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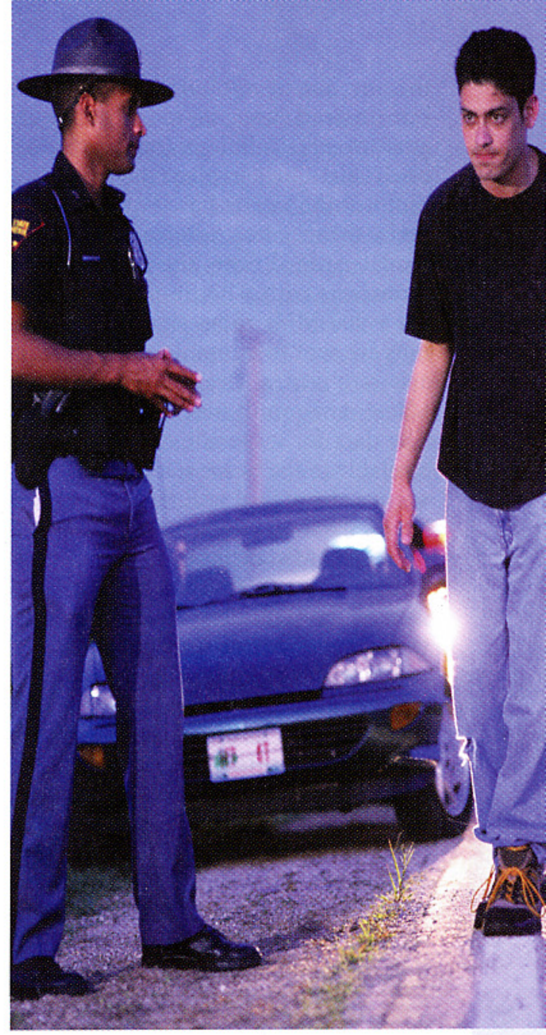

Alcohol Monitoring Ankle Bracelets: Junk Science Or Important Scientific Breakthrough?

Because all drinking driver cases involve an at least alleged use of alcohol, it is not unusual for the courts to require abstinence from alcohol while the case is pending. It is also common to make continued abstinence a term of probation. The dilemma for the courts then becomes how to best monitor the offender so that there is some reasonable assurance that the court's order is being obeyed. Traditionally the courts have employed various methods for this purpose, including random or daily breath testing, attendance at Alcoholics Anonymous or even a breath alcohol tether installed at the offender's home. While each method presents its own host of problems, one common shortfall is that none of them is *continuous*.

To address this perceived need for alcohol monitoring generally, as well the shortfalls of all the available methods, a company that calls itself Alcohol Monitoring Systems, Inc.® (AMS) patented a device known by the acronym SCRAM® (Secure Continuous Remote Alcohol Monitor). The SCRAM device is worn as an ankle bracelet, and while in place the device monitors the subject's blood alcohol transdermally, meaning it measures the migration of alcohol through the offender's skin. The measurements obtained are then converted from a perspiration alcohol level to a blood alcohol content. While the common acronym for blood alcohol is BAC, and for breath BrAC, AMS saw fit to trademark a new acronym TAC for this purpose, which now means transdermal alcohol content.

The idea of using perspiration for BAC dates back to the 1930s. Several studies in the last three decades have shown that there is a fairly good correlation between the amount of alcohol in one's perspiration and the amount in one's blood. Because of recent advances in technology,[1] the devices used to measure perspired alcohol have gotten small enough to be fashioned into something that can be worn continuously, take continuous transdermal measurements, and transmit these measurements to a central monitoring facility.

Science Of Transdermal Alcohol Monitoring

Due to ethanol's affinity for water, it is rapidly distributed throughout the body by the process of diffusion. Upon reaching equilibrium the fluids of the body will contain ethanol in proportion to their water content. The relationship between breath and blood alcohol is a constant ratio such that one volume of blood contains about the same amount of alcohol as 2100 volumes of alveolar air in normal healthy humans. This means that, in spite of a rather large concentration differences, alcohol excreted in the breath parallels that of the blood over the entire excretion phase (rising and falling). This is the underlying principle for using breath to predict BAC, and a similar process would be expected for perspiration.[2]

The manner in which alcohol passes through the skin (pharmacokinetics) is very complex, and is not well understood. This complexity is in part due to the great number of applicable variables including the subject's blood alcohol level, the rate of diffusion through the skin, the skin type and location, the thickness of the *stratum corneum* (the major barrier to water), the amount of eccrine sweating (sweat derived from glands found anywhere other than under the arms), and the cutaneous (within the skin) blood flow.[3] There is also a very interesting delay in peak BAC and peak TAC. One study showed that this delay can vary from 30 minutes to 120 minutes.[4] The amount of delay also depends on where the measurement is made, with the longest delay occurring in measurements taken from the subject's forearm.[5] It appears however that the manufacturers have yet to fully evaluate exactly how this time delay distorts the TAC curve, or how this distortion might vary with location, skin type and age.

