

Transdermal Testing Peer Review:

A Survey of Studies, Research, Articles, and Court Opinions



ARTICLES and BOOK CHAPTERS

(see the below sections on laboratory and field studies for published studies on transdermal alcohol testing)

Fuel Cells

A. Berger, "How does it work?: Alcohol breath testing," 325 British Med. J. 1403 (2002)

- The author is the Science Editor of the journal
- The author described breath testing basics and recognized that fuel cell devices may be used for evidential breath testing

G.W. Currier, A.J. Trenton, P.G. Walsh, "Relative Accuracy of Breath and Serum Alcohol Readings in the Psychiatric Emergency Service," 57 Psychia. Services 34 (January 2006)

- The lead author, Dr. G.W. Currier, M.D., is affiliated with the University of Rochester School of Medicine Department of Psychiatry
- The authors compared breath alcohol levels with simultaneous serum blood alcohol levels for 32 patients
- The authors used the Alco-Sensor III, a fuel cell device, to measure breath alcohol levels, and a gas-chromatograph to measure blood alcohol levels
- The authors noted that fuel cell devices "are relatively specific and do not respond to typical interfering substances"
- The authors noted that fuel cell devices have a low false-positive rate
- The authors expressed a concern about using breath testing for medical (as opposed to legal) purposes because the breath test devices underestimated the patients' serum alcohol levels in 31 of 32 cases
 - The authors found that the discrepancy between reported breath and blood alcohol levels increased as blood alcohol level climbed above 0.20
 - In 25% of the cases, the breath tests underestimated serum alcohol levels by 0.10 or more

Transdermal Transport, Generally

S. Brusilow and E. Gordes, "The Permeability of the Sweat Gland to Nonelectrolytes," 112 Amer. J. Dis. Child. 328 (Oct. 1966)

- Dr. Saul Brusilow, M.D., and Dr. Ellen Gordes, M.D., were affiliated with the Johns Hopkins University School of Medicine
- The conducted a study to determine how the body processes alcohol and non-electrolytes in or about the skin
- They interpreted their data to suggest "[t]hat the final composition of sweat is not determined to a major degree by the back diffusion of water"

H. Johnson and H. Maibach, "Drug Excretion in Human Eccrine Sweat," 56 J. Investig. Dermatol. 182 (1971)

- Howard Johnson was affiliated with the Life Sciences Division at the Stanford Research Institute. Howard Maibach was associated with the Department of Dermatology, School of Medicine, University of California San Francisco Medical Center
- The researchers reviewed some of the literature on transdermal transport and noted that the concentration of drugs and ethanol in sweat are related to corresponding levels in the blood

R. Scheuplein, "Permeability of the Skin: A Review of Major Concepts," 7 Curr. Probl. Dermatol. 172 (1978)

- Dr. Robert Scheuplein was affiliated with the FDA's Dermal and Ocular Toxicity Branch
- Scheuplein discussed general concepts of transdermal transport

D. Kidwell, J. Holland and S. Athanaselis, "Testing for drugs of abuse in saliva and sweat." 713 K. Chromatography B 111 (1998)

- David Kidwell was affiliated with the U.S. Naval Research Laboratory; James Holland worked with GeoCenter, Incorporated; and Sotiris Athanaselis was associated with the University of Athens' Department of Forensic Medicine and Toxicology
- The researchers discussed transdermal transport of alcohol and other drugs and reported on experiments they conducted to determine the efficacy of urine and drug testing to determine alcohol and/or drug use

Transdermal Transport, Alcohol

M. Phillips, "Subjective Responses to the Sweat-Patch Test for Alcohol Consumption," Dual Addiction (Haworth Press 1984)

- Dr. Michael Phillips, M.D., MRCP, was associated with the Division of General Medicine and Clinical Pharmacology at the Chicago Medical School, Georgetown University and the Institutes for Behavioral Resources
- This study was presented at the annual meeting of the American Medical Society on Alcoholism and Research Society on Alcoholism in 1982 along with a companion study
- The study was supported by a grant from the United States Brewers Association
- The object of the study was to determine how comfortable sweat patches are
- Researchers tested the patches on 41 volunteers and surveyed them about the patches' usefulness
- Most subjects reported no discomfort or irritation; most forgot about the patches "within a few hours of their application"

- The subjects generally “liked” the patches, “tend[ed] to drink less alcohol than usual” while wearing the patches (though they were “equivocal” about this), and recognized the patches’ “potential benefits”

M. Phillips, “Sweat-Patch Testing Detects Inaccurate Self-Reports of Alcohol Consumption,” 8 Alcohol. Clin. Exp. Res. 51 (Jan./Feb. 1984)

- Dr. Michael Phillips, M.D., MRCP, was associated with Georgetown University and the Institutes for Behavioral Resources
- This study was presented at the annual meeting of the American Medical Society on Alcoholism and Research Society on Alcoholism in 1982 along with a companion study
- The study was supported by a grant from the United States Brewers Association
- The object of the study “was to measure how accurately drinkers report their consumption of alcohol”
- The researchers monitored 22 volunteers for one week. They compared the volunteers’ reports of drinking with toxicological testing
- The researchers found that the volunteers significantly under-reported their drinking and concluded that “[a]ny self-reported claim concerning alcohol consumption or abstinence should be received with a degree of skepticism”
- The researchers also urged greater use of laboratory tests, including the sweat patch, as diagnostic aids

D. Brown, “A Method for Determining the Excretion of Volatile Substances Through Skin,” 7 Meth. and Find. Exptl. Clin. Pharmacol. 269 (1985)

