinois Vehicle Code.

Secretary of the Senate



Originated in the Senate

PUBLIC ACT 91-881

1 AN ACT to amend the Illinois Vehicle Code by changing 42
2 Section 11—501.5.
3 Be it enacted by the People of the State of Illinois 46
4 represented in the General Assembly: 47
5 Section 5. The Illinois Vehicle Code is amended by 50
6 changing Section 11—501.5 as follows 52
7 (625 ILCS 5/11—501.5) (from Ch. 95 1/2, par. 11-501.5) 55
8 Sec. 11—501.5. Preliminary Breath Screening Test. (a) 57
9 If a law enforcement officer has reasonable suspicion to 58
10 believe that a person is violating or has violated Section 60
11 11-501 or a similar provision of a local ordinance, the 61
12 officer, prior to an arrest, may request the person to
13 provide a sample of his or her breath for a preliminary 62
14 breath screening test using a portable device approved by the 63
15 Department of Public Health. The person may refuse the test. 64
16 The results of this preliminary breath screening test may be 65
17 used by the law enforcement officer for the purpose of 66
18 assisting with the determination of whether to require a 67
19 chemical test as authorized under Sections 11—501.1 and 68
20 11—501.2, and the appropriate type of test to request. Any
21 chemical test authorized under Sections 11—501.1 and 11—501.2 69
22 may be requested by the officer regardless of the result of 70
23 the preliminary breath screening test, if probable cause for 71
24 an arrest exists. The result of a preliminary breath 72
25 screening test may be used by the defendant as evidence in
26 any administrative or court proceeding involving a violation 73
27 of Section 11—501 or 11—501.1. 74
28 (b) The Department of State Police shall create a pilot 76
29 program to establish the effectiveness of pupillometer 78
30 technology (the measurement of the pupil’s reaction to light) 79
31 as a noninvasive technique to detect and measure possible

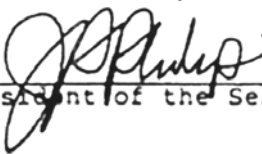


1	<u>impairment of any person who drives or is in actual physical</u>	80
2	<u>control of a motor vehicle resulting from the suspected usage</u>	81
3	<u>of alcohol, other drug or drugs, intoxicating compound or</u>	82
4	<u>compounds or any combination thereof. This technology shall</u>	83
5	<u>also be used to detect fatigue levels of the operator of a</u>	
6	<u>Commercial Motor Vehicle as defined in Section 6—500(6J,</u>	84
7	<u>pursuant to Section 18b—105 (Part 395-Hours of Service of</u>	85
8	<u>Drivers) of the Illinois Vehicle Code. A State Police officer</u>	86
9	<u>may request that the operator of a commercial motor vehicle</u>	87
10	<u>have his or her eyes examined or tested with a pupillometer</u>	
11	<u>device. The person may refuse the examination or test. The</u>	88
12	<u>State Police officer shall have the device readily available</u>	89
13	<u>to limit undue delays.</u>	
14	<u>If a State Police officer has reasonable suspicion to</u>	91
15	<u>believe that a person is violating or has violated Section</u>	92
16	<u>11-501, the officer may use the pupillometer technology, when</u>	93
17	<u>available. The officer, prior to an arrest, may request the</u>	94
18	<u>person to have his or her eyes examined or tested with a</u>	
19	<u>pupillometer device. The person may refuse the examination</u>	95
20	<u>or test. The results of this examination or test may be used</u>	96
21	<u>by the officer for the purpose of assisting with the</u>	97
22	<u>determination of whether to require a chemical test as</u>	98
23	<u>authorized under Sections 11-501.1 and 11-501.2 and the</u>	99
24	<u>appropriate type of test to request. Any chemical test</u>	
25	<u>authorized under Sections 11-501.1 and 11-501.2 may be</u>	100
26	<u>requested by the officer regardless of the result of the</u>	102
27	<u>pupillometer examination or test, if probable cause for an</u>	
28	<u>arrest exists. The result of the examination or test may be</u>	103
29	<u>used by the defendant as evidence in any administrative or</u>	104
30	<u>court proceeding involving a violation of 11-501 or 11-501.1.</u>	105
31	<u>The pilot program shall last for a period of 18 months</u>	107
32	<u>and involve the testing of 15 pupillometer devices. Within</u>	108
33	<u>90 days of the completion of the pilot project, the</u>	109
34	<u>Department of State Police shall file a report with the</u>	



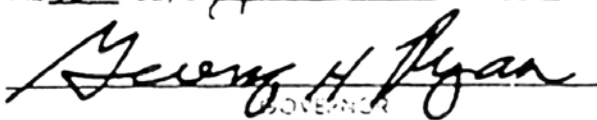
1 President of the Senate and Speaker of the House evaluating 110
 2 the project
 3 (Source: P.A. 88-169.) 112

4 Section 99. Effective date. The Act takes effect upon 115
 5 becoming law.


 _____ 121
 President of the Senate 123


 _____ 126
 Speaker, House of Representatives 127

APPROVED

THIS 30th day of June . 20 00 A.M.


 GOVERNOR

92nd General Assembly

Summary of SB1517

[[Home](#)] [[Back](#)] [[Legislation](#)]

[Full Text Bill Status](#)

Senate Sponsors:

[DILLARD.](#)

House Sponsors:

[WINTERS-JEFFERSON-MITCHELL,JERRY-MENDOZA](#)

Short description:

CD CORR-PUPILLOMETR TECHNOLOGY

Synopsis of Bill as introduced:

Amends the Unified Code of Corrections. Makes a technical change in the Section requiring the Department of Corrections to establish one or more receiving stations for committed persons and for persons transferred from the Department of Children and Family Services to the Department of Corrections.

[SENATE AMENDMENT NO. 1.](#)

Deletes reference to: [730 ILCS 5/3-8-1](#)

Adds reference to:

[730 ILCS 5/3-2-2](#) from Ch. 38, par. 1003-2-2

Deletes everything. Amends the Unified Code of Corrections.

Requires the Department of Corrections to, on January 1, 2002, create and implement a pilot program to establish the effectiveness of pupillometer technology (the measurement of the pupil's reaction to light) as an alternative to a urine test for purposes of screening and evaluating persons committed to its custody who have alcohol or drug problems. Requires the Department to use pupillometer technology in at least 50% of all screening and evaluation tests performed and to report to the General Assembly on the effectiveness of the program on January 1, 2003.

[HOUSE AMENDMENT NO. 1.](#)

Provides that the pilot program shall require the pupillometer technology to be used in at least one Department of Corrections facility rather than in at least 50% of all screening and evaluation tests performed. Provides that the Director may expand the pilot program to include an additional facility or facilities as he or she deems appropriate. Provides that a minimum of 4,000 tests shall be included in the pilot program (rather than 50% of all screening and evaluation tests performed). Provides that the Department must report to the General Assembly on the effectiveness of the program by January 1, 2003 rather than on January 1, 2003.

Last action on Bill: PUBLIC ACT..... [92-0444](#)

Last action date: AUG-17-01

Location: Senate

Amendments to Bill: AMENDMENTS ADOPTED: HOUSE - 1 SENATE - 1

Protocols for Testing

Guidelines for the collection of data using the pupillometer

Protocols

Include the person's unique number on all tests submitted.

Normative Data

90 Seconds Dark Adaptation 5 scans

- Collect data on persons who are not taking any medication
- Male/Female over 16 YOA
- Conduct scans in normal room light conditions
- Scans must be taken between 6am and 11am
- They must have rested the night before

Controlled Drinking

Before Alcohol Consumption

90 Seconds Dark Adaptation 5 Scans

Alcohol Consumption at 0.04 BAC

90 Seconds Dark Adaptation 5 Scans

Alcohol Consumption Peak BAC (0.08 - 0.10)

90 Seconds Dark Adaptation 5 Scans

Alcohol Consumption at 0.00 (The next day)

90 Seconds Dark Adaptation 5 Scans

- Data will be collected at the Academy during controlled drinking session pursuant to SFST training.
- Conduct scans in normal room light conditions.

Sleep Deprivation Study

Begins at 7:00 A.M. and repeated every 2 hours for a 24 hour period.

Cognitive testing

90 Seconds Dark Adaptation 5

- Conduct scans in normal room light conditions

Field Data Collection DUI (ARREST)

1. Stop Vehicle
2. Interview
3. SFST
 HGN
 WAT
 OLS
4. PBT
5. EyeCheck™ 90 Seconds Dark Adaptation 5 scans
6. Chemical test
 Breath - alcohol
 Blood.- alcohol/drugs
 Urine - drugs
7. To be analysed by ISP Lab.

Field Data Collection (Trucks)

1. Stop Vehicle
2. Interview
3. Examine Log
4. SFST (If the subject will comply)
5. PBT (if necessary)
6. "Epworth Test"
7. EyeCheck™ 90 Seconds Dark Adaptation 5 scans
8. Chemical test if necessary for commercial driver DUI arrest
Breath - alcohol
Blood – alcohol/drugs
Urine - drugs
9. To be analysed by ISP Lab.

Random Data Collection

Subjects who may be taking medication and are willing to submit to a urine test.

1. Obtain "Certification of Assurances"
2. 90 Seconds Dark Adaptation 5 scans
3. Request urine
4. Submit urine to BAT Section

Analysis & Recommendations

Included is the final report submitted by Dr. Jack Richman,
New England College of Optometry

Report On The Use Of The Eyecheck™ Pupillometer Technology Effectiveness As A Non-invasive Technique To Detect And Measure Possible Impairment Resulting From The Suspected Usage Of Alcohol, Drugs, And/Or Detect Fatigue From Sleep Deprivation.



This document was prepared by Dr. Jack E. Richman of the New England College of Optometry, Boston M.A., through a contract with the Illinois State Police and is submitted to the General Assembly pursuant to Public Act 91- 0881 to amend the Illinois Vehicle Code by changing Section 1 1-501.5.

Submitted January 30th 2002

Selection Rationale For The Academic Evaluator Of The Eyecheck™ Pilot Project

For the EyeCheck™ instrument to have scientific validity, the results of the testing needed to be published in a scientific journal and subject to peer review. The individual most capable of providing the results of test data was Dr. Jack E. Richman, OD, FAAO, FCOVD. The following information provides rationale for his selection:

- Dr. Richman was and continues his tenure as a Professor of Pediatric Optometry and Binocular Vision at the New England College of Optometry. He has published over 40 research articles on the diagnosis and management of visual disorders in children. The clinical research which Dr. Richman has been involved with includes the development of the Broken Wheel Visual Acuity Test and the development of an Eye Movement Test.
- Dr. Richman is an outspoken advocate of Standardized Field Sobriety Testing (SFST), Horizontal Gaze Nystagmus Testing (HGN), and Drug recognition Expert (DRE) evaluations performed by police officers around the country. He is certified by the National Highway Traffic Safety Administration (NHTSA) and the International Association of Chiefs of Police (IACP) as a SFST Instructor and a DRE Instructor. He works closely with officers in the New England area and assists with their training. Dr. Richman is a member of the Technical Advisory Panel for IACP. The Technical Advisory Panel for IACP makes recommendations to the IACP and to NHTSA regarding the use of technology in law enforcement. In addition, the panel approves changes to existing SFST and DRE curriculum.
- Dr. Richman worked closely with MCJ, Inc. regarding the use of the EyeCheck™ instrument. He used the instrument and believes in its potential to detect impaired motor vehicle drivers. His recommendations were designed into the new EyeCheck™ instrument.
- Dr. Richman had possession of all existing data collected during controlled drinking demonstrations and the 24-hour sleep study. He analysed this data and formed a conclusion regarding its effectiveness.
- Dr. Richman had the ability to gather additional data utilising officers in the New England area and the resources of the New England College of Optometry.

The final report will outline the scope of the project, testing methodology, evaluation criteria and recommendations. Dr. Richman's involvement will ensure the review of the EyeCheck™ data is conducted to established academic and peer review standards. Thus further enhancing the possibility the results will be publishable in an appropriate and recognized peer reviewed scientific journal.

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INTRODUCTION

Report on the Use of the EyeCheck™ pupillometer technology effectiveness as a non-invasive technique to detect and measure possible impairment resulting from the suspected usage of alcohol, drugs, and/or detect fatigue from sleep deprivation.

This report represents and acknowledges the cooperation and data collection from numerous law enforcement agencies and sources from:

- Illinois
- Massachusetts
- Wisconsin
- Arizona
- Tennessee
- West Virginia
- MCJ.Inc.

MANDATE OF THE PROJECT

In 1999, The General Assembly of Illinois approved Public Act 91-0881 to amend the Illinois Vehicle Code by changing Section 11-501.5. The purpose of this act was to establish the effectiveness of pupillometer technology (the measurement of the pupils reaction to light) as a non-invasive technique to detect and measure possible impairment of any person who drives or is in actual physical control of a motor vehicle resulting from the suspected usage of alcohol, drugs, intoxicating compound and or to detect impairment due to fatigue and sleep deprivation.

1. Introduction

1.1 Background and History of Pupil Measurements

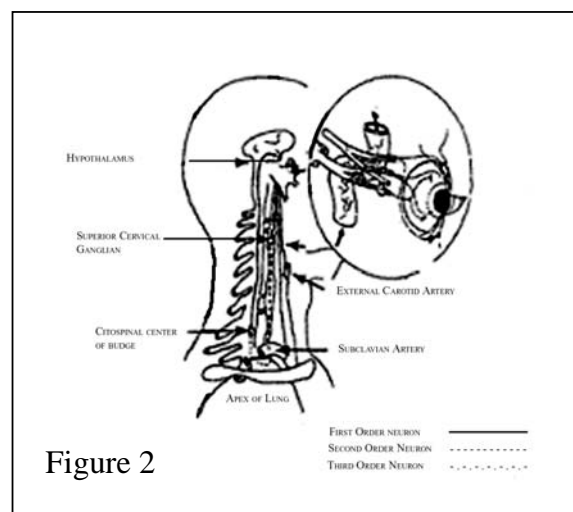
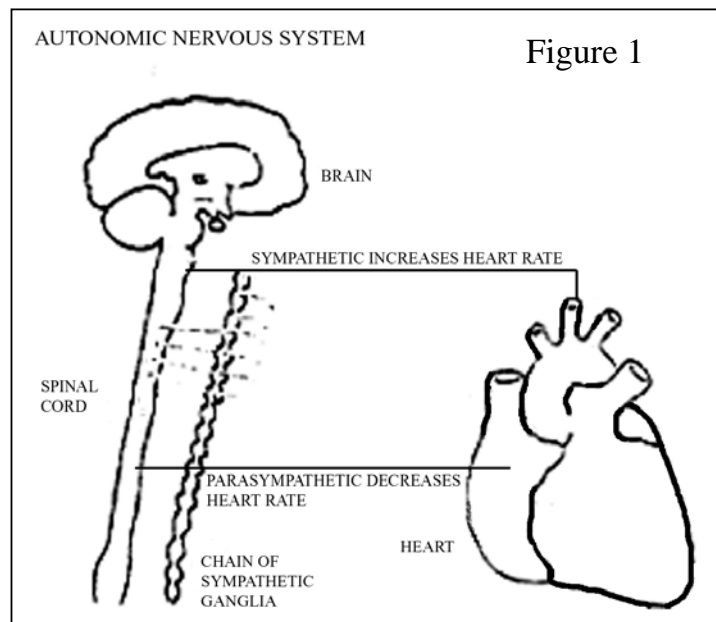
The central nervous system plays a tremendous part in enabling us to survive in the world. It can be conceived as the tuner and radio system of the body. It sends information from various sources to the brain which analyses and solves the problems presented to it and then passes the appropriate information out to the field i.e., muscles, glands etc.; enabling the appropriate actions to take place in a coordinated way.