Because the measurement of alcohol passing through the skin is complicated as well as attenuated, BAC cannot be accurately estimated from perspired alcohol content the same way that it is estimated from BrAC. Therefore, detection of alcohol consumption using a sweat collection system can only be regarded as a screening tool to help establish continued abstinence.[6] How well it performs even this limited function is of course subject to debate.

The Science and Practice Of The SCRAM Bracelet

The SCRAM bracelet measures alcohol using the same fuel cell technology used by most portable breath testing devices. With this particular device, the fuel cell is manufactured by Draeger. A fuel cell is a device designed to continually convert fuel and an oxidant into direct current. The reaction that takes place in an alcohol fuel cell is alcohol oxidation, and for these purposes, the "fuel" is alcohol. So, as alcohol is converted in the fuel cell to acetic acid it produces two electrons for each alcohol molecule. This oxidation creates a current, and the intensity of the current correlates directly to the amount of alcohol consumed by the fuel cell. This measurement can be further converted into an alcohol concentration.

What makes SCRAM unique is that it uses this technology not to measure the amount of alcohol in one's breath, but instead uses it to measure the amount of alcohol migrating through one's skin. Once in place the device will monitor the wearer based on a schedule set by the monitoring agency. Then, at a predetermined time, the bracelet communicates with a home-placed modem via a 900 MHz radio signal. The readings are sent to a remote computer that acts as a central clearing house of data where it is monitored and interpreted. The data for a specific offender is then available to the home state's monitoring agency through a secure Internet Web site.

SCRAM's alcohol measuring technology became feasible based on advances in technology that allowed a transdermal device to be small enough to be worn continuously, and sophisticated enough to communicate the readings obtained to a remote location for analysis. Prior to AMS, several other transdermal methods had been tested, including sweat patches and a competing and very similar device worn on the wrist. This wrist device was manufactured by Gither, Inc., and was the subject of research performed by Dr. Robert M. Swift, who first published on the topic in 1992. Ultimately, Dr. Swift published three articles as well as an editorial on the subject of transdermal alcohol measurement, with the last of these published in 2000. In this last article Dr. Swift indicated for the future, that Gither, Inc. plans to perform more experiments that measure transdermal alcohol under more natural drinking conditions.[7] This research has either not been performed or not yet subject to publication. In his 1993 editorial, Dr. Swift states that additional research is being conducted to better elucidate the clinical pharmacology of transcutaneous ethanol and its relation to BAC, and to test reliability, specificity and acceptance of the transdermal methodology in different individuals over a range of research and clinical applications.[8] While the article published in 2000 addressed some of these issues it is clear that much research remains to be done relative to the overall efficacy of transdermal alcohol testing, as well as to its overall applicability the non-clinical setting.

The only published research dealing specifically with the SCRAM bracelet was paid for by AMS, and was researched by J. Robert Zettl. In this paper, Zettl indicates that the objective of this research was to compare the accuracy of readings using the AMS SCRAM bracelet to alcohol concentrations measured by conventional breath analysis. He concludes that this independent research establishes SCRAM technology through its ability to provide accurate, continuous blood alcohol tests on clients who would have normally tested negative in a random testing program. Where random tests during the day might not detect an offender's drinking event, SCRAM's continuous testing will catch the event.[9]

What is particularly noteworthy about the Zettl paper is that he is not a research scientist, and his research appears not to have been published in any peer reviewed scientific journal. In fact, it appears not to have been actually published by anyone other than AMS. Also, the only indication of the methodology employed is an indication that hundreds of subjects were tested over an approximately 9-month period. The paper indicates also that the results of the SCRAM bracelet were confirmed not through the use of blood tests, but instead through the use of various breath testing devices. There is no statistical analysis done with the numbers obtained by Zettl in this study. It is also unknown whether or not the data was actually recorded. What is clear is that no statistical data is included in the text of this paper. After Zettl's testing, unspecified modifications were made to enhance the SCRAM unit's precision, comfort, communication software and data links and detector clearance. What changes were made to address what problems with what rate of success are questions left unanswered by this paper.