- Dr. Daniel Brown, Ph.D., was affiliated with the Department of Pharmacology and Toxicology at the Indiana University School of Medicine
- Brown performed the study at the Institute for Toxicology, Swiss Federal Institute of Technology and University of Zurich
- The purpose of this “preliminary” study “was to investigate the excretion of volatile substances as gases or vapors from skin as a potential alternative technique for monitoring breath and blood concentrations”
- The researchers collected samples from one subject by placing his hand into a bag, allowing the air in the bag to reach equilibrium with the vapors coming from his skin, collecting gas samples at various BACs/BrACs and measuring vapor ethanol levels with a gas chromatograph
- They determined that “volatile substances are excreted through the skin in sufficient quantities to allow reliable estimation of blood concentration provided that equilibrium has been achieved.” However, the author noted that transdermal alcohol levels exceed BAC and BrAC levels late in the elimination phase
- The author indicated that it appears that there is a “fixed concentration ratio” between “the blood and the gases excreted from the skin”

D. Davidson, P. Camara, and R. Swift, "Behavioral Effects and Pharmacokinetics of Low-Dose Intravenous Alcohol in Humans," 21 Alcohol. Clin. Exp. Res. 1294 (Oct. 1997)

- Dr. Dena Davidson, Ph.D., Dr. Robert Swift, M.D., Ph.D., and the Peter Camara were affiliated with the Brown University Department of Psychiatry. Swift also was associated with Giner, Incorporated
- The National Institutes of Health funded this study
- The researchers dosed twelve volunteers with single-blind intravenous infusions of ethanol to "(1) assess the ability of humans to perceive subjective effects of low BACs; (2) measure behavioral effects of low BACs on a psychomotor performance task; and (3) test the sensitivity and accuracy of the [Giner] transdermal alcohol sensor (TAS) for measuring low BACs from the skin"
- The researchers collected blood, breath and transdermal samples
- They found that BAC, BrAC and TAC were closely correlated
- They also found that the TAC curve lagged behind the BAC and BrAC curves (which were more closely correlated)

Transdermal Alcohol Testing

J.P. Allen, P. Sillanaukee, N. Strid and R.Z. Litten, "Biomarkers of Heavy Drinking," (National Institute on Alcohol Abuse and Alcoholism August 2004)

- Dr. John Allen, Ph.D., is a Scientific Consultant to the National Institute on Alcohol Abuse and Alcoholism; Dr. Pekka Sillanaukee, Ph.D., is affiliated with the Research Unit at the Tampere University Hospital and Medical School of Tampere University in Finland; Dr. Nuria Strid, Ph.D., works with NS Associates in Stentorp, Sweden, and Dr. Raye Litten, Ph.D., is the Chief of the Treatment Research Branch of the Division of Clinical and Prevention Research at the National Institute on Alcohol Abuse and Alcoholism
- The authors recognized that the "[c]oncentration of ethanol in transdermal fluid and mean concentration of ethanol in blood are related in a linear fashion"
- They noted that sweat patches have worked well in the laboratory, but have not been as effective in the field due to the difficulties with "ethanol storage and losses due to evaporation, back-diffusion, and bacterial metabolism"
- They also discussed the development of the Giner device (WrisTAS), which measures transdermal alcohol levels with a fuel cell

J.C. Anderson and M.P. Hlastala, "The kinetics of transdermal ethanol exchange," 100 J. Appl. Physiol 649 (October 2005)

- Joseph Anderson and Dr. Michael P. Hlastala, Ph.D., are affiliated with the Departments of Medicine and Physiology and Biophysics at the University of Washington. Hlastala is a well-known defense expert who has testified on multiple issues for the past 20 years

- This paper was supported, in part, by a grants from the National Institute for Biomedical Imaging and Bioengineering and the National Heart, Lung and Blood Institute
- The authors presented a mathematical model predicting the “transient exchange of ethanol across the skin”
- They noted that the “kinetics of ethanol transport can be highly variable between subjects” and that “the water content and temperature of the stratum corneum along with the volume and flow rate of gas above the skin need to closely controlled to ensure accurate measurements”
- Nonetheless, when they calculated TAC and BAC using their mathematical model, the “ethanol concentration in the gas compartment [above the skin] *always* took longer to reach its maximum, had a lower maximum, and had a slower apparent elimination rate than the BAC” (emphasis added)
- They noted that the models’ predications were “consistent with experimental data from the literature”
- They reported that the SCRAM device “shows promise as a means for measuring a pseudocontinuous supradermal ethanol concentration, ethanol concentration in the gas space above the skin, at multiple points in time as a means for identification of violation of abstinence form alcohol”

“The Role of Biomarkers in the Treatment of Alcohol Use Disorders,” 5 Substance Abuse Treatment Advisory 1 (Substance Abuse Mental Health Administration September 2006)

- The article addressed the efficacy of biomarkers for identifying alcohol use and recommended “possible monitoring by means of a transdermal alcohol-sensing device” to confirm positive biomarker test results

G. Webster and H. Gabler, “Feasibility of Transdermal Ethanol Sensing for The Detection of Intoxicated Drivers,” 51st Annual Proceedings, Association for the Advancement of Automotive Medicine 449-464 (October 2007)

- The authors were affiliated with the Virginia Polytechnic and State University Center for Injury Biomechanics
- The researchers recognized that transdermal testing “has been shown to very accurately shadow the concentration profile of the ethanol in the blood via proportionally smaller concentrations of ethanol emitted at the surface”
- They noted, however, that researchers have consistently identified a substantial lag time between BAC and TAC peaks. Using a validated model, they examined the effects that body weight, metabolic rate and ethanol dose have on the time lag between BAC and TAC peaks
- They found that the time lag was insensitive to body mass and “only moderately sensitive to metabolic rates”
- They determined that the more alcohol a person consumes, the greater the lag time

SCRAM

K. Phillips, "Reducing alcohol-related crime electronically," 65 Fed. Probation 42
<http://www.aamva.org/Pulbications/TWiR/2006/Month06/Day05/SCRAMGuides.htm>
(September 2001)