The central nervous system works in close conjunction with another body system known as the autonomic nervous system (ANS). This ANS has an important function in maintaining the internal environment of the human body in a balanced condition or what is called homeostasis. As various changes occur within the environment, both internal and external, the ANS reacts by regulating such things as the blood pressure, heart rate. We do not consciously direct the rate of our heart beating nor are we normally aware of the diameter of our blood vessels or changes in the size of the pupil in the eye. An interruption of the supply from one ANS division leaves the input from the other division acting unopposed creating an imbalance.

There are two parts of the ANS that work to keep these automatic functions in balance. They are the Sympathetic and Parasympathetic Systems.

For example, the sympathetic system causes dilation of coronary arteries, increased heart rate, and increased force of contraction of the heart, while the parasympathetic system slows, reduces contraction and conduction. By working together, they maintain a balance of heart activity. Any imbalance can lead to serious effects.

In the same way, the pupil in the eye is controlled by these two combinations of the ANS. The parasympathetic system causes the pupil to “close” or constrict when light is introduced. To reverse this constriction, the sympathetic system causes the pupil to “open” or dilate. Pupil size is regulated exclusively by the autonomic nervous system, and in darkness is proportional to the level of central sympathetic tone. (Figure 2))



1.2 How is Pupil Size measured?

Interest in measuring pupil sizes goes back over 800 years to the time of the Greeks. Galileo, over 500 years ago, was most likely the first to measure pupil's sizes as we do today clinically. This is not a new interest or concept. Methods are quite varied in their degree of detail and sophistication.

The basic method used by most doctors is with the use of a millimetre ruler following specific procedures. The pupil size will be observed and measured under different stationary conditions. The pupil diameter is measured in millimetres across the horizontal plane.

The initial conditions measured often consist of pupil size in room lighting, (Fig 2). Then, the pupil's dynamic reaction to light is measured.

This is the light reflex, which occurs when a penlight or other stimulus is placed in the pupil causing a constriction. This is called *miosis*. (Fig 3) Several important characteristics are observed. The speed in which the pupil constricts is observed qualitatively as well as ability to hold the constriction size relatively steady over several seconds. Finally, the light is withdrawn and the observer watches to see how rapidly the pupil opens up or *dilates*.

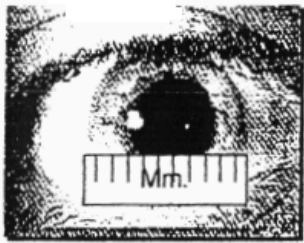


Fig 2. Normal pupil Dilated in Room Illumination

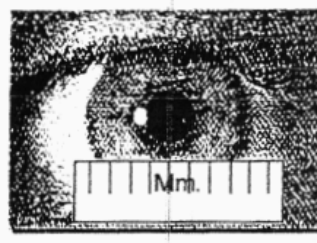


Fig 3. Normal pupil constriction from the light reflex

The parasympathetic system causes the pupil to “close” or constrict when light is introduced. This is called the light reflex. To reverse this constriction, the sympathetic system causes the pupil to “open” or dilate. There is a constant balancing act going on like a see-saw to keep the pupil size in balance. When we see imbalances or changes in the way the pupil changes size, then there may be disturbances in the central nervous system that is reflected by Autonomic Nervous System. By evaluating the pupil, its reactions to light and the accompanying changes, we can potentially gauge changes, e.g., effects of drugs and/or fatigue, in the Central Nervous System.

However, the basic method used with only a penlight by doctors has limitations. Only the more obvious and larger pupillary changes are seen with this method with many of the more subtle dynamic changes are not observed or measured. Over the past century, the use of photography has expanded our view of the changes in the pupil. Other more sensitive and intricate devices and techniques have been developed over the years

More recently, the use of video recordings and infrared technology have significantly improved the measurement of these tiny pupillary changes. The purpose of these instruments was to capture and assess these pupillary changes with greater fine distinction. This led to the more refined pupil measurements called Pupillography or pupillometry.

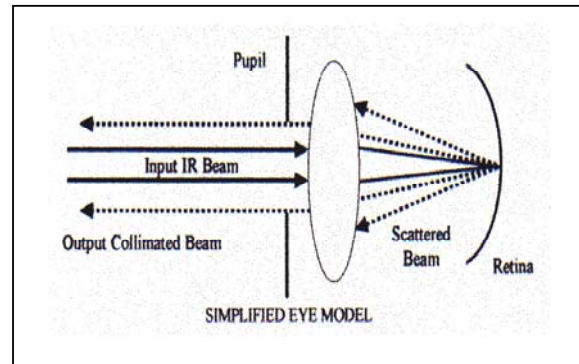
1.3. What is Infrared Pupillography and The Eyecheck™ Infrared Pupillometer?

The changes in pupil reactions may allow detailed interpretation of brain function because of the autonomic innervation of the pupil. The need to view tiny size changes and fluctuations in the pupil dynamics led to the use of infrared light. Infrared has the ability to be invisible to the bare eye thereby allowing pupil measurements in near total darkness and much finer control on the stimulus environment.

Essentially, what occurs with an infrared (IR) pupillometer is that the beam of light is invisible and the responses can be gathered instead of a white light, e.g., a penlight, stimulating the eye. With newer instrumentation, which is smaller and computerized, the ability to evaluate pupil dynamics and changes with an infrared pupillometer is now possible.

One such instrument is the EyeCheck™ IR pupillometer. The EyeCheck projects a beam of infrared light into the pupil and measures the pupil diameter as a function of the amount of light that “bounces” off the retina and leaving the pupil. Light leaving the pupil is responsible for the phenomenon called “red-eye.” In some photographs the eyes look red because the light from the camera flash enters the pupil, bounces off the blood vessels in the back of the eye, and then leave the eye. The EyeCheck™ Pupillometer projects a small IR optical beam as the input into the eye. The eye focuses the IR beam onto the retina where it is scattered. Some of the scattered light returns from the eye in an optical beam.

The optical power, measured over a period of time, provides the assessment relating to pupillary dynamics (Fig 4). The EyeCheck™ resembles a pair of binoculars and measures the pupil dynamics of the eye. The information is stored in the binocular testing unit and is retrieved onto a laptop computer where the data is read and evaluated. The process takes about a minute.



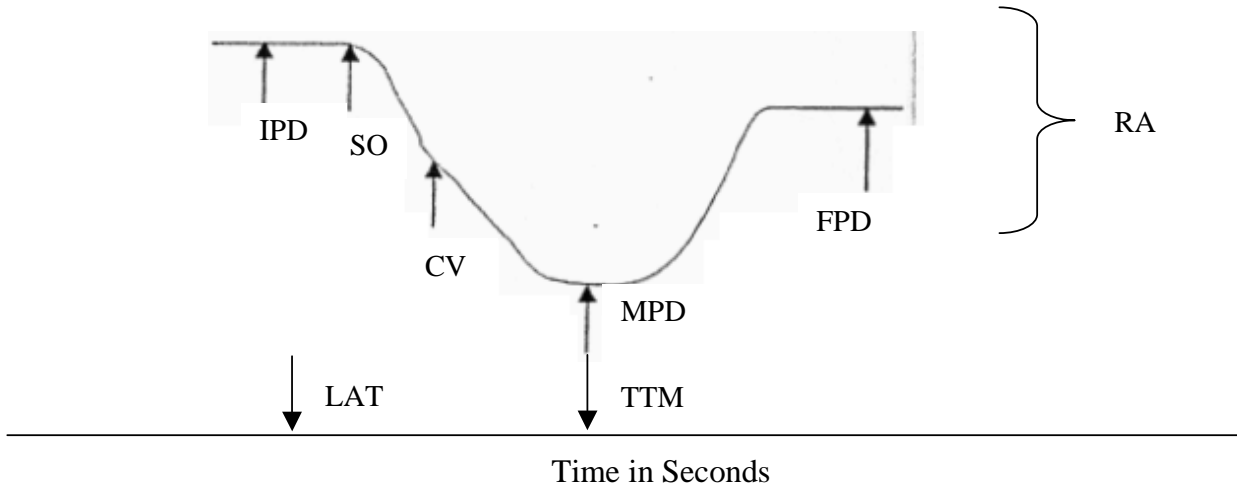
Instrumentation and Measurement Principle

Instead of the simple pupil diameter that is used in the basic technique with a millimetre ruler or pupil gauge, the EyeCheck IR pupillometer can measure many other more finite changes in the pupil that cannot be seen in the basic method. These additional measures include:

- The Initial Pupil Diameter (IPD) to one hundredth of a mm. after sitting in near total darkness for a precise time period.
- A Controlled Flash of light directed into the pupils
- The Light reflex reaction including
- The time, in milliseconds, to initiate the pupil constriction (TTI)
- The length of time to go to full constriction. (TTM)
- The change in pupil size from the dark to light condition (RA%)

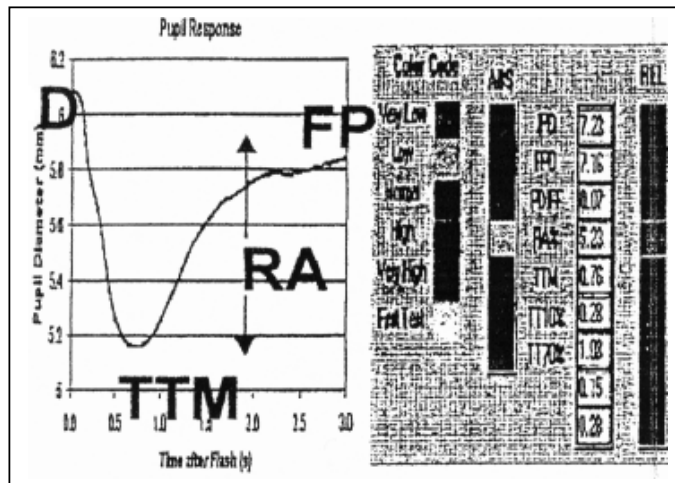
- Following the flash of light, the Pupillometer measures the final pupil diameter, i.e., how large pupils dilated or opened up after the test flashes in hundredths of a mm. and the difference between the initial and final pupil diameter. (FPD)

This information is graphically illustrated in the diagram below. This is further seen on the EyeCheck™ computer screen for further analysis.



Relevant output measures in pupillary response to light.

Output Data from Eyecheck™



To achieve this significantly increased sensitivity and collection of pupillary responses, the EyeCheck™ is measuring and tabulating the pupil size and its changes every tenth of a second.

The use of infrared pupillography potentially allows for highly repeatable and consistent minute measurements of changes in the central and autonomic nervous system that could not be observed with the naked eye. With the application of video and infrared pupillography over the past several decades, scientists and doctors were able to more accurately investigate the effect of loss of sleep, fatigue, and systemic drugs on the nervous system through pupillary changes.

1.4 Can Pupillometry measure the effects of impairment from fatigue or drugs?

1.4.1 Fatigue

Fatigue is a critical obstacle to endurance and concentration in many occupations. Consequently its detection is an important step in reducing instability in performance and ultimately protecting the health and safety of all. An objective and efficient method for determining whether an individual is tired could provide an important tool in a variety of fields, including sleep disorder studies, industrial medicine? Clinical pharmacology and psychiatry. This is particularly true for truck drivers and pilots in whom fatigue may be significant contributor to misjudgements and potential accidents. The autonomic nervous system has long been associated with the sleep and wakefulness since pupillary activity is one of the most observable barometers of the autonomic nervous system balance. Pupil size and response have been identified as possible indicators of fatigue and non-invasive devices that measure these parameters are becoming more available. If this technology, called pupillometry, could be used in short duration tests in the field to reliably document the presence of fatigue or decreased alertness, then fatigue-related human error may be significantly reduced.

A brief review of fatigue research with pupillary measures indicate that there are pupil changes with fatigue and sleep deprivation. (REF) Studies have reported that normal fatigued subjects developed severe pupillary fatigue waves (graphed as oscillations over time) over a 15-minute test period in darkness.

A particularly relevant reference regarding pupillometry and fatigue is Loewenfeld's book entitled, The Pupil (1993), which details the history of the major issues regarding the pupil. Research is reported that examines both the static and dynamic response of the pupil in fatigued subjects. In the studies of static pupil size, subjects sitting in a darkened room were instructed to look at a small red light some distance away. These studies report the onset of inconsistency in pupil diameter (pupillary fatigue waves) appearing as fluctuations over roughly 10 minute test periods. Smaller initial pupil diameter (miosis) in fatigued versus alert persons is consistently reported. Other studies also report significant differences in static pupillary size in healthy fatigued subjects. A decreased mean pupil diameter and inconsistency in pupil size over an 11-minute test in thirteen normal subjects during twelve hours of sleep deprivation was reported in another study. One interesting study compared the static pupillary size of 10 alert men with those of 12 sleepy men.

They report decreased initial pupil diameter and increased pupillary unrest index scores. Pupillary fatigue waves have increasingly large variations in pupil size (amplitudes) and slower frequencies

Overall, these studies indicate that measures of pupillary function are good indicators of fatigue in normal healthy subjects.

1.4.2 Drugs

People have taken drugs for healing, religious and recreational purposes for hundreds of years. At the end of the last century, however, due to advances in the field of chemistry and pharmacology, stronger and highly addictive substances such as cocaine and heroin were synthesized. In addition, the invention of hypodermic syringes enabled people to inject these drugs, making their effects more powerful and the risk of addiction more serious. Drugs of abuse either are ingested, inhaled, smoked, injected or snorted.

Other substances of abuse include psychoactive substances. This is any substance that people take to change either the way they feel, think, or behave.

This often includes alcohol and tobacco as well as natural and manufactured drugs. In the past, most drugs were made from plants, such as the coca bush for cocaine, opium poppies for heroin and cannabis or hashish or marijuana. Now drugs such as Ecstasy or LSD are produced by synthesising various chemicals. These drugs tend to fall into three categories: depressants (e.g. heroin, barbiturates), stimulants (e.g. cocaine, crack, amphetamines) and hallucinogens (e.g. marijuana, Ecstasy, LSD).

Drugs impair our bodies in a variety of ways. When our central nervous system function is altered by these substances, our muscle and nerve functioning is thrown out of balance. These alterations often can be exhibited in changes in the normal functioning in numerous organs, including the heart, lungs, and the eyes through the autonomic nervous system. They may blur our vision, make us tired or too excited, alter depth perception, make us see or hear things that may not be there, raise or lower blood pressure, make us react too quickly or too slowly or not at all. They frequently cause problems with concentration and alertness as well.

These problems can result from taking any type of drug, regardless of their type or source, e.g., illegal, prescription or over-the-counter medications. For example, stimulants can enhance or increase activity of the central nervous system. They include amphetamines, cocaine, as well as synthetic stimulant appetite suppressants such as phenmetrazine (Preludin) or methylphenidate (Ritalin). Stimulants can give rise to symptoms suggestive of intoxication, including tachycardia, pupillary dilation, and elevated blood pressure.

Numerous studies have been reviewed and report many adverse effects that involve the eye from the use of systemic drugs. As stated above, these changes often can be exhibited in changes in the normal autonomic nervous system functioning and equilibrium. The light reflex in the pupil relates to the stimulation of the parasympathetic and sympathetic inputs to the iris in a characteristic fashion while the latency and amplitude of the response are mainly due to the activation of the parasympathetic input. The re-dilation is also influenced by the activation of the sympathetic nervous system stimulation.

It is these responses and their maladjustments that often reveal the impairment due to the drugs effects in Pupillometry. Changes include deviations from normal in the initial pupil size, the final pupil size, increased time to respond, reduced light reflex amplitude and shortened recovery time of the light reflex response. With the use of Pupillometry, an efficient non-invasive method to evaluate the potential effect of drug impairment is possible. The next phase of the report will discuss the specifics of the study and the data analysis performed for the Illinois State Police.

Objectives Of This Study

2. Phase One: NORMAL

- **To determine the characteristics and reactions of pupils in normal (non impaired) persons with the EyeCheck™ pupillometer.**

2.1 Subjects

To establish the behaviour of the normal pupil using the EyeCheck Pupillometer, three hundred and eleven subjects were recruited from various sources including police academy recruits, college students, and volunteers from multiple sources in Illinois as well as other states, e.g., Massachusetts and West Virginia. Each subject was screened for any medical conditions, eye abnormalities, had reportedly not been awake greater than ten hours, and were reportedly free of any pharmacological agents.