A second paper commissioned by AMS and written by Zettl addressed the issue of tamper verification.[10] The device has three critical tamper safeguards. The first of these is an infrared (IR) sensor. The device emits an infrared light signal directly at the subject's skin, and the skin absorbs a given amount of the signal's energy. The portion of the signal that is reflected back to the device's receiver is then converted to a voltage. When the device is placed into service, an initial infrared baseline reading is taken. (Interestingly though, no similar baseline is taken to individualize the bracelet's ability to properly monitor the wearer's alcohol use). Subsequent signals are compared against this baseline. In theory, if the subject attempts to frustrate the device's ability to monitor ethanol by inserting a foreign object between the device and the skin, the strength of the reflected infrared signal will increase due to reflection. The device also continuously monitors the subject's temperature. The theory here is that if the bracelet is tampered with by blocking or removal, the device will detect this tampering by detecting a change in the temperature measurement. The third tamper safeguard is in assuring that the device is not cut-off or otherwise removed. This is accomplished by measuring a small electrical signal that is continuously passed through the front and back straps to both halves of the device. If a break in the electrical signal occurs then the device will generate a message that is sent to the monitoring agency.

Limitations Of The SCRAM Bracelet

The manufacturer readily acknowledges that transdermal alcohol measurements can only be used to estimate the amount of alcohol in a subject's blood, and therefore, the SCRAM device can only be used to make qualitative rather than a quantitative assessments. This position is supported by the scientific literature.[11]

However, the essential theory of the SCRAM device is that it can detect a drinking episode by comparing its periodic measurements with an expected blood alcohol curve (taking into consideration the absorption, distribution and elimination of alcohol). If the ostensible ethanol measurements rise and fall in a gradual manner, then it is presumed that the measurements can be attributed to the metabolism of beverage alcohol. The manufacturer claims that this curve looks and behaves like a blood alcohol curve, but differently than a curve associated with a non-drinking episode. With an interferant, rather than a gradual rise and fall, the curve will show a rapid peak followed by a rapid falling off. What this essentially means then is that the monitoring agency is relying on the quantitative measurements of the device in creating the curve when it is acknowledged that transdermal measurements are only qualitatively valid.

However, the most pervasive problem with the SCRAM technology is that it is non-specific for beverage alcohol. In published experiments where skin vapor ethanol is measured, a system very similar to that used by SCRAM, the researchers concluded that an effort should be made to exclude extraneous ethanol. Such ethanol can come from a variety of ethanol containing toilet products used by many persons[12]. This non-specificity is due in part to the fact that the measurements are taken above the skin, allowing environmental factors to be inadvertently measured by the device. Perhaps more problematic is that the fact that fuel cells are used to detect the alcohol, and fuel cells are generally non-specific for ethanol, and can potentially respond to other alcohols such as methyl-, isopropyl-, and n-propyl alcohol, and to acetaldehyde.[13] At least in theory, because fuel cells are non-specific, these other types of alcohol, if endogenous, can produce a curve that looks identical to one produced from a verifiable drinking episode.

Another significant limitation is the fact that the entire predicate for distinguishing a drinking episode from a non-drinking episode, which of course is the behavior of the curve, has never been subjected to any legitimate scientific scrutiny. The only testing that has been done was commissioned by AMS, and performed by Zettl. There are no published research studies confirming that the SCRAM device can distinguish between drinking and non-drinking. There are also no published research studies confirming that a non-drinking curve will always contain a rapid rise and fall. In fairness to AMS, one study was published suggesting that the sweat-patch has been shown to be 100 percent specific and sensitive in distinguishing drinkers from non-drinkers.[7] The problem is that this study involved only a small number of individuals who were monitored under tightly controlled circumstances, and needless to say, the sweat patch is not the SCRAM device. Additionally, this study did not address or control the possibility that interferents could be inhaled, ingested or produced endogenously. In these cases one might expect that the interferent curve would closely mimic a drinking curve, thereby reducing both the specificity and sensitivity of this testing method.

Defending The SCRAM Case

Defending one accused of violating a condition of bond or probation based on a SCRAM report requires a thorough understanding of the science behind transdermal alcohol testing, as well as the manner in which the SCRAM bracelet operates. From this research counsel is likely to conclude that transdermal alcohol monitoring has not yet been subjected to an appropriate level of scientific scrutiny, and in order for there to be any likelihood of success this conclusion must be effectively communicated to the Judge. This conclusion appears to be supported by the fact that during development AMS was in competition with Gither, Inc., and their very similar wrist bracelet. Apparently, this competition lead to AMS placing their SCRAM bracelet into service without proper research first having been done.