- Kirby Phillips founded Alcohol Monitoring Systems, Incorporated, manufacturer of the SCRAM device
- The author reviewed some of the scientific literature supporting transdermal testing and SCRAM's components and methods of operation
- He also noted that transdermal alcohol readings correlate well with breath alcohol readings

J.R. Zettl, "The Determination of Blood Alcohol Concentration by Transdermal Measurement,"
<http://www.alcoholmonitoring.com/pdf/TransdermalWhitePaper.pdf> (July 2002)¹

- J. Robert Zettl is an award winning forensic scientist and consultant who works with both prosecutors and defense attorneys. He is a former President of the Society of Forensic Toxicologists (SOFT) and a Diplomat of the American Board of Forensic Examiners
- The analysis was commissioned by Alcohol Monitoring Systems, Incorporated, maker of the SCRAM device
- The author participated in efforts to compare the accuracy of SCRAM readings to breath alcohol concentrations
 - The author participated in hundreds of tests on more than 100 different individuals from October 2000 through June 2002
 - The author determined that transdermal alcohol readings correlate well with breath alcohol readings, but that drinking curves are right shifted

J.R. Zettl, "Tamper Detection Utilizing the SCRAM Transdermal Alcohol Monitoring Device; a White Paper," <http://j.b5z.net/i/w/2099113/i/TamperDetectionWhitePaper.pdf> March 2004)

- J. Robert Zettl is an award winning forensic scientist and consultant who works with both prosecutors and defense attorneys. He is a former President of the Society of Forensic Toxicologists (SOFT) and a Diplomat of the American Board of Forensic Examiners
- This analysis was commissioned by Alcohol Monitoring Systems, Incorporated, maker of the SCRAM device

D. Powers and D. Glad, "The SCRAM Tether as Seen Through the Eyes of Davis-Frye and Daubert," Mich. Bar J. (June 2006)²

¹ Although this document was not published in a journal, it has been considered by at least some members in the scientific community. See e.g. T.D. Ridder, C.D. Brown, and B.J. Ver Steeg, "Framework for Multivariate Selectivity Analysis, Part II: Experimental Applications," 59 Applied Spectroscopy 804, 812 (2005).

² <http://www.michbar.org/journal/pdf/pdf4article1014.pdf>.

- Judge Dennis Powers is a Michigan District Court Judge. Daniel Glad was his clerk
- Judge Powers conducted a Daubert hearing in 2004, in which he excluded SCRAM testimony and evidence. Unfortunately, he was not provided with all of the information necessary to a proper determination
- The authors opined that SCRAM fails both the Frye and Daubert tests for admissibility
- The authors either were unaware of or ignored the wide range of literature summarized in this document
- The authors relied heavily on evidence produced at the earlier Daubert hearing. Not surprisingly, their article contained numerous misunderstandings, factual errors and/or omissions including, but not limited to the following:
 - The authors indicated that “[i]f one were to eat [foods like chocolate cake, apple walnut bread, raisin bread, sourdough English muffins, wheat bread and chocolate donuts], a positive reading on a transdermal alcohol measuring device could result.” However, the literature clearly demonstrates that this would be unlikely unless someone ate an obscenely large amount of food. See e.g. B. Logan and S. Distefano, “Ethanol Content of Various Foods and Soft Drinks and their Potential for Interference with a Breath-Alcohol Test,” 22 Journal of Analytical Toxicology May/Jun 1998. In that article, Logan and Distefano indicated that a person would need to eat 3.6 pounds of bourbon cake, 6.2 pounds of apple walnut rolls, 21 pounds of raisin bread, 13 pounds of English muffins or 12 pounds of wheat bread to bring their BAC over .02. Not surprisingly, Logan and Distefano concluded that “the likelihood of anyone testing positive for alcohol from cooked bread consumption, let alone becoming intoxicated, is therefore remote.” See also A. Al-Awadhi, IA Wasfi, F Al Reyami and Z Al-Hatali, “Autobrewing revisited: Endogenous concentrations of blood ethanol in residents of the United Arab Emirates,” 44 Sci. & Just. 149 (2004). In that article, Al-Awadhi, et al, described their study of 1,557 residents of the United Arab Emirates. They found that the “overall median, minimum, maximum, 25% percentile and 75% percentile” blood ethanol concentrations of sober people were 0.04, 0.00, 3.52, 0.01 and 0.09 mg/dl (“far too low to have any forensic significance”) [note that the illegal limit is 80 mg/dl]
 - The authors considered unconfirmed “drinking events” that never would have been classified as such by AMS personnel trained to read the raw data
 - The authors dismissed the Sakai study (discussed below), noting that it was “paid for by AMS.” The authors neglected to mention and may not have known that the study also was funded by NIDA, NIMH and NIH, the Colorado Multiple Institutional Review Board and the General Clinical Research Center’s Scientific Advisory Committee approved the research protocol and that “by contract, the researchers were free to publish any results without prior approval by company representatives.” The authors suggested that the study was conducted on a small sample; apparently unaware that the literature is replete with experiments performed with much smaller groups than the one used by Sakai. Finally, the authors ignored the fact that the article was published in a peer review journal, *Alcoholism: Clinical and Experimental Research*

J.S. Hawthorne and M.H. Wojcik, "Transdermal Alcohol Measurement: A Review of the Literature," 39 Can. Soc. Forensic Sci. J. 65 (2006)

- Jeff Hawthorne invented SCRAM and is Alcohol Monitoring Systems, Incorporated's (AMS) Chief Technological Officer; Mark Wojcik is AMS's Vice President of Products
- The authors reviewed that scientific literature on transdermal alcohol measurement
- They concluded that "(1) ethanol is excreted through the skin in sufficient quantities to estimate BAC; (2) those who have not consumed alcohol do not produce signals that can be interpreted as a transdermal alcohol cure; (3) TAC is correlated with BAC in both magnitude and shape of the alcohol curve; (4) the TAC alcohol curve is right shifted from the BrAC alcohol curve and takes longer to reach zero; and (5) measuring TAC on a constant basis provides an effective screen for alcohol consumption and an approximation of the magnitude of that consumption