There were 70% males and 30% females ranging in age from 17-59 years of age with a mean and median age of 36 yrs.

This group's racial composition included 87% Caucasian and 13% other including African American, Native American, and Asian American. Consent to participate in pupillometry was obtained from each subject after the nature of the procedure had been explained fully.

2.2 Methods:

Subjects were seated with the EyeCheck™ pupillometer in a relatively quiet darkened room. The examiner followed the instructions for administration of the EyeCheck™. They were allowed to dark adapt for 90 seconds before pupil diameter was measured. Following the dark adaptation period, there was a series of 5 flashes to assess the light reflex. This would allow for measuring internal reliability of the data. Once this data is collected on the subject, a quick analysis was performed on the data by the EyeCheck™ pupillometer and the accompanying laptop computer and software. This yields the pupillary characteristics for the subject, including the initial pupil diameter (IPD), the light reflex reaction including the time, in milliseconds, to initiate the pupil constriction (TTI), the length of time to go to full constriction (TTM), the change in pupil size from the dark to light condition (RA%), and the difference between the initial and final pupil diameter (FPD). This data was collected for each subject. The mean, median, standard deviation, variance, and standard error was calculated for all the normal subjects. This data was stored and will act as the baseline for normal subjects. By this method, we established the criteria for normal responses. This will act as a foundation to compare with the abnormal pupillary performance as we look at the various impairment situations.

3. Phase Two: FATIGUE

To determine the capability of the EyeCheck™ pupillometer to discriminate and identify fatigue and sleep deprived impaired subjects from normal (non impaired).

3.1 Subjects

To establish the effect of lack of sleep and related fatigue on behaviour of the pupil, forty-eight volunteer subjects were recruited from Illinois State Police Academy. Each subject was screened for any medical conditions, eye abnormalities, had reportedly not been awake greater than ten hours, and were reportedly free of any pharmacological agents. This was confirmed with urinalysis employing a comprehensive drug screen, which complies with Federal (SAMHSA) regulations.

There were 83% males and 17% females ranging in age from 21-40 years of age with a mean and median age of 28 years of age. Consent to participate in pupillometry was obtained from each subject after the nature of the procedure had been explained fully.

3.2. Method

All the subjects were instructed to sleep at home for the entire night.

Upon awakening they were instructed to avoid alcohol, caffeine and strenuous physical activity, which are known to alter pupillary activity.

Each subject agreed to remain awake for a twenty-four hour period in which their pupils would be assessed five times every six hours. This provided a baseline (alert, non sleep deprived) pupil activity profile, then one at six hours, twelve hours, eighteen hours, and finally twenty-fours of wakefulness.

Subjects were seated with the pupillometer in a relatively quiet darkened room. Since previous studies (REP') have shown that when alert subjects sit in a darkened environment, their pupils remain dilated and relatively stable in size and fluctuation. Drifts toward smaller pupil diameter (miosis) occurs more in fatigued versus alert persons. Fluctuations and change in pupil size is also consistently reported. Often these changes are monitored; changes in alertness can be measured. Based on this approach, the examiner followed the instructions for administration of the EyeCheck™. The subjects were allowed to dark adapt for 90 seconds before pupil diameter was continuously measured for a period of eight minutes. The pupil size was sampled continuously each tenth of a second and measured to a hundredth of a millimetre in size.

Once this data is collected on the subject, an analysis was performed on the data by the EyeCheck™ pupillometer and the accompanying laptop computer and software.

3.3 Results

Did the EyeCheck™ pupillometer discriminate and identify fatigue and sleep deprived impaired subjects from normal (non impaired).

3.3.1 Method of Analysis:

The data was analysed using the mathematical algorithm or model described by McLaren (REP) and Morad (REF). The first phase evaluated the miosis or shifting to smaller pupil size as a sign of fatigue and reduced alertness. This was calculated using the data relative to pupil size over the eight minutes. This yields a mathematical computation called the cumulative miosis or CM value. As alertness decreases and miosis increases, this CM value becomes more positive (+) in value. The second phase evaluates the range in fluctuations in the pupil size as alertness decreases. In a similar manner, this was calculated using the data relative to range in pupil size fluctuations over the eight minutes. This yields a mathematical computation called the cumulative variability or CV value. As alertness decreases and pupil fluctuations increase, this CV value becomes more positive (+) in value, in previous studies these values of CM and CV have been shown to be objective indicators of fatigue.

3.3.1.1 Sensitivity and Specificity

The terms and application of the “sensitivity” and “specificity” of a diagnostic test were first defined over fifty years ago and are the most widely used statistics used to describe the value of a screening or diagnostic test. The sensitivity of a test is the probability, as a percentage, that the diagnostic test correctly classifies subjects with the targeted problem. In this case, it would be identification of sleepiness or decreased alertness. Conversely, specificity of the screening test measures the extent to which the diagnostic test correctly classifies subjects free of the targeted problem. In this case, it would be identification of non-sleepy or reduced alertness.

While measures of sensitivity and specificity reflect the performance of the screening test among subjects with a known condition, the predictive accuracy of the proposed diagnostic test measures its performance as a screening test in a target population where the true problem condition of the subjects is unknown. The predictive accuracy of a diagnostic test is defined in terms of two components, depending on the test results: positive predictive accuracy is the probability that a randomly selected subject from the population actually has the problem given that the screening test is positive, while, negative predictive accuracy is the probability that a randomly selected subject from the population is actually free of the problem given that the screening test is negative.

3.3.2 Results

If pupil size decreases while variability increases, then we may be able to identify pupillary criterion that can identify sleepiness and reduced alertness. These oscillations had a tendency to increase during the 10-minute duration of the test, while the subject was sitting in the dark quiet examination room.

3.3.2.1 Cumulative Miosis.

In this investigation, the CM value for all subjects was compared in the alert stage (Normative value) with the CM value after 18 hours of sleep deprivation. A paired t-test indicated that there was a significant difference between the alert and sleep-deprived conditions ($p < .01$). The sensitivity was 81.82% and the specificity was 94.29%. The positive predictive value, i.e., does a randomly selected subject from the population actually have the problem, was 93.10%.

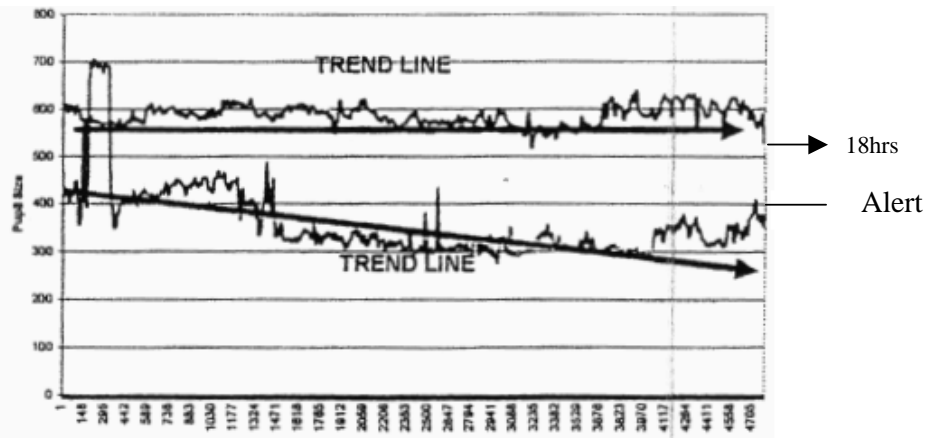
The negative predictive value, i.e., does a randomly selected subject from the population not exhibit problem, was 84.62%. This indicates that the EyeCheck™, using this parameter as a physiological objective measure, evaluation identified reduced alertness as a product of sleepiness and fatigue.

Below is a graphic example of the change in pupil size as a function of reduced alertness and sleepiness. The blue line is when the subject was alert and rested sitting in a dark environment for 8 minutes, while the red line illustrates the continual reduction or miosis in the pupil in the same subject after being awake eighteen hours. In the second below, a statistical trend line (Black) illustrates the shift toward smaller pupil size as a sign of decreased alertness and fatigue.

**Comparison of Pupil Size Variation
(Cumulative Miosis CM) from Alert to Fatigue at 18 hrs**



**Comparison of Pupil Size Variation
(Cumulative Miosis CM) from Alert to Fatigue at 18 hrs**



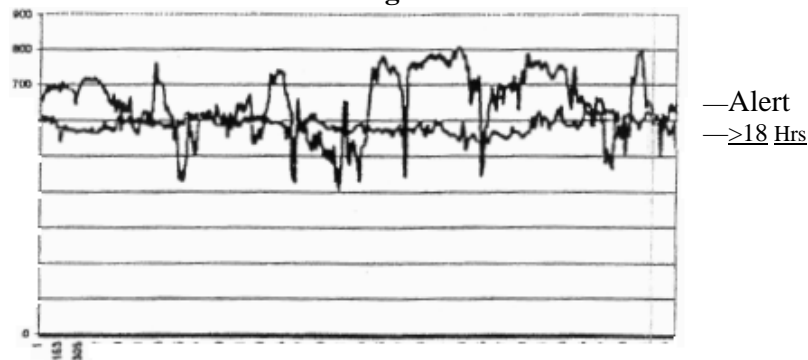
Pupil Size In Dark over 8 minutes

3.3.2.2 Cumulative Variability.

In this investigation, the CV value for all subjects was compared in the alert stage (Normative value) with the CM value after 18 hours of sleep deprivation. A paired t-test indicated that there was a no significant difference between the alert and sleep-deprived conditions. The sensitivity was only 34.78% and the specificity was 89.19%. The positive predictive value, i.e., does a randomly selected subject from the population actually have the problem, was 66.67%.

The negative predictive value, i.e., does a randomly selected subject from the population not exhibit the problem, was 68.75%. This indicates that the EyeCheck™, using this CV parameter as a physiological objective measure, was less effective than CM in identifying reduced alertness as a product of sleepiness and fatigue. Below is a graphic example of the change in pupil size fluctuations and variability as a function of reduced alertness and sleepiness. The blue line is when, the subject was alert and rested sitting in a dark environment for 8 minutes, while the red line illustrates the significant fluctuations in the pupil in the same subject after being awake eighteen hours.

**Comparison of Pupil Size Variation
(Cumulative Variability CV)
From Alert to Fatigue at 18 hrs**



Pupil Size In Dark over 8 minutes

Our results, like those of other investigators, demonstrated that pupillary parameters such as changes in pupil size and fluctuations can identify sleepiness and reduced alertness.

4. Phase Three: DRUGS

To determine the capability of the EyeCheck™ pupillometer to discriminate and identify drug impaired subjects from normal (non impaired).

As stated earlier, drugs can impair our bodies in a variety of ways. When our central nervous system function is altered by these substances, our normal nervous system functioning is thrown out of balance. These changes in the normal functioning often can be exhibited in the eyes through the autonomic nervous system. They may blur our vision and disturb our normal pupillary functions.

4.1 Subjects:

To establish the effect of drugs on the normal pupil functioning, two hundred and thirty subjects were recruited from various sources. These ranged from suspects arrested and evaluated for potential impairment due to drugs to subjects on probation and being monitored for potential illegal drug use to, finally, incarcerated subjects at correctional facilities. These subjects were obtained with cooperation and consent from law enforcement agencies in Arizona, Wisconsin, Tennessee, Massachusetts, West Virginia, and unfortunately only a small part in Illinois. Without the assistance of other participating sources, this phase would not have been completed in Illinois alone. The presence or absence of a pharmacological agent was determined and confirmed with urinalysis employing a comprehensive drug screen, which complies with Federal (SAMHSA) regulations.

There were 64% males and 36% females aging in range from 21-44 years of age with a mean and median age of 32 years of age.

This group's racial composition included 58% Caucasian and 42% other including African American, Native American, and Asian American. Consent, when applicable, to participate in pupillometry was obtained from each subject after the nature of the procedure had been explained fully.

4.2. Method:

Subjects were seated with the EyeCheck™ pupillometer in a relatively quiet darkened room. The examiner followed the instructions for administration of the EyeCheck™. They were allowed to dark adapt for 90 seconds before pupil diameter was measured. Following the dark adaptation period, there was a series of 5 flashes to assess the light reflex. Once this data is collected on the subject, a quick analysis was performed on the data by the EyeCheck™ pupillometer and the accompanying laptop computer and software. This yields the pupillary characteristics for the subject, including the initial pupil diameter (IPD), the light reflex reaction including the time, in milliseconds, to initiate the pupil constriction (TTI), the length of time to go to full constriction (TTM), the change in pupil size from the dark to light condition (RA%), and the difference between the initial and final pupil.

This data was stored and was compared with the normal subjects baseline information.

4.3 Results:

Did the EyeCheck™ pupillometer discriminate and identify drug-impaired subjects from normal (non impaired)?

4.3.1 Method of Analysis:

The results could be assessed in terms of sensitivity and specificity as previously described. The sensitivity of a test is the probability, as a percentage, that the diagnostic test correctly classifies subjects with the targeted problem. In this case, it would be identification of the presence of an impairing drug. Conversely, specificity of the screening test measures the extent to which the diagnostic test correctly classifies subjects free of the targeted problem. In this case, it would be identification of drug free individual. The positive and negative predictive accuracy of the data was further determined for identifying subjects demonstrating signs of impairment in the pupil responses and confirmed by toxicological measures, e.g., urine.

Urinalysis is carried out in two phases. The first is a screening process, which gives either a negative or a tentatively positive result. No further action is taken with negative results. The second phase of testing is then conducted on using a process called Gas Chromatography Mass Spectrometry (GCMS) or Liquid Chromatography Mass Spectrometry (LCMS), to confirm not only the presence of the drug or its metabolite but also the level of the drug in the person's body.

4.3.2. Results

In this phase of the study, the sensitivity was 79.25% and the specificity was 75.0 1%. The positive predictive value, i.e., does a randomly selected subject from the population actually have the problem, was 73.04%. The negative predictive value, i.e., does a randomly selected subject from the population not exhibit the problem, was 80.87%. This indicates that the EyeCheck™, using the pupil characteristics as a physiological objective measure, was effective, in identifying subjects drug impaired and confirmed with urine analysis. The drugs identified by toxicological evaluation were: marijuana, stimulants, including amphetamine, cocaine, tranquillisers, including diazepam, benzodiazepine, hallucinogenics, e.g., mushrooms, and opiates, including heroin. Specific analysis of each drug class was not reported for several reasons;

- (1) The objective of this study was to determine the presence of any illegal or impairing drug, not a specific drug or category of drugs, and
- (2) Almost all these drugs exert their effects through disturbances in the autonomic nervous system stability
- (3) Nevertheless, there was no significant difference found between the different classes of drugs when taken into account retrospectively.

The sensitivity value in this case would be identification of impairment due to the presence of a drug. Conversely, specificity in this case would be identification of non-drug impaired.

It is necessary to mention that lack of physical pupillary impairment revealed in the eye measurement may be due to the method of toxicological testing. In other words, many drugs may remain as a metabolite in the system well after it has lost its impairing properties and will be reported as present in the body. For example, Methamphetamine has an average duration of its effects for 2 to 6 hours, yet the presence in the urine may last 3 to 5 days; heroin lasts an average duration of its effects for 4- 6 hours yet the presence in the urine may last 3 to 4 days. This may account, for the disparity in predictive value and the presence of actual impairment in the pupil function.

5. Phase Four: ALCOHOL

To determine the capability of the EyeCheck™ pupillometer to discriminate and identify alcohol intoxicated subjects from normal (non impaired).

5.1 Subjects

Detection of alcohol in car drivers by means of pupillography is presently being discussed in various groups. Therefore, we tested the influence of alcohol on pupillary behaviour. To establish the possible effect of alcohol on the normal pupil functioning, twenty-six subjects were recruited from various sources. These subjects were obtained with cooperation and consent from law enforcement agencies in Illinois and Massachusetts. There were 87% males and 13% females aging in range from 18-34 years of age with a mean and median age of 26 years of age. This group's racial composition included 77% Caucasian and 23% other including African American, Native American, and Asian American.