Once the science is understood, defense counsel must next obtain from the monitoring agency the graphs that ostensibly reflect the drinking episode. The graphs should be accompanied by a linear read-out of each individual TAC reading. The graphs will contain three curves, one each for the infrared signal, the subject's temperature, and the alleged TAC. These graphs must be scrutinized to determine if in fact the numbers appear to reflect a typical blood alcohol curve, and whether or not any blocking episode actually coincides with the drinking. With respect to an analysis of the blocking aspect, bear in mind the delay in TAC relative to BAC. While it may appear that they coincide, actually they may not, because the infrared signal is in real time while the TAC may actually be attenuated by as much as 120 minutes or more.

It is also helpful to obtain a detailed medical history so that it can be determined if the offender has any medical condition or chemical exposure that could cause a false positive. The accused should also report exactly what they were doing during the entire day before and after the alleged drinking episode, and this history should be examined for possible interferant exposure. If possible, counsel should attempt to match up the medical condition or chemical exposure with the alleged drinking.

If it appears that there is a legitimate argument against drinking, defense counsel should request an evidentiary hearing based on FRE 702 and 703, and if the rules applicable to evidentiary hearings in your State allow, pursuant also to the *Daubert* and *Kumho Tire* cases.[15] At the hearing the limitations of the scientific research can be elucidated for the Court.

It is only with this level of advocacy that the judiciary can be properly educated about the significant limitations of the SCRAM device, and if the violation is approached in this way defense counsel should obtain a much higher likelihood of success beating what might otherwise appear to be an unbeatable allegation of drinking.

Notes

1. *Behavior Effects and Pharmacokinetics of Low-Dose Intravenous Alcohol in Humans*, David Davidson, Paul Camara, and Robert Swift in ALCOHOLISM: CLINICAL AND EXPERIMENTAL RESEARCH, Vol. 21, No. 7, pp. 1294-1299 (1997).

2. *The Pharmacokinetics of Alcohol Excretion in Human Perspiration*, D.J. Brown, METHODS AND FINDINGS EXPERIMENTAL CLINICAL PHARMACOLOGY, Vol 7(10), pp 539-544.

3. *Transdermal Alcohol Measurement for Estimation of Blood Alcohol Concentration*, R. Swift in ALCOHOLISM: CLINICAL AND EXPERIMENTAL RESEARCH, Vol. 24, No. 4, pp. 422-423(2000).

4. *Id.*

5. *Id.*

6. *The Pharmacokinetics of Alcohol Excretion in Human Perspiration*, D.J. Brown, METHODS AND FINDINGS EXPERIMENTAL CLINICAL PHARMACOLOGY, Vol 7(10), pp 539-544 (1985).

7. *Sweat-Patch Testing Detects Inaccurate Self-Reports of Alcohol Consumption*, M. Phillips, ALCOHOLISM, CLINICAL AND EXPERIMENTAL RESEARCH, Vol. 8, No. 1, pp 532-534 (1984).

8. Editorial: *Transdermal Measurement of Alcohol Consumption*, Robert M. Swift in ADDICTION, Vol. 88, pp. 1037-1039 (1993).

9. THE DETERMINATION OF BLOOD ALCOHOL CONCENTRATION BY TRANSDERMAL MEASUREMENT, J. Robert Zettl, (2002).

10. TAMPER DETECTION UTILIZING THE SCRAM TRANSDERMAL ALCOHOL MONITORING DEVICE, J. Robert Zettl, (2004).

11. *Id.*

12. *Ethanol Vapor above Skin: Determination by a Gas Sensor Instrument and Relationship with Plasma Concentration*, H.G. Giles, S. Meggiorini, G.E. Renaud, ALCOHOLISM, CLINICAL AND EXPERIMENTAL RESEARCH, Vol. 11, No. 3, pp 249-253 (1987).

13. MEDICAL-LEGAL ASPECTS OF ALCOHOL, 4th Edition, p. 197 (2003).

14. *Sweat-Patch Testing Detects Inaccurate Self-Reports of Alcohol Consumption*, M. Phillips, ALCOHOLISM, CLINICAL AND EXPERIMENTAL RESEARCH, Vol. 8, No. 1, pp 532-534 (1984).

15. Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999).

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