R. Robertson, W. Vanlaar and H. Simpson, "Continuous Transdermal Alcohol Monitoring: A Primer for Criminal Justice Professionals" (Traffic Injury Research Foundation October 2006)

- The Traffic Injury Research Foundation is an internationally recognized charitable road safety institute based in Canada
- The report summarized the literature on transdermal alcohol testing
- The authors recognized that
 - "[a]fter more than 70 years of research and 22 peer-reviewed studies into the science underpinning this new technology, it has been clearly established that ingested alcohol can be validly measured in perspiration through the process of transdermal alcohol testing, i.e., testing of alcohol that is excreted through the skin
 - "Research studies over the past 10 years have demonstrated that transdermal alcohol readings or results are correlated to blood alcohol concentrations. There is a recognized and measurable delay in the absorption and elimination of alcohol, *so simultaneous breath or blood and transdermal alcohol readings should not be expected to produced similar results at a specific point in time*" (emphasis in original)
 - "Transdermal alcohol testing is a valid way of determining whether an individual has consumed a small, moderate, or large amount of alcohol, and is designed to be a screening device to determine alcohol use. This testing method is not designed to produce a specific blood alcohol concentration (BAC) reading"
- The report was funded by Alcohol Monitoring Systems, Inc. However, the content was scrutinized by nationally recognized and impartial reviewers including
 - Judge Harvey Hoffman, District Court Judge from Eaton County, Michigan,
 - Paul Biderman, Director of the Institute of Public Law at the University of New Mexico School of Law and Past President of the National Association of State Judicial Educators

- Drew Molloy, Senior Policy Advisor for Corrections at the Bureau of Justice Assistance
- Carl Wicklund, Executive Director of the American Probation and Parole Association
- Zachary Dal Pra, Deputy Chief of Maricopa County Adult Probation
- David Wallace, Michigan Traffic Safety Training Attorney

“Taking Law Enforcement Seriously in Colorado,” 8 Catalyst 1 (Winter 2007)

- The Catalyst is published by the United States Department of Education’s Higher Education Center for Alcohol and Other Drug Abuse and Violent Prevention
- The author discussed Greeley City’s use of SCRAM to combat underage drinking

J. Pollard, E. Nadler and M. Stearns, “Review of Technology to Prevent Alcohol-Impaired Crashes (TOPIC),” National Highway Traffic Safety Administration (September 2007)

- The authors are affiliated with the Volpe National Transportation Systems Center, a division of the Research and Innovative Technology Administration (United States Department of Transportation)
- The researchers evaluated a range of vehicular technologies that could be used to detect driver blood alcohol levels and alcohol impaired driving
- They noted that SCRAM “has been used successfully on thousands of individuals to monitor compliance with court-ordered “Do not drink” mandates”
- They recognized that SCRAM can read alcohol caused by alcohol-containing skin-care products, but opined that “these patters in the data stream can easily be recognized as such”

LABORATORY STUDIES

Optical Vapor³

H. Giles, S. Sandrin and V. Saldivia, “Noninvasive Estimation of Blood Alcohol Concentrations by Eye Vapor Analysis Using an Electrochemical Fuel Cell Detector,” 13 Alcohol.: Clin. Exp. Res. 461 (May/June 1989)

- The researchers were affiliated with the Addiction Research Foundation and the Department of Pharmacology at the University of Toronto
- The researchers compared alcohol in the eye vapor of rats and mice to blood alcohol concentration for the purpose of developing a new, noninvasive approach to alcohol analysis in laboratory animals

³ Optical vapor testing relies on the same theories as transdermal testing. It is analogous, but not identical, to transdermal testing.

- They determined that eye vapor alcohol levels correlated closely with blood alcohol levels
 - They noted that there was not a significant temporal lag between vapor alcohol levels and blood alcohol levels as there is with breath, urine and “perspiration” testing
- The authors used a modified fuel cell device taken from a breath testing instrument to conduct their experiment

Sweat Studies with Unknown Collection Methods

G.L.S. Pawan and K. Grice, “Distribution of Alcohol in Urine and Sweat After Drinking.” The Lancet 1017 (November 9, 1968)

- The researchers were affiliated with the Department of Medicine and the Institute of Clinical Research, Middlesex Hospital Medical School, London
- The researchers dosed three men and three women with alcohol and measure alcohol levels in simultaneously collected urine and sweat
- Conclusions:
 - “The alcohol levels in sweat and urine samples, simultaneously collected, were found to be practically identical when expressed in terms of the water content of the specimens analyzed”
 - “[A]lcohol is uniformly distributed between sweat water and urine water. . . . alcohol, after absorption and equilibration, is evenly distributed throughout the total body water.”

L. Davidoff, “Alcohol in Urine and Sweat,” The Lancet 1350 (December 21, 1968)

- Davidoff noted that Pawan and Grice reported lower alcohol levels in sweat than urine and proffered mathematical computations to account for differences

G.S.L. Pawan and K. Grice, “Alcohol in Urine and Sweat,” The Lancet 56 (January 4, 1969)

- The researchers responded to Davidoff’s commentary. They disagreed with Davidoff’s conclusions, explaining that the “minute differences found between sweat and urine alcohol levels⁴ may easily be explained by the difficulty in preventing alcohol evaporation during sweat collection and alcohol analysis”

Sweat Patch Studies

M. Phillips, “A Sweat-Patch Test for Alcohol Consumption: Evaluation in Continuous and Episodic Drinkers,” 4 Alcohol. Clin. Exp. Res. 391 (Oct. 1980)

⁴ In their study, supra., Pawan and Grice measured sweat alcohol levels slightly below simultaneous urine alcohol levels.