Consent, when applicable, to participate in pupillometry was obtained from each subject after the nature of the procedure had been explained fully. Each subject was screened for any medical conditions, eye abnormalities, had reportedly not been awake greater than eight hours, and were reportedly free of any pharmacological agents. Each subject was initially tested for the presence of alcohol with a properly calibrated breath test instrument. Each breath test sample was preceded by a 15-minute deprivation period of any alcoholic beverage. Each subject ingested ethanol under controlled supervision and directions by a law enforcement officer. Blood alcohol levels were determined on a systematic basis after a predetermined number of drinks.

5.2. Method

Each subject was tested four times with the EyeCheck™ pupillometer. The sequence of trials was, first, a pre-drinking measurement of pupil responses, then two times during the drinking at different blood alcohol content levels (BAC levels), and finally a post-drinking trial. For each trial, the subjects were seated with the EyeCheck™ pupillometer in a relatively quiet darkened room. The examiner followed the instructions for administration of the EyeCheck™. They were allowed to dark adapt for 90 seconds before pupil diameter was measured. Following the dark adaptation period, there was a series of 5 flashes to assess the light reflex characteristics. Each trial was recorded with the corresponding BAC. Once this data was collected from the subject, a quick analysis was performed on the data by the EyeCheck™ pupillometer and the accompanying laptop computer and software. This data was stored and was compared with the baseline for normal non-intoxicated subjects. The results were *not* compared with each subject's pre-drinking level since that would not be a realistic scenario in the field. The method we used was applying an established criterion for normal performance based on a large separate population. Then, the determination of any differences between normal versus the alcohol intoxicated and impaired subjects may be evaluated.

5.3 Results

Did the EyeCheck pupillometer discriminate and identify alcohol-intoxicated subjects from normal (non impaired).

In this phase of the study, the sensitivity was 36.36% and the specificity was 95.45%. The sensitivity of a test is the probability, as a percentage, that the diagnostic test correctly classifies subjects with the targeted problem. In this case, it would be identification of alcohol intoxication above a 0.10% BAC. Conversely, specificity of the screening test measures the extent to which the diagnostic test correctly classifies subjects free of the targeted problem. In this case, it would be identification of alcohol intoxication below a 0.10% BAC.

The positive predictive value, i.e., does a randomly selected subject from the population actually has the problem, was 80%. The negative predictive value, i.e., does a randomly selected subject from the population not exhibit the problem, was 75%. This indicates that the EyeCheck™, using the pupil characteristics as a physiological objective measure, was minimally effective in identifying alcohol-intoxicated subjects confirmed with alcohol breath testing.

5.3.1 Results: Discussion:

Persons intoxicated with alcohol will typically show eye movement disorders, e.g., exaggerated endpoint nystagmus, failure of smooth pursuit, lateral-gaze nystagmus, and occasional diplopia. Those who have consumed very high levels might also show vertical-gaze nystagmus. This is the basis for the Horizontal Gaze Nystagmus test as part of the Standardized Field Sobriety Testing used by law enforcement throughout the country. Pupil size and function tend to be influenced significantly less, if at all, by alcohol. It has been reported that several active measures of the pupil's light reaction do change under acute alcohol influence, but not all of them significantly over the whole range of time and BAC levels. Various studies report changes in pupil function following alcohol intoxication. However, in these studies, all the observed effects are subtle and were always related to the initial criterion in the *same* individual.

This lack of effect on pupil size reported in other studies is consistent with the sensitivity reported in this phase of the study of 36.36%. It appears that pupillometry is rather insensitive in its intended purpose of identifying alcohol intoxication above a 0.10% .BAC level. This low sensitivity implies that the pupillometry, in isolation, is not a good predictor of people under the influence of alcohol. There were a significant number of false negatives, meaning it passed individuals that were truly intoxicated. Accordingly, based on our results, pupillography in alcohol ingestion is of scientific interest but does not appear to be a useful screening method at this time.

Conclusions And Future Recommendations

I. The Mandate Of This Research and Results:

The mandate of this investigation was to determine if the EyeCheck™ pupillometer technology as a non-invasive technique has any effectiveness to detect and measure possible impairment of a person who drives or is in actual physical control of a motor vehicle resulting from the suspected usage of alcohol, drugs, intoxicating compound and/ or to detect impairment due to fatigue and sleep deprivation. Based on this mandate, there were three fundamental questions examined.

- (1) Can an infrared pupillometer discriminate and identify fatigue and sleep deprived impaired subjects from normal (non-impaired).
- (2) Can an infrared pupillometer discriminate and identify drug-impaired subjects from normal (non-impaired)?
- (3) Can an infrared pupillometer discriminate and identify alcohol-intoxicated subjects from normal (non-impaired).

The EyeCheck™ pupillometer was employed as the non-invasive instrument to answer these questions in a series of four separate studies. In an attempt to determine if a device or method has the ability to screen or identify a “normal” from an “abnormal”, the data is analysed using a specific approach. This was application of the “sensitivity” and “specificity” concept and is the most widely used statistic to describe the value of a screening test. Therefore, based on the results described specifically above, the following conclusions may be made.

(1) Did the EyeCheck™ pupillometer discriminate and identify fatigue and sleep deprived impaired subjects from normal (non-impaired).

In short, the answer is yes. It appears that the results indicated that the EyeCheck™, using pupils as a physiological objective measure, could screen and identify subjects with reduced alertness as a product of sleepiness and fatigue. Our results, like those of other investigators, demonstrated that pupillary parameters such as changes in pupil size and fluctuations can identify sleepiness and reduced alertness.

(2) Did the EyeCheck™ pupillometer discriminate and identify drug-impaired subjects from normal (non-impaired)?

Yes, it appears that the results indicated that the EyeCheck™, using pupils as a physiological objective measure, could screen and identify subjects that were potentially under the influence of a drug and were impaired which was confirmed with urine analysis.

(3) Did the EyeCheck™ pupillometer discriminate and identify alcohol-intoxicated subjects from normal (non-impaired).

Somewhat, but just barely. The results indicate that pupil measurements were, at best, borderline in effectively screening and identifying alcohol intoxicated subjects that were confirmed with alcohol breath testing. Pupil size and functioning tend to be influenced significantly less, if at all, by alcohol. Screening for subjects potentially under the influence of alcohol should be subjected to valid and reliable measures, such as, Standardized Field Sobriety Tests (SFST) as described by the National Highway Traffic and Safety Administration.

The EyeCheck™ pupillometer may serve as an additional screening tool to provide supplementary information as to the presence of impairment.

II. COMMENTS, OBSERVATIONS, AND RECOMMENDATIONS

(1) FATIGUE AND PUBLIC HEALTH:

Concepts and Meaning of Fatigue:

The terms “fatigue” and “inattention” are sometimes used interchangeably with sleepiness. However, these terms have distinctive meanings. Fatigue is not the same as drowsiness, but the desire to sleep may accompany fatigue. Apathy is a feeling of indifference; this may accompany fatigue but may also exist independently. In many cases, fatigue is related to boredom, unhappiness, disappointment, lack of sleep, or hard work. Because fatigue is such a common complaint and is often caused by psychological problems, its potential seriousness is often overlooked.

- **Fatigue and Driving:**

In regard to driving, fatigue may lead to a mental inconsistency in the drivers mind between the feeling to stop driving and the need to continue to drive. The result may be a shifting and reduction of attention to the tasks required for safe driving. Inattention can result from the fatigue, as well as other causes e.g., daydreaming, distractions inside the vehicle, and other behaviours.

It has been demonstrated in various controlled environment studies that sleepiness impairs performance.

This reduced alertness can lead to crashes because it impairs mental performance functions that are critical to safe driving. Relevant impairments identified in laboratory and in-vehicle studies include:

- ***Slower reaction time.*** Sleepiness reduces optimum reaction times, and moderately sleepy people can have a performance-impairing increase in reaction time that will hinder stopping in time to avoid a collision. Even small decrements in reaction time can have a profound effect on crash risk, particularly at high speed*.
- ***Reduced vigilance.*** Performance on attention-based tasks declines with sleepiness, including increased periods of non-responding or delayed responding.
- ***Deficits in information processing.*** Processing and integrating information takes longer, the accuracy of short-term memory decreases, and performance declines.

Consumption Of Alcohol Interacts With Sleepiness To Increase Drowsiness And Impairment:

Even if sleepiness and alcohol are different crash causes, there is data to show an overlap. In nearly 20 percent of all sleepiness-related, single-vehicle crashes it was found that drivers had consumed some alcohol. More than one in three New York State drivers, surveyed in drowsy-driving crashes said they had consumed some alcohol, and police-reported, fall-asleep crashes had a higher proportion of alcohol involvement than other types of crashes in that State.

It becomes evident from the information available regarding the concept of fatigue, sleepiness and reduced alertness that it is multifaceted and a complex condition to define and measure. It may be a very mild cause of impairment or contribute significantly to impairment from other causes, e.g., alcohol. In alcohol-related crashes, there are subjective and objectives of impairment, e.g., field sobriety tests and breath measurements. Unfortunately, even though there is data that indicates that fatigue may significantly contribute to driving impairment and accidents, there are no tests that currently exist that can be administered to a driver at the scene of an accident for sleepiness. If drivers are unharmed in a crash, the mental stimulation and alertness following the incident usually eliminates any residual impairment that could assist investigating officers in attributing a crash to sleepiness alone. Presently, there is no definitive criterion available for establishing how sleepy a driver is or a threshold at which driver sleepiness affects safety.

RECOMMENDATION:

- The use of pupillometry may be a valuable adjunct tool to assist in identifying drivers or workers at risk for impairment from fatigue and sleepiness. Though the instrument can detect physiological signs of potential impairment from fatigue, it should not be used as the only source of information if at all possible. It is important that other methods of detecting fatigue and/as well as other causes of impairment be used in conjunction with the pupillometer. Such measures include standardized field sobriety test (SFST), portable breath testers (PBT), and subjective questionnaires and brief history assessment tools for sleepiness.

- It is recommended that prevention of sleep and fatigue still appears as the best approach. By getting adequate sleep before driving, drivers can plan ahead to reduce the risk of drowsy driving. The physiological changes in the pupil as measured with the use of pupillometry, specifically The EyeCheck™ may serve as a method to advise a driver of reduced alertness or fatigue, its associated risks, and the need for preventative action.

RECOMMENDATION:

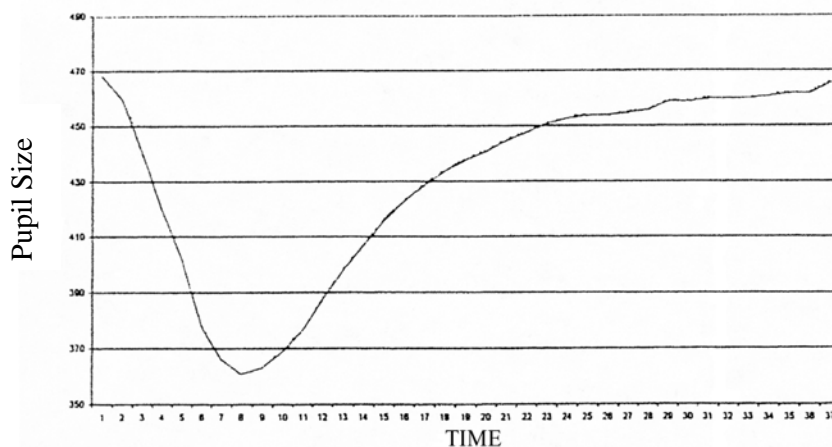
(1) IMPAIRMENT VS. TOXICOLOGY

- **Impairment Tests:** There is a clear difference between the presence of measurable impairment and the presence of a chemical substance, i.e., drugs, in the body. Drugs create impairment in various central nervous system functions. It may be exhibited in various ways in an impaired individual e.g., slurred speech, bloodshot eyes, difficulty balancing and walking. The use of standardized field sobriety tests, portable alcohol breath testers (PBT), as well as other methods are designed to identify the signs of impairment and possible causes occurring simultaneously. Many drugs, e.g., cocaine, opiates, alcohol, and marijuana, have short duration of their effects. It is during that period of the activity where the impairment is apparent. When the drug has worn off, the signs of the impairment are gone or have diminished significantly.
- **Toxicology Tests:** Toxicology tests, either blood or urine, are often used to detect the presence of a drug. The detection times in urine are significantly greater than detection times in blood. Blood tests generally are much more expensive and may be prohibited for other reasons. The presence of a drug or drugs in urine does not provide information as to whether the individual is actually under the influence at any particular drug at that time unless impairment is measured concurrently. Likewise, no determination can be made from urine as to the amount of the dose or the time of the dose. For example, when smoked, the effects of cannabis begin almost immediately. The effects of smoked cannabis peak after about 20 minutes and last for 1-2 hours, however, the presence of cannabis metabolites may be present in the urine for 24 to 72 hours from a single use. Another example are the effects of amphetamines, e.g. Methamphetamine, which can last from 8-20 hours, however, the presence of its metabolites may be present in the urine for 4 to 5 days. Therefore the presence of the drug in the urine does not indicate impairment. Since pupillometry is intended to measure impairment, it is quite possible to have a positive toxicological result without any sign of impairment. This was evident in several subjects in this study.

The first figure is of a subject who had a false negative on pupillometry, (Normal on pupillometry, Positive in the urine)

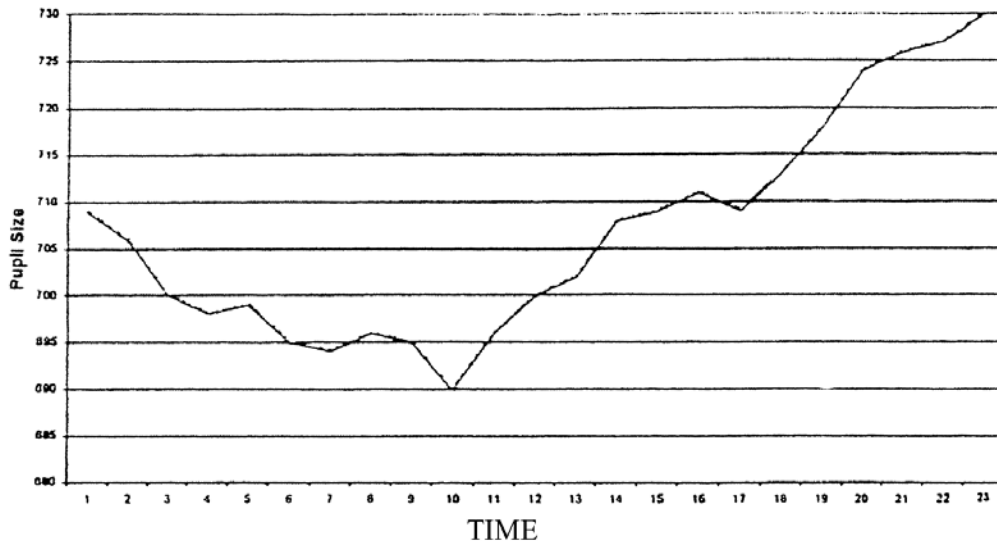
This indicates that there is no sign of impairment at this time.

**Amphetamine: Pupil Response Curve from EyeCheck
Positive in Urine and Negative in Pupils**



The next one shown below illustrates the presence of impairment as well as the presence of the drug in the urine. (Failed on pupillometry, Positive in the urine)

Amphetamine: Pupil Response Curve from EyeCheck Positive in Urine and Positive In Pupils



• **Other Causes of Impairment in Pupil Responses:** The pupillometer will measure impairment, however, it is significantly less discriminating as to the cause of the impairment. Subjects suffering from various medical problems, e.g., multiple sclerosis or diabetes may yield false positive tests on the pupillometer, depending on the severity of their condition at the time they are tested. Since these conditions may not be known to the subject or that impairment has even occurred, the results do have a public health value for the subject by indicating there is a need for further testing as to the cause of the impairment.