- Dr. Michael Phillips, M.D., MRCP, was an Assistant Professor of Medicine with Georgetown University. This study was performed at the University of Connecticut Health Center in partnership with the Newington Veterans Administration Medical Center
- The study was approved by the Human Experimentation Committee of the University of Connecticut and the Research and Development Committee of the Newington Veterans Administration Hospital
- The researchers collected blood and sweat samples from 8 drinking subjects for eight days
- The sweat patch was 100% sensitive and specific
- There was a linear relationship between the concentration of ethanol in the blood and ethanol in the sweat

M. Phillips, "An Improved Adhesive Patch for Long-Term Collection of Sweat," 8 Biomat., Med. Dev., Art. Org. 13 (1980)

- Dr. Michael Phillips, M.D., MRCP, was affiliated with the Division of General Medicine with the University of Connecticut Health Center
- Phillips applied four sweat patches to subjects above their ankles to test the patches' ability to collect sweat for drug testing (e.g. alcohol) purposes
- Phillips found that the uptake rate of the patches varied from "site to site, and person to person," but that it "[appeared] to be steady at a particular site upon a particular person"
- He also noted that the patches' collection rates "remained quite steady" even though the study was performed in "mid-summer" and all of the wearers "were constantly entering and leaving an air-conditioned building"

M. Phillips, "Sweat-Patch Test for Alcohol Consumption: Rapid Assay with an Electrochemical Detector," 6 Alcohol. Clin. Exp. Res. 532 (Fall 1982)

- Dr. Michael Phillips, M.D., MRCP, was affiliated with the Division of Internal Medicine, Georgetown University Hospital, and the Institute for Behavioral Research
- This paper was supported by a grant from the United States Brewers Association
- Phillips analyzed the collected samples with a handheld electrochemical (fuel cell) detector
- Phillips determined that collecting sweat samples and analyzing them for alcohol with an electrochemical detector "[appeared] to be rapid, simple, and robust"

H.G. Giles, S. Meggiorini, G.E. Renaud, J.J. Thiessen, E.I. Vidins, K.V. Compton, V. Saldivia, H. Orrego and Y. Israel, "Ethanol Vapor above Skin: Determination by a Gas Sensor Instrument and Relationship with Plasma Concentration," 11 Alcohol. Clin. Exp. Res. 249 (May/June 1987)

- Giles, Ph.D., Meggiorini, BSc, G.E., Renaud, Thiessen, Ph.D., Vidins, M.D., Compton, Saldivia, BA, Orrego, M.D., and Israel, Ph.D., were affiliated with the Addiction Research Foundation and the Department of Pharmacology, University of Toronto
- They noted that “the excretion of ethanol through skin has been known for many years,” but that “few” methods for measuring it had been developed
- They conducted experiments to determine the efficacy of measuring ethanol vapor above the skin using a gas sensor instrument
 - They tested the instrument on nine rats, four healthy human subjects and 15 liver disease outpatients
- They found that the method provided a “good estimate” of the plasma ethanol concentration
- They also found that “normal interindividual variation in skin characteristics plays only a limited role”
- Significantly, they recognized that “extraneous alcohol” which can come from a variety of “toilet products” may affect readings. Accordingly, they investigated the potential effect of contaminants by swabbing two subjects’ hands with alcohol. Although alcohol effected the readings for longer than expected, Figure 4 demonstrates that the alcohol registered almost instantly and the readings dropped precipitously (far faster than one would expect from normal elimination; figure 4 shows that the wearers’ TACs fell from almost .15 to under .05 in one hour. A normal person eliminates, on average, .015-.020 per hour)

WRISTAS Studies

R. Swift, C. Martin, L. Swette, A. LaConti and N. Kackley, “Studies on a Wearable, Electronic, Transdermal Alcohol Sensor,” 16 Alcohol. Clin. Exp. Res. 721 (July/Aug. 1992)

- Dr. Robert Swift, M.D., Ph.D., was affiliated with the Brown University Center for Alcohol and Addiction Studies and Giner, Incorporated
- This article was supported by a grant from the Alcohol, Drug Abuse, and Mental Health Administration
- The researchers tested the Giner WrisTas, a transdermal alcohol concentration (TAC) measurement device that relies on fuel cell technology, for the first time
- They noted that “electrochemical [fuel cell] detection of ethanol has been used for many years in sensor cells which oxidize ethanol and produce currents proportional to the ethanol concentration. Such cells are used in commercially available portable breathalysers (e.g., Alco-Sensor III by Intoximeters, Inc., St. Louis, MO). The readings are well correlated with blood alcohol concentration (BAC)”
- They tested the device on 10 non-alcoholic drinkers under laboratory conditions, five intoxicated people who went to the hospital for inpatient detoxification, and four sober subjects. They also tested the device on four people who wore the device for five to seven days who drank alcohol according to their “usual custom”
- There were no false positive results in sober subjects, “including those with liver or renal disease”

- They found that the TAC device “closely [followed] the pattern of the blood alcohol concentration curve, although with a delay.” They noted that “[u]rinary alcohol levels show a “similar lag when compared with blood”

R. Swift, “*Transdermal measurement of alcohol consumption,*” 88 *Addiction* 1037 (1993)

- Dr. Robert Swift, M.D., Ph.D., was affiliated with the Brown University Department of Psychiatry and Human Behavior and Giner, Incorporated
- In this Editorial, Swift discussed three types of transdermal testing including fuel cell testing via the WrisTAS device and noted,
 - “It is well established that ingested ethanol is partitioned into the body water and measurable quantities of ingested ethanol are secreted through the human skin”
 - “Multiple studies . . . demonstrate that transdermal ethanol concentration generally follows the time course and amplitude of the blood alcohol concentration”
 - Transdermal testing is “non-invasive and atraumatic”
 - “The methodology shows high sensitivity and specificity for ethanol and with calibration for different conditions, shows high correlations with BACs”

R. Swift, “*Transdermal Alcohol Measurement for Estimation of Blood Alcohol Concentration,*” 24 *Alcohol. Clin. Exp. Res.* 422 (Ap. 2000)

- Dr. Robert Swift, M.D., Ph.D., was affiliated with the Brown University Center for Alcohol and Addiction Studies and Giner, Incorporated and was the Associate Chief of Staff for Research and Education at the Providence VA Medical Center
- In this presentation, Swift noted:
 - “It is well known that ingested alcohol dissolves in the body water and is present in various body fluids, including eccrine sweat and insensible perspiration”
 - “The idea of using perspiration to measure BAC goes back to the 1930s, when it was determined that the concentration of alcohol in sweat is approximately equal to that of blood”
 - “The transdermal alcohol curve is delayed with respect to the breath alcohol curve. The relative peaks of the two curves are separated by approximately an hour, and the time to achieve zero is delayed as well”
 - In discussing the WrisTAS transdermal testing a device (which relies on fuel cell technology), Swift wrote that TAC peaks are “highly correlated” (0.6 to 0.7) with BAC peaks and that the areas under the respective curves “are extremely highly correlated, with correlation co-efficients of 0.9 or better”
 - The WrisTAS is equipped with temperature and skin electrical resistance sensors to “verify that subjects [wear] the TAS device or not. . . . Changes in skin temperature and skin resistance curves can document if the subject [removes] the device”

M.A. Dumett, I.G. Rosen, J. Sabat, A. Shaman, L.A. Tempelman, C. Wang, and R.M. Swift, “Distributed Parameter Modeling, Estimation, Simulation and Deconvolution for the Transdermal Transport of Alcohol in Humans”

- Dumett, Rosen, Sabat and Wang are affiliated with the Department of Mathematics at the University of Southern California; Tempelman works for Giner, Incorporated, and Swift, M.D., Ph.D., was associated with Brown Medical School, Providence VAMC
- The researchers collaborated to develop and report on “an integrated data analysis system” to allow them to determine specific blood alcohol levels from transdermal alcohol testing

SCRAM Studies

J. Sakai, S. Mikulich-Gilbertson, R. Long, T. Crowley, “Validity of Transdermal Alcohol Monitoring: Fixed and Self-Regulated Dosing,” 30 Alcohol. Clin. Exp. Res. 26, 28 (Jan. 2006)

- The authors are affiliated with the University of Colorado School of Medicine Department of Psychiatry. The lead author is Dr. Joseph Sakai, M.D.
- The results were presented at the Annual Meeting of the Research Society on Alcoholism in 2005
- The study was funded by NIDA, NIMH and NIH. AMS also contributed to the study. However, “by contract, the researchers were free to publish any results without prior approval by company representatives” and the Colorado Multiple Institutional Review Board and the General Clinical Research Center’s Scientific Advisory Committee approved the research protocol
- The researchers conducted a laboratory study involving 24 subjects on the SCRAM device
 - 80 samples were collected from no-dose subjects. Each time SCRAM reported a TAC of 0 (there were no false positives)
 - SCRAM consistently detected consumption of approximately two standard drinks (there were no false negatives)
 - TAC curves were right-shifted relative to BrAC curves; transdermal peaks occurred later than BrAC peaks
 - TAC peaks were lower than BrAC peaks
 - SCRAM reliably differentiated between low dose and high dose drinkers
 - The bracelet was “adequately comfortable for most users”

L. Rapp and R. Nichols, The Nanogram 2 (Louisiana Association of Forensic Scientists September 2006)

- The authors reported on a study they conducted to determine SCRAM’s effectiveness in a “casual” atmosphere
- 12 volunteers consumed alcohol

- The device correctly recognized all drinking episodes
- The authors concluded “[a]s in previous studies, this study also indicates that the transdermal monitoring devices currently used today cannot directly replace breath testing as a quantitative technique for determination of alcohol concentration. These transdermal devices can be used, however, to semi-quantitatively identify drinking episodes in a continuous screening environment. These devices could be used in criminal justice programs to identify drinking episodes, to monitor drinking among alcohol dependent offenders to reduce recidivism, and potentially identify individuals in need of treatment”
- Two volunteers used products containing alcohol to see if they would register as a drinking event
 - One volunteer took a “normal dose” of cough syrup
 - The other volunteer used hair spray, body spray and body lotion
 - The device did not recognize any usage of these products as drinking episodes; the highest reported reading was 0.005, well below the 0.02 cutoff

Pacific Institute of Research and Evaluation (National Highway Traffic Safety Administration January 2007)

- NHTSA contracted with PIRE to conduct this study in 2004. The researchers examined first generation SCRAM devices. They concluded their work in February 2006 (this is important because the researchers identified a moisture accumulation issue which has since been corrected)
- The researchers noted, “[t]here is no doubt that the transdermal concept is valid as long as expectations of quantitative parity with BAC are moderated”
- The researchers also said that two wearers indicated that the device “helped goad them toward sobriety in a way that other motivators were unable to do”
- The researchers found:
 - SCRAM detected 88% of drinking episodes resulting in BACs of 0.08 or higher (and 57% of all drinking events of 0.02 or higher)
 - SCRAM reads all alcohol it is exposed to, regardless of source
 - False positives (incidents where SCRAM generated a curve that would have been mistaken for a drinking event) were not a problem
 - The researchers noted that there were “no false positives of any note” with SCRAM
 - The circumvention system “performed well” and it “seems unlikely that circumvention by obstruction can constitute a real threat to the integrity of this system while drinking”
 - SCRAMNET is “well designed and works well”
 - “[T]he communication of the SCRAM bracelet with its remote server, along with data retrieval and reporting technology, is exceptionally innovative”
 - The system is “fairly seamless in the way it communicates and uploads data from the ankle bracelet”

FIELD EVALUATIONS

S. Bock, "Michigan DOC Runs BETA Test of New Remote Transdermal Alcohol Monitoring System," J. Offender. Monitoring 2 (Winter/Spring 2003)