RECOMMENDATION:

- Pupillometry can measure a physiological sign of impairment. It will not determine if a person was impaired several days ago and now has recovered to normal. Conversely, the use of urine tests may indicate the presence of a drug or substance, but not impairment at that time.
- Therefore, it is fundamental requirement for the examiner and/or administrative personnel requiring the use of this technology to determine the intended purpose and use of the results of the pupillometer testing.

(3) FUTURE RECOMMENDATIONS

There is need for further studies on the use and applications of pupillometry, e.g., the EyeCheck™ These could be in the areas of:

- Fatigue identification and prevention measures
- Non invasive signs of impairment from drugs and/or fatigue in
 - (1) Public schools and universities
 - (2) Probation services
 - (3) Public employees responsible for public safety
 - (4) Correctional facilities
 - (5) Health care facilities

EYECHECK™ COMPARISON

**Joseph J. Gordon, Director
Champaign County Probation and
Court Services Department**

What Is EyeCheck™ ?

The MCJ EyeCheck™ Pupillometer website, describes the EyeCheck™ Pupillometer as “a lightweight, hand-held instrument that measures the absolute pupil dynamics to presumptively detect drugs and intoxicants with immediate results. The instrument is used by law enforcement, corrections (including probation and parole) and the instrument is used as a tool in private employment testing.

What Prompted A Review Of The EyeCheck™ Instrument?

Several months ago, a sales representative from MCJ EyeCheck™ contacted the department and asked if we were interested in previewing a pre-screening drug-testing tool. In a subsequent conversation, the department agreed to test the instrument for 30 days in an attempt to determine the accuracy of the instrument. At that time, we knew very little about the instruments capabilities; however, the offer was very appealing. Accordingly, on 11/22/02, the Champaign County Probation and Court Services Department agreed to conduct testing on the EyeCheck™ instrument. After a brief training period conducted by the EyeCheck™ representative, three officers from the department were assigned to conduct testing. The training was not intended to be in-depth, but was sufficient to provide officers with a general understanding of how to use and interpret results. Department protocol for the drug testing process was established.

In essence, if an adult offender was tested on EyeCheck™, he/she was also to be tested on our AXSYM. Each test result on EyeCheck™ was later compared to the results obtained on the AXSYM. A review of test results; using two separate instruments (EyeCheck™ and AXSYM) was then evaluated following the term of the testing period. Initially, the intent was to compare results on approximately 100 samples. Since the department was afforded a longer period to test the instrument, 169 samples were actually compared.

By comparing the results of the EyeCheck™ against results of FPIA testing via the AXSYM drug-testing instrument of Abbott Labs, we hoped to get an idea as to the feasibility of using the apparatus for the department. The drug-testing instrument we presently use is the AXSYM. It is a proven and an accepted instrument-based testing mechanism; commonly used by hospitals and clinics. The AXSYM instrument provides an exact numerical result in nanograms per millilitre NG/ML.

What Are The Advantages To Using The Eyecheck™ Instrument?

In addition to the information previously noted, the instrument is lightweight and portable. Consequently, the instrument could be used at a number of locations. In addition to the viewing instrument and the EyeCheck™ software, the only other component of the system is the computer (we used a laptop during the testing period). The testing process is non-invasive (eliminating the need for officers to handle hazardous body fluid, or view the collection of urine) and very little amount of time is necessary for training on the instrument. Upon being trained, EyeCheck™ is easy to use and provides almost immediate results.

All data is collected, recorded and stored. The results are displayed on the computer screen with data noting either a pass or fail test result. Another major advantage to the apparatus is cost effectiveness.

Why Consider Using Eyecheck™?

During the last fiscal year, officers of the Champaign County Probation and Court Services conducted 2344 drug tests. Each test generally consisted of a 3 or 4 drug panel test. Of the 2344 tests completed, 58% of the tests were determined to be negative (1360 negative test results). If the EyeCheck™ is a reliable pre-screening instrument, then Champaign County could realize a substantial savings by doing fewer tests on the AXYSM.

What Are The Disadvantages Associated With The Use Of The Eyecheck™ Instrument?

As noted by the sales representative, the EyeCheck™ is not intended to be a pre-screening drug-testing tool for everyone. Certain situations/conditions may affect the results of the testing.

For instance, a person who has experienced a serious head/eye injury may prompt a positive test result even though the person may not have any altering substance in his/her system.

Some other examples of situations/conditions that may have a bearing on test results include the following:

- Not recommended for individuals under the age of 16
- Not recommended for individuals over the age 50
- Not considered to be a reliable testing instrument for pregnant women

It should be noted that EyeCheck™ is a pre-screening instrument to determine possible impairment and not a replacement for urinalysis. A positive result on EyeCheck™ alone should not be used as a basis for issuing a sanction. A confirmation by urinalysis testing, or by some other accepted testing procedure is a necessary component for this pre-screening drug testing apparatus.

IMPRESSIONS

During our testing period, 169 individuals participated in the review of the EyeCheck™ apparatus. Following each EyeCheck™ test, the participant was also required to provide a urine sample later tested on the AXSYM. The results indicate that during the testing period, 71 individuals tested positive on EyeCheck™ and 4 individuals obtained yellow indications (a yellow result means the test result was so close to the dividing parameters that the test could either be positive or negative). With that thought in mind, a total 75 individuals (71 plus the 4 tests previously noted) were considered to have positive test results. Approximately half of the 75 (38) tested positive in at least one or more of the panels conducted on the AXSYM (either a 3 or 4 panel test). This does not mean 37 people tested negative and had no altering substance in their system. It only means that since we only tested for three or four drugs, these individuals could have been positive for other drugs not tested; such as alcohol, barbiturates, benzodiazepines, inhalants or some other substance.

Of all the individuals tested, 18 offenders blinked and could not complete the test on the EyeCheck™ instrument. For a test to be successful, the participant must keep his/her eyes open for approximately 6 seconds, when instructed to do so.

Generally, it is our impression that only on rare occasions would a person not be able to successfully complete the test. The officers further expressed the opinion that the blinkers did so in an attempt to spoil the test results.

Of the 18 individuals who blinked, 11 of the 18 were determined to have an illegal substance in their system following the AXSYM test. At the end of the testing period, it became evident to the officers completing the tests that the blinking was intentional (by reviewing the straight lines on the graphs indicating it was not a blink, but an intentional closure of the eyes).

There were 76 EyeCheck™ tests resulting in negative indications. Of this number, six turned out positive on urinalysis. Though this was certainly a problem and a cause for concern, the most recent software was not available for this test and the new software, reportedly, is more sensitive to blinks. The software will prompt the officer conducting the test that the person had blinked. In one instance, the individual was on a prescribed pain medication for a period of time that could have resulted in a negative indication on the EyeCheck™.

The most significant aspect of the five negative indications is that they all occurred between 11/26/02 and 12/10/02. All negative results on EyeCheck™ taken between 12/10/02 and 12/31/02 were later determined to be negative through urinalysis testing. One can speculate that toward the end of the testing period, officers conducting the tests were more familiar with the instrument. Consequently, better results were noticed as officers became more familiar with the instrument.

Based on other surveys conducted on the EyeCheck™, we expected a 3% false negative result; which is considered acceptable percentage. The 5 false negatives out of 169 tests is a 2.9% false negative result. If you only use the three unexplained results, then the false negative result would be 1.7%. Both results (2.9% or 1.7%) were within the expected variance for a pre-screening drug-testing tool.

ADDITIONAL POINTS WORTH NOTING:

- ◆ Blinkers were positive 61% of the time.
- ◆ False negatives were within the acceptable range of 3%.
- ◆ The testers accuracy improved after approximately 2 weeks of regular use of the device
- ◆ Since a urine sample is not needed, EyeCheck™ is not affected by dilution or substitution
- ◆ It takes 3-5 minutes to administer the EyeCheck™
- ◆ THC may not be detectable beyond current impairment. Although THC may stay in your system for 30 days or more, EyeCheck™ may not detect this extended time.
- ◆ If an individual falls into that 3% (passes the EyeCheck™ and is positive on urinalysis) this would not be acceptable. However, since we will use this test more frequently than urinalysis, this individual would be subject to more tests and eventually determined to be positive on subsequent tests.

Champaign County Probation and Court Services was searching for a way to reduce the cost of drug testing without lowering the number of test needed to adequately monitor compliance and not compromise the accuracy of the test. Although EyeCheck™ is not 100% accurate (no test is), officers conducting the test found it to be acceptable pre-screen drug testing device.

It Should Be Noted That This Was Not A Scientific Study And The Department Makes No Specific Claim Based On Data Provided. Information Contained In This Document Notes The Impressions Of The Officers Involved In The Testing Process. Finally, The Aforementioned Information Is Not Intended To Be An Endorsement Of The Eyecheck™ Instrument.

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The Sensitivity And Specificity Of Infrared Pupillometry Measurements In Identifying Drug Impairment In A County Probation Program

Presented

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San Diego CA

Scientific Program American Academy of Optometry

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**Accepted and to be presented at the Scientific Program American Academy of Optometry
December 12-15, 2002 San Diego CA**

Author: Jack E. Richman & S. Noriega

Topic

Abstract

PURPOSE.

Industry and law enforcement, e.g., probation departments employ drug screening to check for drug free compliance. Newer noninvasive physiological methods that measure impairment may be more efficient and less costly than urinalysis. Alterations in pupillary reactions have been shown to be related to drugs. The goal of this pilot program was to determine the sensitivity and specificity for detecting drugs using infrared pupillometry vs. urinalysis

METHOD.

The subjects were drawn from the Dept. of Probation in San Diego County, California. One hundred forty-six subjects, aged 18-50 years participated. Each subject received urinalysis, using the Gas Chromatography Mass Spectrum method to determine the presence of drugs. The subjects pupillary responses were measured by a probation staff member using the EyeCheck™ infrared pupillometer made by MCJ Inc. Based on proprietary algorithms measuring the initial pupil diameter, a controlled flash of light, the light reflex reaction including the time to initiate the pupil constriction, the length of time to full constriction, the final pupil diameter, and the change in pupil size from the dark to light condition, a determination of potential drug impairment vs. normal was determined.

RESULTS.

Under the conditions of this study, the 'sensitivity of the EyeCheck™ pupillometer in detecting potential presence of drugs was 36.2% and the specificity was 78.85%

CONCLUSIONS.

The EyeCheck™ pupillometer appears to effectively differentiate drug impaired subjects from normals in this study. Pupillometry may prove to be a valuable tool in screening for drugs. The EyeCheck™ pupillometer appears to be a valid and cost effective tool. It requires minimum training, to operate, is portable, adaptable to a variety of screening programs. Further familiarization with the instrument, improved differential algorithms, and improved training in its use will most likely increase its sensitivity and specificity.

The Sensitivity And Specificity Of Infrared Pupillometry Measurements In Identifying Drug Impairment In A County Probation Program

Author: **Jack Richman** Affiliation: The New England College of Optometry

Co-author(s) **Roberto S. Noriega**, San Diego County Dept. of Probations

Introduction:

In California, there are approximately 600,000 probationers within the criminal justice system. Drug testing is an important tool to reduce health and workplace costs and to monitor criminal offenders. Unlawful drug use is a violation of the conditions of probation and periodic drug testing is an effective method to deter and to detect drug use. Unlike most forms of misconduct, it leaves a chemical trace that can be detected reliably by relatively inexpensive tests. San Diego and Los Angeles have fairly elaborate testing programs, but neither tests more than a small proportion of its clients.¹

Frequent testing is essential to reducing the rate of drug use. Once-a-week testing produces about a 35% chance of detecting any given incident of drug use. Industry and law enforcement, e.g., probation departments, employ drug screening to check for drug free compliance. Drug testing (urinalysis) itself is relatively low-cost, between \$5 and \$10 per test. However, when such testing is performed thousands of times per month, the cost may be quite costly and possibly prohibitive for an effective compliance program.

An alternative or adjunct approach may utilize newer noninvasive physiological methods that measure impairment. These may be more efficient and less costly than urinalysis. One such method is pupillometry. Alterations in pupillary reactions have been shown to be related to the presence of drugs^{2,3,4} The use of photographic, videographic, and/or infrared pupillometry has been employed experimentally and commercially for the detection of physiological impairment.⁵⁻¹⁰

If an alternative or adjunct approach, e.g., infrared pupillometry, to measure impairment can be demonstrated to be effective, and then more effective compliance in monitoring probationers may be achieved.

Purpose: The objective of this pilot program was to determine the sensitivity and specificity of a commercially available pupillometer to detect possible impairment due to drugs when compared with urinalysis.

Methods:

Subjects:

The subjects were defendants on probation with the San Diego County Dept. of Probation in San Diego County, California. Participating were one hundred forty-six subjects aged 18-50 years (Mean 34.3 (10.2) years) with 72% male and made.

The data is then processed and the results are displayed on your computer screen.

The displayed data indicates a PASS/FAIL results.

Results:

The objective of this investigation was to determine the sensitivity and specificity of a commercially available pupillometer to detect possible impairment due to drugs when compared with urinalysis. In this study, the sensitivity and specificity of the EyeCheck™ pupillometer in detecting potential presence of drugs was determined. The presence or absence of a pharmacological agent was confirmed with urinalysis employing a comprehensive drug screen (GMSA). The drugs identified by toxicology at evaluation included marijuana, stimulants, including amphetamine, cocaine, tranquilizers, and opiates, including heroin.

Applying the positive vs. negative for impairment criteria and scores as part of the analysis software by the manufacturer, the sensitivity and specificity of the EyeCheck™ pupillometer was assessed. The results were based on a total 126 subjects since approximately fourteen percent of the tests conducted on the original 146 subjects were inconclusive on the EyeCheck™ due to various reasons, e.g., defendant's history of drug abuse, prescribed medications, medical conditions, and operator training. Of these, sixty-five percent were negative for drugs or impairment on the EyeCheck™ Pupillometer and urine screen. Fifteen percent of the tests conducted were positive on both the EyeCheck™ Pupillometer and urine screen for a variety of drugs. Seventeen percent were considered false positives on the EyeCheck™ and three percent were considered false negative. Based on this, The EyeCheck™ appears to differentiate subjects who were potentially drug impaired from normal in the majority of cases. The sensitivity was 86.2% and the specificity was 78.85%.

Discussion:

It should be noted that many subjects tested were under the care of physicians and were occasionally prescribed pain and or psychotropic medications. These prescribed drugs may have impacted the results of the pupil tests. The EyeCheck™ system rated these tests as positive where urine screening was designed to rule out the presence of higher dosage level street drugs.

What was the economic and drug free compliance outcome in this study? Based upon the first five months of this fiscal year it is projected that the San Diego County Probation Department will have conducted over 48,000 urine tests. The cost of a five-panel urine toxicological screening test is \$6.55. The estimated total cost for five panel drug screens a year is over \$300,000. In this study, it was found that 65% of the probation subjects were identified with the EyeCheck™ Pupillometer as non-drug impaired and confirmed with urine drug tests. Using the pupillometer solely, the Probation Department could have saved more than half of the drug test expenditure. These funds could have been applied to more frequent testing and drug free compliance, which are essential to reducing the rate of drug use.

Why is there a potential difference between the presence of measurable impairment, e.g., pupils, and the presence of a chemical substance, e.g., urinalysis? Drugs create impairment in various central nervous system functions. It may be exhibited in various ways in an impaired individual e.g., slurred speech, bloodshot eyes, difficulty balancing and walking. Many drugs, e.g., cocaine, opiates, alcohol, and marijuana, have short duration of their effects. It is during that period of the activity where the impairment is apparent. When the drug has worn off, the signs of the impairment are gone or have diminished significantly. However, the presence of a drug or drugs in urine does not provide information as to whether the individual is actually under the influence of the particular drug at that time unless impairment is measured concurrently. Likewise, no determination can be made from urine as to the amount of or the time of the dose. For example, when smoked, the effects of cannabis begin almost immediately. The effects of smoked cannabis peak after about 20 minutes and last for 1-2 hours, however, the presence of cannabis metabolites may be present in the urine for 24 to 72 hours from a single use. Consequently, the presence of the drug in the urine does not necessarily indicate impairment. It is fully possible to have a positive toxicological result without any sign of impairment. This was evident in several subjects in this study.