- Steve Bock was the Michigan Department of Corrections Program Manager for the Electronic Monitoring Center
- He tested the SCRAM System on five officers and 19 volunteer offenders
- He found that the "product is able to detect circumvention of alcohol test sampling, reliably ensures that test samples are from those of the intended test subjects, and detects drinking episodes around the clock regardless of a subject's schedule or location
- He also determined that the system "clearly meets its primary objective of accurately measuring alcohol consumption"
- He reported that overall response from the officers and offenders involved was positive
 - Offenders "call[ed] they system a fast-acting deterrent and a preferred method of testing because of the freedom to maintain work and family schedules"

A. McKelvie, "Justice Center Evaluates SCRAM," 22 Alaska Justice Forum
http://justice.uaa.alaska.edu/forum/22/4winter2006/d_scram.html (Winter 2006)

- Alan McKelvie is the Director of the Statistical Analysis Center at the University of Alaska Anchorage Justice Center
- The Center "analyzed monitoring data from 2003 through mid-2005 for 319 users of the bracelets in Anchorage, Palmer, Fairbanks, Bethel and Kotzebue and conducted structured interviews with personnel from the various state agencies involved with the project to determine problems, ease of use, and failures with the devices"
- Researchers reported that the "results from the analysis and interviews were very consistent, indicating no problems with the technology"

OTHER NOTABLE REFERENCES

R. Voas and P. Marques, "Emerging Technological Approaches for Controlling the Hard Core DUI Offender in the U.S.," 5 Traf. Inj. Prev. 309 (2004)

- The authors are researchers with the Pacific Institute of Research and Evaluation (PIRE)
- The article was "supported by" the National Institute on Alcohol Abuse and Alcoholism
- The authors recognized SCRAM's potential value to the system and the offender

"A Guide for Reducing Alcohol Related Collisions," 16 NCHRP Report 500 V-43 – V-47 (Transportation Research Board 2005)

- The Transportation Research Board is a division of the National Research Council that serves the National Academy of Sciences and the National Academy of Engineering
- The report recognized transdermal testing's utility and use

M. Barrasse, "Promising Sentencing Practice No. 6: Electronic Monitoring and SCRAM," Strategies of Addressing the DWI Offender: 10 Promising Sentencing Practices (NHTSA 2005)

- Judge Michael Barrasse is a Pennsylvania Judge
- The article identified SCRAM as one of the 10 "Promising Sentencing Practices" and briefly described its use

V.E. Flango and C.R. Flango, "What's Happening with DWI Courts," Future Trends in State Courts (National Center for State Courts 2006)

- Victor Flango is the Executive Director of Program Resource Development for the National Center for State Courts
- Carol Flango is the Director of Knowledge and Information Services for the National Center for State Courts
- The authors recognized that "DWI courts require close, frequent contact with the judges and frequent testing, which increase the cost of operating DWI courts. One way to reduce the cost of monitoring is to employ technology"
- The authors noted that 36 states were using SCRAM and the SCRAM costs less than remote electronic alcohol monitoring and incarceration

M. Lewin, "Alternatives to More Prisons Promote Public Safety, Restorative Outcomes, and Fiscal Responsibility," PolicyPerspective (Texas Public Policy Foundation February 2007)

- Marc Lewin, Esq., is the Director of the Center for Effective Justice
- The author recognized that SCRAM allows offenders to be "safely supervised on parole at a much lower cost" than incarceration

PRESENTATIONS ON TRANSDERMAL TESTING (to Scientific Agencies and Groups and other Major Presentations)

R. Swift, "Assessment of Alcohol Consumption with Transdermal Ethanol," Mclean Hospital Alcohol and Drug Abuse Center, Belmont, Massachusetts (March 1992)

R. Swift, "Assessment of Ethanol Consumption with Transdermal Ethanol," University of Chicago Psychiatry Rounds, Chicago, Illinois (April 1992)

R. Swift, "Transdermal Ethanol: Principles and Applications," Research Society for Alcoholism Annual Meeting, Maui, Hawaii (June 1994)



R. Swift, "Transdermal Alcohol Measurement of Alcohol Consumption," Poster Presentation, European College of Neuropsychopharmacology, Glasgow, Scotland (July 1998)

R. Swift, "Measurement of Alcohol Consumption By Transdermal Alcohol," Tufts University Pharmacology Department Conference, Boston, Massachusetts (September 1998)

R. Swift, "Transdermal measurement of alcohol drinking," Poster Presentation, Clinical Pharmacology and Therapeutics Meeting (CPT2000), Florence Italy (2000)

R. Swift and L. Swette, "A wearable transdermal wrist sensor for estimation of blood alcohol levels," ACNP Annual Meeting, San Juan, Puerto Rico (December 2000)

R. Swift, "Transdermal Alcohol Measurement for the Estimation of Blood Alcohol Levels," National Institute of Health Research Facility, Poolesville, Maryland (February 2001)

R. Swift, "Development of a Transdermal Alcohol Sensor," National Institute on Alcohol Abuse and Alcoholism, Workshop on Alcohol Sensors, Washington, District of Columbia (May 2001)

R. Swift, "The Assessment of Alcohol Consumption by Measurement of Transdermal Alcohol," Alcohol Research Group, Public Health Research Group, Berkeley, California (February 2005)

P. Marques, "Evaluating Transdermal Alcohol Devices," 6th Annual Innovative Technologies for Community Corrections Conference, Seattle, Washington (June 2005)

J. Sakai, S. Mikulich, R. Long and T. Crowley, "Validity of Transdermal Alcohol Monitoring: Fixed and Self-regulated Dosing," Poster Presentation, American Academy of Addiction Psychiatry 16th Annual Meeting and Symposium, Scottsdale, Arizona (December 2005)

"Alcohol Impaired Driving and Monitoring Technologies," National Judicial College, Sentencing Vehicle Traffic Law Offenders, Reno, Nevada (August 2006)