As long as this discrepancy is recognized, the use of physiological based tests of impairment when compared with toxicological results will have appropriate meaning to the examiner.

Conclusions:

The Eye Check™ pupillometer appears to effectively differentiate drug impaired subjects from normals in this study. The fifty-six percent identified as non-drug impaired represents the number of subjects that could have been tested using the pupillometer alone yielding significant economic savings and probation staff time. Pupillometry has demonstrated its value as a tool in screening for drugs. Overall, it appears to be a valid and cost effective tool for its intended purpose. It requires minimal training to operate, is portable, and is adaptable to a variety of drug testing and screening programs. Further familiarization with the instrument, improved differential algorithms, and improved training in its use will most likely increase its sensitivity and specificity.

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EFFECTS OF ANTIDEPRESSANTS ON THE HUMAN PUPIL

E.Szabadi. and C.M.Bradshaw 24th Pupil Colloquium

<http://www.jiscmail.ac.uk/files/PUPIL/ca.htm>

<http://www.jiscmail.ac.uk/files/PUPIL/absbook.htm> 23rd Pupil Colloquium, held in Nottingham, UK in August 1999

The Michigan State Police Service

Fatigue & Trucking - Roadside Safety Check - April 1999

Fatigue has many different physiological and behavioural effects on the human body. The physiological changes may include mild nystagmus, hand tremor, slurring of speech, gag reflex, and increased sensitivity to pain. The behavioural indicators may include head nodding, yawning, attention lapse, visual disturbances, task performance, decreased motor function and coordination, impaired short-term memory, exhaustion and microsleep⁽¹⁾.

Studies of sleep and wake mechanisms from a neurochemical perspective suggest serotonin, norepinephrine, and acetylcholine play a major role in sleep and alertness⁽²⁾. One of the major areas of the body that is sensitive to the effects of fatigue is the pupil.

Researchers have determined that the parasympathetic nervous system and acetylcholine control the elements that constrict the pupils. The elements that dilate the pupils are controlled by the sympathetic nervous system and norepinephrine⁽³⁾. Since fatigue leads to decreased sympathetic output as well as hippus and miosis⁽⁴⁾ the elements that constrict the pupil should show different physiological parameters when compared with non-fatigued pupils.

The technological breakthrough of modern day pupillometry has facilitated an increased knowledge in the field of pupillary dynamics. A pupillometer flashes a beam of light on the subject's eyes and records the pupillary response from the light. A computer program collects the pupillary response and typically records the variables such as Initial Diameter, Minimum Diameter, Final Diameter, Reflex Amplitude and Time to Minimum.

Fatigue and Truck Drivers

With more and more workers performing shift work. Researchers in chronobiology have been systematically investigating how fatigue affects workers^(5,6). Researchers have also investigated what types of counter-measures might be developed to prevent negative behavioural and physiological affects⁽⁷⁾.

One group of individuals that is frequently dealing with fatigue issues is truck drivers. Many truck drivers push themselves to their physiological limits in order to increase profit margins for themselves and their organizations. Although there has been some research looking at the effects of fatigue on truck drivers^(6,8). Most studies have extensively explored how fatigue specifically affects pupillary responses in the laboratory setting.

Subjects and Methods

Data was collected for a total of 110 truck drivers. They were participating in a safety check in the Jackson area of Michigan in April 2000. Data was collected on volunteer truck drivers for three days between 08:00 and 15:00 hours as they passed through the scales. Three weeks prior to this, two members of the Commercial Vehicle Enforcement Section of the Michigan State Police and one member of their accident reconstruction section, took part in a 24-hour course on fatigue and drug recognition and use of the EyeCheck™.

The course was conducted at the Illinois State Police Academy in Springfield Illinois.

The Michigan State Police set up two checkpoints each day. These check points intersect the State at major highways in the north, south as well as east and west.

Two EyeCheck™ instruments were used and the Commercial Vehicle Officers (CVO), who were trained in Illinois, conducted the testing. Once the driver went through the safety check, he or she was asked to volunteer to have their eyes scanned for a driving fatigue research study.

The procedure was explained to the driver in the following manner: “We are conducting research on fatigue and what effects driving fatigued has on the eyes for alertness and awareness of your surroundings while driving.”

A verbal survey was then administered to obtain age, gender and time of day. Subjects were also asked: 1) How many hours of sleep they obtained in the last 24 hrs; 2) Number of continuous hours on the road until present time; and 3) Have they had caffeine in the last 3 hours and if they were taking any prescription medication. Once the questions were completed, the EyeCheck™ was given in the following manner:

The individual was asked to place his or her forehead against the binocular device and look into its viewing area with their left eye, since the right eye on the binocular was blanked out. They were to focus with their left eye on the “red-dot” in the instrument. The CVO could then activate the device by depressing and releasing the mouse or touching a pad on the computer which then started the program. A flash of green light would take place, which causes the pupil to react; this series of scans would be repeated two additional times.

For each subject, three pupil scans were taken and averaged to assure statistical reliability. The pupillometer program automatically rejects from the data analysis, statistical outliers caused by blinking. This data was saved in ASCII format converted into an Excel™ Spreadsheet and was finally converted into SPSS software for descriptive and inferential statistical analysis.

Once the individual left the room, the eye-rest was sterilized for the next subject. The whole process for the paper work and the screening took less than five minutes. Of the 110 drivers asked, 103 truck drivers who were stopped at the safety checkpoints agreed to have their pupils scanned. Thus, there was no selection bias for the study.

Data and statistical analysis

Survey questions were used as quasi-independent variables. The dependent variables consisted of the 4 pupillary responses for fatigue and 3 for drugs (Reflex Amplitude, Initial Pupil Diameter, Final Pupil Diameter, and the Time to Minimum Diameter).

Reflex Amplitude was measured automatically by the EyeCheck™ program and was derived by using the 2 points of maximum slope, while the other parameters were calculated in millimetres. The quasi-independent variables consisted of the survey items that asked subjects to self-report caffeine intake, age, hours on the road, and sleep during the last twenty-four hours as well as prescription medications.

Correlation analysis of survey with pupillary responses

The first set of analysis consisted of correlating subjects’ self report characteristics with the four pupillary responses of Reflex Amplitude, Initial Diameter, Final Diameter and Time To Minimum Diameter.

Contrary to the literature we found no correlation between the time of day and pupillary response. A follow-up analysis was done to see if the time of day and pupillary response relationship was mediated by age. When the correlation was run for each age group all correlations were still under 0.1 and non-significant.

Categorical analysis of fatigue and pupillary responses

The correlation analysis suggested that self-reported fatigue via the Sleep Questions had no demonstrable effect of pupillary responses. A follow-up analysis was done to determine if there was some biological cut-off whereby truck drivers would show different pupillary results. A new variable was created from the question asking how many hours of sleep have occurred during the last 24.

We categorised all truck drivers who had 5 or less hours of sleep during the last 24 hours as fatigued and those with more than 5 hours as non-fatigued. T-tests were then performed on pupillary responses to determine if there was any difference between the two groups.

Reflex amplitude was deeper for fatigued truck drivers when compared to non-fatigued truck drivers. Truck drivers that had 5 hours or less of sleep had mean reflex amplitude of 1.28. Truck drivers who had more than 5 hours of sleep had reflex amplitude of 1.09.

Discussion

The results of the present study give a great deal of validity to the concept of being able to physiologically measure truck driver fatigue.

The fact that truck drivers with 5 hours or less of sleep showed larger reflex amplitudes and longer time to minimum diameters than those with more than 5 hours suggest that pupil physiology may be used as an indicator of fatigue.

The fact that these physiological parameters separated at the 5-hour mark is also in agreement with results from insomnia studies⁽¹³⁾. Those studies suggest that getting 5 or less hours of sleep can have profound effects on one's cognitive and behavioural processes.

These results have the potential to be used as a clinical indicator of fatigue in truck drivers and other organisational employees. The data also provide physiological validation for the idea that the parasympathetic nervous system controls pupil constriction and the sympathetic nervous system controls pupil dilation⁽³⁾.

When a truck driver is on the road they get very fatigued and consequently sympathetic activity is greatly decreased. Thus, their response to a pupil scan should show a strong parasympathetic response. This is exactly what our data shows since the reflex amplitude is large. The correlation analysis also shows that these effects are dependent on age, which agrees with other experimental result⁽¹⁴⁾.

The results of this study are quite different from those found when drugs were given to individuals. Those studies indicated that alcohol and depressants slow down constriction velocity and decrease the reflex amplitude^(9,10).

The fact that the effects of sleep deprivation do not depend on time of day also contradicts present research^(6,8). Most of the present research on time of day is done on workers who are working on a stable sleep/wake and light/dark cycle⁽⁶⁾. Since the truck drivers are frequently on the road, their circadian rhythms are desynchronised and thus the time of day has no direct effect on their pupil physiology. The important variable is the sleep they have received over the last twenty-four hours.

One reason why the correlation analysis between self-report fatigue and pupillary responses was not significant may have been self-report biases. The truck drivers were stopped at safety checkpoints and while they were performing the task and answering questions an officer was presenting to them. It is quite possible that the truck drivers could not give their true feelings about sleepiness or that they could not give how many continuous hours they have been on the road. Another reason for the lack of self-report correlations could have been the large amount of individual variability in assessing fatigue.

Most research using pupillometry uses within-subject designs that eliminate individual differences between subjects. The fact is that statistically significant results were still achieved in an ecologically valid setting (not just in the laboratory). This suggests that these physiological differences are real and robust and can be used.

Drug Detection

In the war against drugs, costly and complicated blood and urine tests are the only direct detection method available to law enforcement and corrections officers and industry.

There is no simple standardised screening device - similar to well-known "breathalysers" - which can be used for initial detection.

The so called "war on drugs" consumes many billions of dollars a year in state and Federal funds, a significant portion of which goes into advanced equipment and other technologies intended to stop or discourage drug consumption. However, when it comes to testing someone once they are suspected of consuming illegal drugs, law enforcement and corrections officers - the two groups most involved in direct personal drug detection - have really only one weapon to rely on: blood and urine testing.

To see why this is a potential issue - consider first that blood and urine tests, while accurate, can be very complicated and costly. The material cost for test kits are typically about \$54 each including lab processing, wages etc. In addition, tests must be administered in a laboratory, clinic, or other controlled environment. Specially trained technicians or nurses must follow very specific procedures to ensure that samples are properly collected - to prevent doctoring or substitutions - and documented - to prevent switching or loss.

The time for these procedures can be anywhere from 20-30 minutes per test, adding additional cost to the tests. In collecting samples, technicians must also be very careful to not be exposed to blood products, which can transmit HIV and Hepatitis. Finally, drug and urine tests in most cases require 1 or 2 hours to process, which can be very significant depending on the specific application. All this makes blood and urine tests an awkward and unwieldy weapon in the war on drugs.

Law Enforcement

In law enforcement settings, the most important limitation of drug and urine tests - in addition to the above - is that they cannot be freely administered. Law enforcement officers must first establish "probable cause" that drugs are present through a very specific set of steps, termed a chain of evidence or chain of custody. In many states, the procedure for establishing the evidence chain in a prosecutable drug or alcohol detection case is a lengthy process:

First, the arresting officer must perform a Standardised Field Sobriety Test (SFST) to evaluate balance and coordination and the test results of which must suggest drug impairment. The problem with the SFST in this case is that, in contrast to cases of intoxication, the level or type of drugs may only slightly affect balance and coordination and therefore the test may indicate negative or ambiguous results.

Second, and only if the results of the SFST are positive, the individual must be subjected to a lengthy program of interrogation and testing by an officer specially trained in drug recognition. This is not typically the arresting officer. Currently the leading training program in this area is the Drug Recognition Expert (DRE) taught by the Los Angeles Police Department. The program is relatively high cost - both direct and in time away from patrol - has limited the number of trained DRE officers. For example, the State of Illinois Police only has 18 DRE officers out of 2,600 officers total. In addition, a DRE interview may take as long as 4 hours of test time, limiting its effectiveness as a drug detection method.

Only if both these two steps indicate the presence of illegal drugs can a suspect be asked to submit to a blood or urine test. The results of this test are considered "evidentiary" and are the only pieces of information that can be directly used to make an arrest and prosecute a case. The results of the first two tests are part of establishing "probable cause".

Violating the procedures for establishing an evidence chain can cause an arrest to be thrown out of court under "unusual search and seizure" rulings that exist at the Federal and most state levels. In addition, all probable cause tests for drugs are subjective and can be affected by several factors including the experience of the officer, weather, and time of day.

There is therefore a significant probability that drugs will fail to be detected (i.e., a false negative). Even if drugs are detected, the way in which the test was conducted may be challenged in court to have a charge thrown out.

In contrast to the issues with drug detection, the process for establishing a chain of evidence for an individual suspected of public intoxication or Driving While Intoxicated (DWI) is much easier. Law enforcement officers in this case have for years used a device for analysing breath alcohol levels also termed a "Breathalyser". These devices can be used to quickly and simply establish whether someone's blood alcohol level is over the legal limit. Depending on the rated accuracy of the device, this information can be used to either establish probable cause and or as prosecutable evidence. A similar device is therefore needed to detect drugs, and especially stimulants that can mask fatigue and are often used by drivers. These may be substances of abuse or illegal or over the counter nasal sprays and stimulants.

A breathalyser-type device that could detect drugs, as well as alcohol, would add a very important capability for law enforcement. One reason this is important is to reduce the total amount of equipment that must be carried by the standard field officer. A second subtle, but more critical reason is that it is important in establishing the entire chain of evidence. For example, a truck driver could be stopped for suspicion of driving while fatigue or under the influence of alcohol. After talking to the subject and observing key indicators such as the smell of alcohol or slurred speech, the officer would have probable cause to request the individual be tested by the detection device. If the device indicated drugs were present, in addition to or rather than alcohol or fatigue, the officer would then have probable cause to proceed further and submit the suspect for blood and alcohol testing as well as searching his vehicle, which was done in this study. The detection of drugs while testing for alcohol has a legal precedent in the application of the SFST. The difference is that a single device would automate this process, removing the significant variability and subjectivity inherent in the SFST.

Fatigue Detection

Physical fatigue is increasingly being cited as a safety issue especially with commercial carriers. However, no detection device presently exists for fatigue that can enforce current or proposed laws intended to improve public safety.

Several recent reports have detailed how fatigue is becoming a much more common part of life in the U.S. There are many causes for this, however, chief among these are longer workdays and over-crowded highways, which have forced many people to get up earlier and stay at work later to avoid urban traffic rush hours. According to a poll by the National Sleep Foundation, this has led to roads filled with fatigued drivers with as many as 62% of people surveyed admitting to driving while fatigued. As many as 27% said, they have dozed off while driving in the past year.

Perhaps more importantly, recent studies indicate that a person's reflexes after 18 hours without sleep are comparable to those of a rested person with a 0.05% blood alcohol level.

After 22 hours without sleep, the comparison is to 0.10% blood alcohol levels, which would be over the legal limit in all states. Not surprisingly then, it is estimated that as much as 40% of all accidents have been caused in some part by fatigue, in the trucking community.

Like the current situation with drug detection, no automated, non-invasive device exists that detects fatigue levels. If such a device was available, then it could provide the enabling technology for new safety regulations and other measures to guard against fatigued drivers in the general population, as well as provide the means to enforce current laws for commercial carriers.

Awareness of the role of fatigue in accident rates is growing. For instance, the National Sleep Foundation sponsors a Driver Alert - Arrive Alive public awareness program which includes a "Sleep Awareness" month in many states as well as radio and TV spots alerting the public to the dangers of driving while fatigued.

Trucking

By current Federal law, commercial truck drivers can only drive for 10 hours at time without mandated rest intervals. Airline pilots and railroad operators must follow similar restrictions. Considerable effort has been focused over the last several years in enforcing and potentially increasing these laws. This has been true especially in the trucking industry.

Recent NHTSA data indicates that the number of fatalities from crashes involving large trucks increased 20 percent from 4,462 in 1992 to 5,355 in 1997. It is estimated that between 30-40 percent of these fatalities were due to fatigue of the truck driver.

The growth in truck crash fatalities as well the fact that these crashes are spectacular media events where fatalities are most often the driver and passengers of smaller vehicles has caused these accidents to attract significant attention.

Private groups such as Parents Against Tired Truckers have formed and mounted aggressive campaigns to spur the Federal Government into making the prevention of truck accident fatalities - and trucker fatigue - a major goal. Their efforts have been supported by reports that up to 78% of commercial long-haul truck drivers suffer from sleep loss, which can result in heavy fatigue.

As a result of these and other private efforts, both the House and Senate have recently held hearings and written appropriations bills dealing with fatigue's contribution to trucking and other carrier accidents^(7, 8). In turn, the National Transportation Safety Board (NTSB) has significantly increased research⁽⁹⁾ and education regarding fatigue, especially in its role in truck crashes where it has urged the trucking industry also to take action.

"We were recently directed by Congress to look into the reasons for increases in truck accidents...Our investigations and safety studies show that...driver fatigue play[s] a significant role in truck accidents...It is in the truck industry's best interest to be actively out front on [this issue]."

Jim Hall, NTSB Chairman

Overview

The EyeCheck(tm) technology is based on a medical area of study called pupillometry - the scanning and analysis of the eye pupil to various light stimuli. The pupil's reaction to this stimulus is directly related to the condition of a person's central nervous system. Fatigue and chemical substances can in turn hinder the nervous system response. Pupillometry has therefore been used to detect and diagnose these conditions.

Results

A total of 110 trucks drivers were ask to be administered the EyeCheck™ on a voluntary basis and verbally answer question about their medications, sleep habits and hours of sleep in the previous 24 hours before this test. Seven refused to take part in the testing and were sent on their way.

The EyeCheck™ was used for fatigue, stimulant, depressant, inhalant (Haz-Mat) and alcohol detection. The following are the test results from the remaining 103:

Fatigue	Possible Fatigue	Stimulants	Depressants	Alcohol	Inhalant
9	11	15	9	1	1

The above figures represents 46% of the drivers that volunteered were impaired at the time of testing. Of the fatigued drivers once informed 4 drivers voluntarily removed themselves from service for 2-3 hours and remained in their sleeper-births, one of the possible fatigued drivers was just a few miles from his home and indicated he was ready to go to bed.

Stimulants, Depressants, Alcohol, and Inhalants

What must be understood is the stimulant use among these drivers. Stimulants by definition are just that, excitatory agents to stimulate the neurotransmitters to maintain arousal. Usually in this industry, they are used to mask sleepiness and force wakefulness. Although the focus of this study was fatigued drivers, we must consider the use of stimulants to mask sleepiness and the effects these substances have on the human body once the effects of the stimulant has worn off. These effects can and do have worse consequences on the body than fatigue alone.

Of the stimulants and depressants found by EyeCheck™, several were prescription and/or over the counter antihistamine for colds and asthma. The drivers were cautioned about the use of these medications and their effects. Further search of the operator's vehicles by the officers for other offences, found the following: Rock Cocaine, 3 drivers had THC or cannabis, Alcohol (confirmed by PBT), 1 driver had a variety of stimulants and depressants throughout his cab. He volunteered to go out of service. Some of these drivers were arrested for these offences or put out of service. Also detected was a leak from a vehicle carrying Hazardous Material, this was repaired and corrected with a hardy thank you from the driver, who was unaware of the problem.

There are several areas of support from this project:

Fatigue alone, not only parallels federal statistics but is also under reported.

The number of Stimulants used by drivers tested leads one to believe that fatigue is much more serious than reported. In this study one can assume that stimulants accounted for a 32% increase of fatigued drivers statistics.

These statistics support the use of pupillometry in the enforcement of fatigue drivers and drivers which ingest stimulants to mask fatigue.

An instrument such as the EyeCheck™ could have a great impact in preventing accidents, loss of life, drug detection, property damage and injuries from accidents if implemented. Also a standardised subjective test would also be recommended such as portions of the Standard Field Sobriety Test and questions regarding sleep habits, hours last slept etc. This would most likely establish a chain of events to back up the objective findings of such an instrument for enforcement.

Comments regarding conclusions.

The conclusions and results reached regarding this study are based on the reviews used in the medical and scientific fields, together with a review of the data collected, are based on this reviewers interoperations of the documents and data. As such do not carry weight of law and none is intended.

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West Virginia Division of Corrections

EyeCheck™ vs. Urine Toxicology

Pupillary reactions have been studied for centuries. Their use as indicators in physiology and medicine for changes in nervous system activity began in the 18th century. The reaction or reflex of the human pupil to light and its characteristics provides invaluable information and insight to the brain sensory and motor function. There have been literally thousands of studies regarding pupillary reactions in many situations. Such situations include systemic and neurological disease, fatigue, psychological states, tumours, trauma, psychiatric conditions, and the effect of various drugs. It is no accident that the human iris, pupil, and its nerve supply have been used as indicators of fatigue, psychological states, and drug effects for generations.

The measurement of pupil reaction, often called pupillometry, is still ideally suited for qualitative and quantitative documentation of central nervous actions. The great benefit of the use pupillometry is that it is non-invasive, avoiding body fluid measures, e.g., blood, urine, etc. These non-invasive measurements tend to be quite sensitive, accurate, and repeatable as indications of changes in the human nervous system functioning. As computer technology has increased dramatically, so has its application in pupillometry using smaller, lighter and more efficient equipment.

Utilizing parole, probation, work release and corrections inmates at Mount Olive, Prunytown, Huntington, and Charleston West Virginia, under a cooperative agreement with the State of Illinois and West Virginia, 116 clients were tested using the following procedures:

All urine collection, instant checking using Gene Cup, Accusign, Med Tox, and iris scanning using the EyeCheck™ was conducted at the respective facilities. Emit was also used for screening at the West Virginia Laboratory in the Anthony Correctional facility. Once this was completed the urine was frozen and sent to the Illinois State Police Crime Lab in Chicago for additional EMIT testing and final GC/MS confirmatory testing. The match of the urine was for only the positive presence of drugs and not for the identification of drug types. The data was than match against the EyeCheck™ for Pass/Fail indicators. The collection, testing and analysis were conducted under the supervision of the Institutional Review Board of the University of Illinois. The Illinois State Police in West Virginia conducted collection of all data, to include urine and iris scanning.

Since the West Virginia Division of Corrections uses a five panel screening technique for drug detection this was also used for the Accusign, Med Tox, Gene Cup and EMIT, the same reagents were also used for drug types in all and GCMS identify all drug types.

The same urine sample was used from each person for each of the screenings and GC/MS. A total of 116 people were tested for this study and the following are the results of the study.

TOTAL TESTED 116

INSTRUMENT	PEOPLE IDENTIFIED FOR DRUGS
Accusign	0
Med Tox	5
Gene Cup	12
W.V Lab EMIT	8
IL Lab for EMIT	8
IL Lab for GC/MS	17
EyeCheck™	20

All instant checks were confirmed by GC/MS, additionally GC/MS identified more than the instant checks. Although drug classification were not matched in this study, it is clear that the instant five panel screens are far less accurate than EyeCheck™ or GC/MS. Which indicates that more illicit drugs are being used than previously thought, to include inhalants.

Of the 20 EyeCheck™ identified, 17 were matched with GCMS, which indicates a 90% accuracy for the EyeCheck™ when compare to GCMS. When compared to EMIT from West Virginia and the Chicago Crime Lab, EyeCheck™ had matched and exceeded this testing when confirmed by GC/MS. The question of the additional 3, which EyeCheck™ identified as having drugs, was identified as inhalants, which EMIT or GCMS could not have identified.

In conclusion, the EyeCheck™ could be a useful instrument for the screening of drugs to eliminate unneeded urine test.

22nd Pupil Colloquium

September 2-6, 1997

*Point Clear Alabama
United States*

Pupillometry & Trucking Fatigue

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Summary:

The purpose of the present research was to determine if fatigued truck drivers show different pupillary responses than non-fatigued truck drivers.

A total of 166 truck drivers were stopped at a safety checkpoint in a large Midwest City. They answered survey questions about their level of fatigue and then volunteered to have 3 scans taken of their eyes.

The Pupil Response Measuring Device© flashed a green light onto the pupil and recorded a number of pupillary response variables including constriction velocity and reflex amplitude.

Statistical results indicated that fatigued truck drivers had significantly faster constriction velocities and larger reflex amplitudes than non-fatigued truck drivers. Time of day and Stanford Sleepiness Scale scores were not correlated with pupillary responses. The results of this research suggest that pupil physiology has the potential to be used as an accurate indicator of fatigue in truck drivers.

Fatigue has many different physiological and behavioural effects on the human body. The physiological changes may include mild nystagmus, hand tremor, slurring of speech, gag reflex, and increased sensitivity to pain. The behavioural indicators may include head nodding, yawning, attention lapse, visual disturbances, task performance, decreased motor function and coordination, impaired short-term memory, exhaustion and microsleep ⁽¹⁾.

Studies of sleep and wake mechanisms from a neurochemical perspective suggest serotonin, norepinephrine, and acetylcholine play a major role in sleep and alertness ⁽²⁾.

One of the major areas of the body that is sensitive to the effects of fatigue is the pupil. Researchers have determined that the elements that constrict the pupils are controlled by the parasympathetic nervous system and acetylcholine. The elements that dilate the pupils are controlled by the sympathetic nervous system and norepinephrine ⁽³⁾. Since fatigue leads to decreased sympathetic output as well as hippus and miosis ⁽⁴⁾ the elements that constrict the eye should show different physiological parameters when compared with non-fatigued pupils.

The technological breakthrough of modern day pupillometry has facilitated an increased knowledge in the field of pupillary dynamics.

A pupillometer flashes a beam of light on the subject's eyes and records the pupillary response from the light. A computer program collects the pupillary response and typically records the variables such as Initial Diameter, Minimum Diameter, Final Diameter, Constriction Velocity, Reflex Amplitude and Time to minimum ^(Figure 1).

Fatigue and Truck Drivers

With more and more workers performing shift work. Researchers in chronobiology have been systematically investigating how fatigue affects workers ^(5,6). Researchers have also investigated what types of countermeasures might be developed to prevent negative behavioural and physiological affects ⁽⁷⁾.

One group of individuals that is frequently dealing with fatigue issues is truck drivers. Many truck drivers push themselves to their physiological limits in order to increase profit margins for themselves and their organizations. Although there has been some research looking at the effects of fatigue on truck drivers ^(6,8), none have extensively explored how fatigue specifically affects pupillary responses. Thus, the goal of the present research was to determine if truck drivers who are behaviourally fatigued would show different pupillary responses than a group of non-fatigued truck drivers.

There were a number of specific research hypotheses that we sought to evaluate:

1) What is the specific relationship between self-report indicators of fatigue and physiological indicators of fatigue?

One frequent instrument used to define fatigue behaviour is the Stanford Sleepiness Scale (SSS) ⁽⁹⁾. High scores indicate a fatigued individual while low scores indicate a non-fatigued individual. Thus, truck drivers were given these questions as a behavioural index of fatigue. Because of the subjective nature of the SSS and the fact that state troopers were present when the truck drivers were answering these questions. We decided to ask additional objective survey questions as an index of fatigue.

Truck drivers were asked:

- A) How many consecutive hours have they been on the road until now; and
- B) How many hours of sleep they had obtained during the last 24 hrs. We predicted that truck drivers who had obtained a poor night's sleep would show different pupil physiological compared with a truck driver who had obtained a good night's sleep.

2) Does the pupillary response depend on time of day?

Previous research has shown that most accidents and errors on motor tasks occur during the hours of 2-5 p.m. and 2-5 a.m. ^(6,8). Such results correspond well with circadian rhythms which are typically low during these times. Since truck drivers are often on the road for many hours they may not show the same normal cycle as the average worker.

3) Will the fatigued pupil respond in a manner similar to those observed after drug absorption?

The literature has shown that morphine, alcohol and diazepam generally slow down pupil constriction time and reflex amplitude. Thus, the eyes may slow down when fatigued ^(10,11). Conversely, a loss of sympathetic tone in the eyes may disrupt the balance between the parasympathetic and sympathetic nervous system. The effect of this imbalance would favour the parasympathetic nervous system and may lead to a rapid constriction of the pupil and large reflex amplitude.

Subjects and Methods

Data was collected for a total of 166 truck drivers. They were participating in a safety check in the Quad City area of Illinois in early June 1997. Data was collected on volunteer truck drivers for seventy-two continuous hours as they passed through the checkpoint, for "real" truck driver conditions. Two weeks prior to this, the Commercial Vehicle Enforcement Section of the Illinois State Police took part in a seven-hour course on fatigue recognition and the use of the Pupil Response Measuring Device©. The U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama, established the fatigue course, entitled "Leader's Guide to Crew Endurance" ⁽¹²⁾.

The course was modified for use and understanding for the Illinois State Police to fit their own work environment and fatigue problems. We felt that understanding ones own levels and signs of fatigue would not only educate, but also enhance awareness of what to look for as fatigue relates to drivers. The Pupil Response Measuring Device© course was to instruct the officers on the effects of the instrument for the detection of fatigue by physiological means.

The Illinois State Police set up four checkpoints. These checkpoints intersect the State at major highways, north, south as well as east, west. Five officer inspectors were used for every eight-hour shift at each checkpoint, who were required to do safety checks on seven trucks, each officer per shift. The study for the Pupil Response Measuring Device© took place in only one of the checks points, the first east bound weight station on I80 after crossing the Mississippi River from Iowa into Illinois.

Once the driver went through the safety check he or she was asked to volunteer to have their eyes scanned for a driving fatigue research study. If the driver agreed they were escorted to the command vehicle where the testing took place. Officers were present at the time of the testing, as the vehicle was also used for communications for the safety check. The back of the Command Vehicle was used for the testing which had a door, which could be closed for privacy during the test and question period.

The driver was escorted into the room by an officer and greeted by one of the staff of the Regional Sleep Disorder Centre; the officer then left or went into another room. The procedure was explained to the driver in the following manner: “We are conducting research on fatigue and what effects driving fatigued has on the eyes for alertness and awareness of your surroundings while driving.” The driver was then asked to sign an informed consent, which indicated it was strictly voluntary for the purpose of collection of scientific data and that any information could not be used against them for the purpose of law enforcement or evidence gathering and the questionnaire is anonymous.

A survey was then administered to obtain age, gender, time of day and SSS score. Subjects were also asked: 1) How many hours of sleep they obtained in the last 24 hrs; 2) Number of continuous hours on the road until present time; and 3) Have they had caffeine in the last 3 hours (see Table 1). Once this was completed the Pupil Response Measuring Device© was given in the following manner:

The individual was asked to place his or her forehead against the device and look into the two holes, to focus with their right eye on the “bull’s-eye” in the instruments. Once they did this, they could activate the device by depressing and releasing a red button on the top of the device, which than illuminated a white screen. They would then see four black dots against a white screen. Once they could bring all four black dots into the white screen, they were asked to release the button and hold still and not blink until told to do so. The technician could see exactly the same image via a computer screen and would indicate to the subject to release the button and encourage them not to move or blink. Once this was completed the individual was asked to lift his or her head for about 20 seconds, and it was repeated again for a total of three scans in the same manner. For each subject, 3 pupil scans were taken and averaged to assure statistical reliability. The pupillometer program automatically rejects statistical outliers caused by blinking from the data analysis.

This data was saved in ASCII format converted into an Excel™ Spreadsheet and was finally converted into SPSS software for descriptive and inferential statistical analysis. Once the individual left the room the headrest was sterilized for the next subject.