R. Robertson, "Alcohol Impaired Driving & Monitoring Technologies," Texas Annual Judicial Conference, Houston, Texas (September 2006)

Various Speakers, National 24/7 Sobriety Conference, Sioux Falls, South Dakota (September 2006)

R. Robertson, "Strategies for Addressing the Higher-Risk Driver: Repeat and High BAC Offenders," Lifesavers Conference, Chicago, Illinois (March 2007)

R. Robertson, "A Criminal Justice Perspective on Impaired Driving Technologies," Lifesavers Conference, Chicago, Illinois (March 2007)



R. Robertson, "A Drunk Driving Systems Approach," 9th Annual Traffic Safety Summit, Lansing, Michigan (March 2007)

R. Robertson, "Continuous Transdermal Alcohol Monitoring," Lifesavers Conference, Chicago, Illinois (March 2007)

R. Robertson, "Continuous Transdermal Alcohol Monitoring: An Overview," Alcohol Issues Panel, Toronto, Ontario (April 2007)

R. Robertson, "Continuous Transdermal Alcohol Monitoring: An Overview," Canadian Association of Road Safety Professionals Conference, Montreal, Quebec (June 2007)

R. Robertson, "Continuous Transdermal Alcohol Monitoring," National Law Enforcement and Corrections Technology Conference, St. Louis, Missouri (June 2007)

R. Robertson, "Technologies for DWI Offenders," National Judicial College, Sentencing Vehicle Traffic Law Offenders, Reno, Nevada (August 2007)

R. Robertson, "Alcohol Impaired Driving and Monitoring Technologies," DWI Conference for Judges, Fort Worth, Texas (August 2007)

S. Talpins, "Alternatives (or Supplements) to Incarceration," International Council on Alcohol, Drugs & Traffic Safety Annual Conference, Seattle, Washington (August 2007)

P. Marques, A. McKnight, and R. Voas, "Transdermal Alcohol Detection in the Laboratory and In the Field," International Council on Alcohol, Drugs & Traffic Safety Annual Conference, Seattle, Washington (August 2007)

J. Hawthorne, "Transdermal Alcohol Measurement: A Review of the Literature," International Council on Alcohol, Drugs & Traffic Safety Annual Conference, Seattle, Washington (August 2007)

R. Robertson, W. Vanlaar and H. Simpson, "Transdermal Alcohol Monitoring," International Council on Alcohol, Drugs & Traffic Safety Annual Conference, Seattle, Washington (August 2007)

G. Webster and H. Gabler, "Feasibility of Transdermal Ethanol Sensing for the Detection of Intoxicated Drivers," 51st Annual Proceedings of the Association for the Advancement of Automotive Medicine (October 2007)

M. Wojcik, "Continuous Alcohol Monitoring and the SCRAM System," National Institute on Alcohol Abuse and Alcoholism, Bethesda, Maryland (November 2007)

WRITTEN COURT OPINIONS

(Listed by State)

State v. Knuppel, Case No. 05M00542 (Colorado County Court, August 10, 2007)

- In a probation violation hearing, the court held that SCRAM evidence “is scientifically reliable, having been subjected to extensive controlled testing and validated by peer-reviewed scientific literature” and admissible under Daubert

State v. Martinez, Case No. 2006-018213-DV (Colorado Municipal Court, December 12, 2007)

- The court recognized that “[t]he underlying principles of the SCRAM Unit have been accepted as reliable by a substantial portion of the scientific community” and determined that SCRAM results are admissible under Daubert

State v. Gass, Case No. 06-DT-212 (Illinois Circuit Court, August 8, 2007)

- In a probation violation hearing, the court ruled that SCRAM evidence is reliable and admissible under Frye
- The defendant claimed that the alcohol detection was caused by a gas leak in his van. The court, relying on expert testimony that gasoline and consumed alcohol cause distinctly different curves, rejected this claim

In Re Post, 686 N.W.2d 529 (Minnesota Supreme Court, 2004)

- The Court disciplined an attorney who was convicted of DWI
- The Court ordered the defendant to wear a SCRAM bracelet for one year

State v. Duffee, Case No. 05-CR-252 (Ohio Court of Common Pleas, October 10, 2006)

- In a probation violation hearing, the court ruled that SCRAM evidence is reliable and admissible under Daubert
- The defendant argued that endogenous alcohol could affect SCRAM results. However, the court recognized that “[a] human cannot eat enough food to produce enough alcohol to show a result with the SCRAM unit”

City v. Carpenter, 2006 TRC 003272 (Ohio Municipal Court, November 3, 2006)

- In a probation violation hearing, the court ruled the SCRAM testimony and evidence is admissible under Daubert
 - The court recognized, “[w]hile newer than breath alcohol testing and blood alcohol testing, trans-dermal alcohol testing has been proven reliable as a qualitative indicator of alcohol consumption since 1936”
- The court found that Mr. Hawthorne was qualified to testify regarding SCRAM results



- The defendant claimed that the SCRAM readings were caused by Band-Aid brand Anti-Itch gel
 - The court noted that the defendant violated his SCRAM Program Participation Agreement which prohibited him from using alcohol based products if he, in fact, had used the gel
 - The court also noted that AMS tested the Anti-Itch Gel and found that the TAC curve it created fell well outside of accepted absorption and elimination parameters
 - The court rejected the defendant's claim

State v. Reliford, TRC-06-02-1454 (Ohio Municipal Court, January 1, 2007 and January 18, 2007)

- Two judges issuing separate written orders found SCRAM to be reliable

State v. Wallace, Case No. 2003-CR-05-0130 (Ohio Court of Common Pleas, July 3, 2007)

- In a probation violation hearing, the court found that SCRAM testimony and evidence was “relevant and admissible”
- The court took judicial notice of the “scientific reliability of the SCRAM Device/Technology for the purpose of adjudication of future cases in [that] Court”