The whole process for the paper work and the screening took less than five minutes. All truck drivers who were stopped at the safety checkpoint agreed to have their pupils scanned. Thus, there was no selection bias for the study.

Data and statistical analysis

Survey questions were used as quasi-independent variables. The dependent variables consisted of the 6 pupillary responses (Constriction Velocity, Reflex Amplitude, Initial Pupil Diameter, Minimum Pupil Diameter, Final Pupil Diameter, and the Time to Minimum Diameter).

The Pupil Response Measuring Device© program measured constriction velocity automatically and was derived by using the 2 points of maximum slope, while the other parameters were calculated in millimetres. The quasi-independent variables consisted of the survey items that asked subjects to self-report caffeine intake, SSS score, age, hours on the road, and sleep during the last twenty-four hours.

Results

Correlation analysis of survey with pupillary responses

The first set of analysis consisted of correlating subjects' self report characteristics with the six pupillary responses of Constriction Velocity, Reflex Amplitude, Initial Diameter, Minimum Diameter, Final Diameter and Time To Minimum Diameter. Table 1 illustrates the results.

The only significant correlation's were between age and the 2 pupil variables of initial pupil diameter and minimum pupil diameter $r(170) = -.158, p=.038$, and $r(170) = -.154, p=.044$. Agreeing with other research, we found the older the individual the smaller the initial pupil diameter and the smaller the minimum diameter. Table 1 also indicates that there was no significant correlation between the SSS score, Sleep over the last twenty-four hours, hours on the road, and pupillary responses.

Contrary to the literature we found no correlation between the time of day and pupillary responses⁽⁶⁾. A follow-up analysis was done to see if the time of day and pupillary response relationship was mediated by age⁽⁶⁾. When the correlation was run for each age group all correlations were still under 0.1 and non-significant.

Categorical analysis of fatigue and pupillary responses

The correlation analysis suggested that self-reported fatigue via the SSS had no demonstrable effect of pupillary responses. A follow-up analysis was done to determine if there was some biological cut-off whereby truck drivers would show different pupillary results. A new variable was created from the question asking how many hours of sleep have occurred during the last 24. We categorised all truck drivers who had 5 or less hours of sleep during the last 24 hours as fatigued (n=33) and those with more than 5 hours as non-fatigued (n=133). T-tests were then performed on pupillary responses to determine if there were any difference between the two groups⁽¹⁾.

Table 2 illustrates that constriction velocity was significantly faster $t(41.73) = 2.976, p=.005$ and reflex amplitude was marginally deeper $t(38.307) = 1.886, p=.067$ for fatigued truck drivers when compared to non-fatigued truck drivers. Truck drivers that had 5 hours or less of sleep had a mean constriction velocity of 4.365 and mean reflex amplitude of 1.28. Truck drivers who had more than 5 hours of sleep had a constriction velocity of 3.682 and reflex amplitude of 1.098.

Discussion

The results of the present research give a great deal of validity to the concept of being able to physiologically measure truck driver fatigue. The fact that truck drivers with 5 hours or less of sleep showed faster constriction velocities, larger reflex amplitudes and longer time to minimum diameters than those with more than 5 hours suggest that pupil physiology may be used as an indicator of fatigue. The fact that these physiological parameters separated at the 5-hour mark is also in agreement with results from insomnia studies⁽¹³⁾. Those studies suggest that getting 5 or less hours of sleep can have profound effects on one's cognitive and behavioural processes.

These results have the potential to be used as a clinical indicator of fatigue in truck drivers and other organisational employees. Future research should also focus on developing specific dietary, environmental, and physiological countermeasures to prevent some of the negative effects of fatigue.

The data also provide physiological validation for the idea that the parasympathetic nervous system controls pupil constriction and the sympathetic nervous system controls pupil dilation⁽³⁾. When a truck driver is on the road they get very fatigued and consequently sympathetic activity is greatly decreased. Thus, their response to a pupil scan should show a strong parasympathetic response. This is exactly what our data shows since the constriction velocity is large and the reflex amplitude is also large. The correlation analysis also shows that these affects are dependent on age, which agrees with other experimental results⁽¹⁴⁾.

The results of this study are quite different from those found when drugs were given to individuals. Those studies indicated that alcohol, valium, and marijuana slow down constriction velocity and decrease the reflex amplitude^(9,10). This is the first research documenting an increase in constriction velocity and larger reflex amplitude.

The fact that the effects of sleep deprivation do not depend on time of day also contradicts present research^(6,8). Most of the present research on time of day is done on workers who are working on a stable sleep/wake and light/dark cycle⁽⁶⁾.

Since the truck drivers are frequently on the road their circadian rhythms are desynchronised and thus the time of day has no direct effect on their pupil physiology. The important variable is the sleep they have received over the previous twenty-four hours.

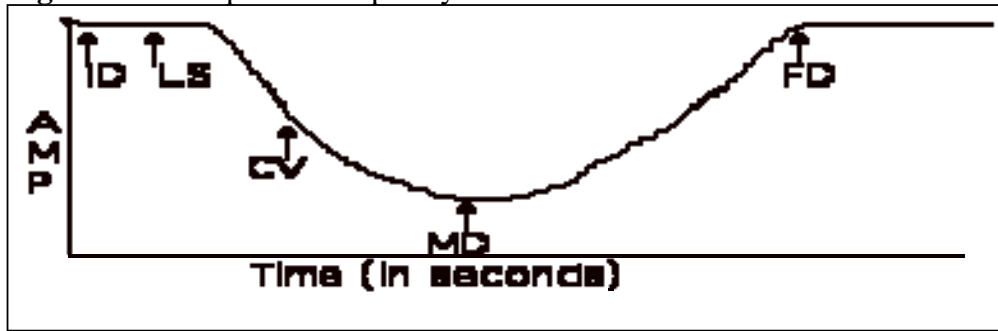
One reason why the correlational analysis between self-report fatigue and pupillary responses was not significant may have been self-report biases.

The truck drivers were stopped at safety checkpoints and while they were performing the task and answering questions an officer was present in the command vehicle. It is quite possible that the truck drivers could not give their true feelings about sleepiness or that they could not give how many continuous hours they had been on the road.

Another reason for the lack of self-report correlations could have been the large amount of individual variability in assessing fatigue. Most research using pupillometry uses within-subject designs that eliminate individual differences between subjects.

The fact is that statistically significant results were still achieved in an ecologically valid setting (not just in the laboratory). This suggests that these physiological differences are real and robust and can be used for future trucking research.

Figure 1. Description of Pupillary Variables



1. ID = Initial Diameter of Pupil
2. LS = Light Stimulus Onset
3. CV = Pupil Constriction Velocity
4. MD = Minimum Diameter of Pupil
5. FD = Final Pupil Diameter of Pupil after dilation
6. Amp = Wave amplitude
7. Time = in seconds

Table 1. Correlation Matrix of Pupillary Response Variables with Subjective Questions

	Sleep24	Hours on Road	Age	Gender	Caffeine	Stanford Score	Time of Day
Constriction Velocity	-.155*	-.002	.038	.038	.146	.055	-.069
Reflex Amplitude	-.110	-.014	-.024	.072	.036	-.031	-.033
Initial Diameter	-.024	.003	-.158*	.011	-.024	-.08	.094
Minimum Diameter	-.004	.003	-.154*	-.016	-.026	-.071	.112
Final Amplitude	-.015	.015	-.147	-.015	.017	-.113	.073
Time to Minimum	-.100	-.012	-.064	.030	.057	.033	-.002

*Significant at .05

Table 2. Comparison of Eye Parameters for Fatigued to Non-Fatigued Truck Drivers

Parameter	Fatigued Subjects (N=33)		Non-Fatigued Subjects (N=133)		T	Prob.
	Mean	S.D.	Mean	S.D.		
Constriction Velocity	4.365	1.2	3.68	.99	2.976	.005
Reflex Amplitude	1.28	.53	1.09	.37	1.886	.067
Initial Diameter	4.78	1.5	4.79	1.1	-.059	.953
Minimum Diameter	3.51	1.4	3.68	1.01	-.665	.510
Final Diameter	4.55	1.6	4.63	1.07	-.270	.788
Time to Minimum	.98	.48	.86	.26	1.353	.184

Appendix A. Survey Questions.

1. Subject Identification Number _____
2. Time of Day _____
3. Gender _____
4. Age Category 1=18-25, 2=26-50, 3=50+
5. Stanford Sleepiness Scale Rating _____
6. Continuous hours on the road until present _____
7. Number of hours of sleep during the last 24 _____
8. Have you had caffeine in the last 3 hours _____

Stanford Sleepiness Scale

This is a quick way to assess how alert you are feeling. If it is during the day when you go about your business, ideally you would want a rating of a one. Take into account that most people have two peak times of alertness daily, at about 9 a.m. and 9 p.m. Alertness wanes to its lowest point at around 3 p.m.; after that it begins to build again. Rate your alertness at different times during the day. If you go below a three when you should be feeling alert, this is an indication that you have a serious sleep debt and you need more sleep.

An Introspective Measure of Sleepiness

The Stanford Sleepiness Scale (SSS)

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not at peak; able to concentrate	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	X

THE EPWORTH SLEEPINESS SCALE

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

0 = no chance of dozing
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

SITUATION	CHANCE OF DOZING
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place (e.g a theatre or a meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car, while stopped for a few minutes in traffic	_____

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Acknowledgments:

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Special consideration: U.S. Army Aeromedical Research Laboratory, Fort Rucker, Al.

A Levene's homogeneity of Variance test was computed automatically by SPSS and the results indicated a violation of the homogeneity of variance. Thus t-test were computed without the assumption of homogeneity of variance. The net result was a major reduction in degrees of freedom for the computation of t-test results.

BROWN COUNTY PROBATION DEPARTMENT

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December 11, 2002

MR DIRCK RHEIN
MCJ EYECHECK
810 EAST STATE ST STE 104
ROCKFORD IL 61104

Dear Mr. Rhein:

I want to thank you for the opportunity to test your EyeCheck system in our agency. As you know, we utilized this new product for a period of six weeks starting in late October, 2002.

We trained eight probation officers to use this equipment and conducted nearly 100 eyescans in this time period with adult offenders and staff. Our results were conclusive. 100 percent of the eyescans that showed a result of "negative," proved to be negative with a follow-up urine test. This in itself showed how this product is very reliable in screening out "non-using" offenders, saving a tremendous amount of time and money.

As to the positive tests, our results were close to what you informed us it would be. Of the approximate 100 tests, we had a false positive rate of 21 percent. Those that were positive, the primary reason appeared to be medication issues or offenders would relate a history of diabetes in their family. These individuals were referred to a physician for follow-up.

Our probation staff loved this product. It was easy to use, results are simple to read and the software system was easy to navigate. Offenders also liked this product as many have a legitment problem providing urine samples with someone watching them. If they are negative, it only takes a few moments of time and they are on their way.

MCJ EyeCheck is a "must have" for any agency that conducts a large number of daily drug screens. Not only will it save money for the agency by screening out non-using offenders; it will save staff time and aggravation when offenders are unable to provide a urine sample. This product has so much potential in the corrections field and it is no doubt going to be a part of every corrections agency in the future.

Thank you again for allowing us to test this exciting new product.

Sincerely,



Les P. Schultz, Director
Brown County Probation Department



Wisconsin Department of Transportation

Scott McCatlum
Governor

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Acting Secretary

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VIA E-MAIL

John Dal Santo
MCJ, Inc
810 East State Street, Suite 104
Rockford, IL 61104

June 24, 2002

Dear John:

As you are aware, I retired from the Milwaukee Police Department in August 1999, after having served twenty-seven plus years as a motorcycle officer. I was the lead Instructor and Coordinator of their Drug Recognition Expert (DRE) and Standardized Field Sobriety Testing (SFST) programs. In March 2000, was asked to become the Wisconsin Department of Transportation, Bureau of Transportation Safety DRE and SFST Coordinator. In August 2000, I became an instructor (train the trainer) in the National Highway Traffic Safety Administration (NHTSA) Drug Impairment Training for Educational Professionals (DITEP) program. Where as trained DRE's go out into the community and train the school administrator, teachers, counselors and school nurses how to recognize drug-impaired students. Like the DRE program, the DITEP program addresses impairment from herbal substances over the counter medications, prescription and illicit drugs. We also cover some of the medical situations that may mimic drug impairment. The concept of this program is to train the academic community to recognize the drug category/categories that are being abused, and for early intervention for a better learning environment. When a student comes to school to learn and their concentration is being affected by any of the mentioned substances it may not be from the intentional use of an illicit drug.

I appreciated the opportunity of working with you first hand to see how your EYECHECK could and should be used as a screening device, not only for law enforcement but also in the academic community. Early detection and intervention of substance abuse is an ever-increasing concern to the community. I was very impressed with the corroboration of the results of your EYECHECK and the urine analysis of our 2001 and 2002 DRE Field Certification training; Not only the 97% and 100% respectfully for the accuracy for the drug categories, but also how fatigue may have played a factor. Some thing that should be studied with the various drug categories and lower BAC's.

We know that certain drugs usually cause sedation, but more information is needed on what the DRE considers the down side of the drugs. There may not be physical impairment, but mental/fatigue impairment is a factor in more crashes than is being recognized. Your EYECHECK appears to address both issues

Our DRE class for 2001 included five Milwaukee County Sheriff deputies. Three of these duties were assigned to the Milwaukee County Criminal Justice Facility (county jail). I was able to convince Milwaukee County Sheriff Lev Baldwin, that training three of the deputies assigned to the jail, as DRE's was a very prudent idea. They could be utilized by all of the agencies of Milwaukee County at that facility. It didn't really take much convincing for him to send the deputies. I also used the fact that an incarcerated person had died in their custody. That person had been transferred from another facility for being impaired. It turned out to be more of a medical impairment than drugs. A DRE may have been able to recognize this. A screening device as the EYECHECK would also have been an ideal instrument to be used.

I take my hat off to the Minnesota State Patrol. I traveled to Minnesota to observe their TRUCK CHECK May 22, 2002. It was to say the least very impressive. It took place near Albertsviile, MN. All trucking going north was subject to this massive truck check. I observed just about every aspect of law enforcement being used. This included your EYECHECK being used by the Commercial Motor Vehicle Examiners. I was glad to see a number of the Minnesota DRE's were also involved.

I just got back from the International Association of Chiefs of Police, DRE 8th Annual Drug, Alcohol & Impaired Driving Conference in Plano, Texas. Captain Chuck Hayes from the Oregon State Police gave a presentation on several of the TRUCK CHECKS that have occurred there. I informed him of Minnesota's involvement with your EYECHECK. He stated it would be an avenue he would like to look at.

I truly believe the EYECHECK has an important role as a screening device for the DRE and all of the law enforcement community. Please keep the Wisconsin Department of Transportation, Bureau of Transportation Safety and myself informed of any studies or programs involving your instrument. I would be honored to help in anyway to bring the EYECHECK to Wisconsin's highways.

Respectfully,

William Kraus
DRE/SFST/DITEP Coordinator
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11 November 2002

Mr. John Dal Santo, President
MCJ, Inc.
810 E. State Street
Suite 104
Rockford, IL 61104

Subject: EyeCheck™

Dear Mr. Dal Santo,

This letter is in reference to your inquiry regards the use of pupillometry instrumentation as a form of advanced technology for non-invasive drug detection in the field of law enforcement and corrections.

Over the past five years I have tracked the subject of non-invasive drug detection and the collateral commercialization opportunities presented by this area of study. Over this time I have not witnessed any law enforcement and corrections technologies or products that replicate the application or functionality of the EyeCheck™ instrument. I am aware of instrumentation that utilizes a similar, mythology but is not based upon pupillometry technology.

It should be noted that reference to any specific commercial product, process or service by trade name, trade mark or manufacturer, does not imply an endorsement, recommendation or favoring by OLETc.

Hopefully this information is responsive to your inquiry. Should you need additional information, feel free to call upon me.

Sincerely,

F. Wayne Barte
Project Manager



A PROGRAM OF THE NATIONAL INSTITUTE OF JUSTICE