The Patch: A New Alternative for Drug Testing in the Criminal Justice System

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Introduction

SINCE THE beginning of conventional testing for drugs of abuse in humans, urine has been the body fluid chosen as the most reliable specimen for analysis. Recently, other specimens have been proposed and tested as options to either augment or replace urinalysis. Hair analysis for drugs of abuse has been proposed as an alternative by several investigators (1, 3 & 6). Saliva has also been suggested for use under certain conditions (5, 11 & 14).

Research has also suggested sweat as a candidate for consideration (2, 12, 16 & 17). A sweat collection device has been developed by Sudormed, Inc. This sweat collection patch has successfully undergone extensive clinical testing (8 & 9) as well as evaluation in drug rehabilitation and detoxification programs. In addition, this device has been evaluated in several independent programs in the criminal justice system.

Description of the Patch

The patch, which is best described as a Band-aid®, consists of a simple cellulose fiber absorption pad which is covered and held to the skin by an adhesive (figure 1). The patch allows for the normal exchange of water, oxygen, and carbon dioxide to the skin through the patch and, at the same time, is resistant to water and environmental contaminants from the outside. The absorption pad collects and contains the various components of sweat which do not evaporate such as salts, proteins, and the parent drug and analytes from consumed drugs which are present in perspiration.

The patch is easy to apply to a subject's skin and can be worn for only a few days or for as many as 14 days. Any single episode of significant drug use during the wear period will be detected once the patch is removed by the authorized professional and analyzed using conventional drug testing procedures. It is tamper-evident, which means that it cannot be removed and then reapplied by the wearer without being detected.

The polyurethane and adhesive layers of the patch are unique in their properties to “self-destruct” at the time of removal. An alpha-numeric code which is unique to each patch helps prevent counterfeiting. This code is also useful to integrate into standard chain of custody procedures.

A Brief Review of Basic Physiology

A brief review of basic human physiology may be in order to provide an understanding of perspiration and the role it plays in the elimination of waste products from the body. There are two distinct ways the body sweats. Sensible perspiration is the reaction to exercise, increased environmental temperatures, or the basic need to cool the surface of the skin. Insensible perspiration is a slow but continuous uncontrolled elimination of fluid through the skin. This process is constant and is not affected by the environment, humidity, or temperature. A significant volume of fluid (up to 700 ml. or approximately 4/5 quart) is excreted from the body each day through insensible perspiration alone (7).

It is well recognized that an individual with drugs in his or her system can attempt to “beat” the urine test by “flushing” or consuming large quantities of water in order to lower the urine specific gravity (10). It has also been recommended to users to consume acid drinks in order to mask the detection of certain drugs in the urine (10). Sweat is not susceptible to these covert manipulations. The source of sweat is the interstitial fluid which is located in the tissue compartments. Consuming large quantities of water will have no effect on the concentration of salts, proteins, or drug analytes in this fluid (15). The interstitial fluid and sweat will not be affected by the consumption of acids. Elimination of excess water and acids in the gastrointestinal tract is primarily through the kidneys and the urinary system.

Scientific Studies Using the Sweat Patch

Once the patch had been developed, patented, and tested, highly controlled clinical studies were begun at various research institutions and universities. These investigations have focused on the detection of several controlled substances (cocaíne, marijuana, amphetamines, opiates, and phencyclidine) using the patch. Results from some of these trials have documented and validated the efficacy of this new patch system as...
an alternative to urinalysis for the detection of cocaine and opiate use (4, 8 & 9). Results from clinical studies on detection of amphetamines, marijuana, and phencyclidine use are yet to be published but also confirm that these substances are detected by the patch.

**Investigations in the Criminal Justice System**

In mid 1992, product evaluation studies were initiated at both the United States Probation Office and the United States Pretrial Services Office, Central District of California, and at the California State Department of Corrections, Parole and Community Services Division. A study was later conducted with the County Probation Department of Orange County, California. This article will report only the results from the study conducted with the U.S. probation and U.S. pretrial services offices. However, observations from the other field evaluations will also be included.

The objectives of these studies were to evaluate the usability, wearability, practicality, and acceptability of the patch in the “real life” environment in which it will be used. Testing the product under the conditions in which it is intended to be used provides the ultimate evaluation of a product. The acceptability of the patch was evaluated by probation officers and parole agents, as well as by offenders. The studies were not rigorous, controlled scientific studies; the results from individual urinalysis tests were compared to the participant’s patch analysis for the presence of drugs.

Following necessary governmental approvals, the program was initiated at several key Federal probation contract drug testing sites in the Los Angeles area. It is important to note that approval for this program was conditional upon it being completely voluntary for participant defendants and offenders.

**Procedures and Methods**

The sponsor, Sudormed, retained a qualified consultant from the Drug Use Forecasting program to act as the authorized professional to recruit subjects from the population of defendants and offenders undergoing mandatory drug testing. Volunteer participants were required to sign an informed consent. Following the required urine specimen collection, a patch was applied to the participant’s skin. Patch placement on the skin was designated within one of three locations at the discretion of the participant. These locations were (1) the lower chest along the lower rib cage, left or right of the mid-line, (2) the lower back above the belt line and left or right of the mid-line; or (3) the outside of the upper arm. Sites with skin lacerations, irritation, scars, excessive hair, and wrinkles were avoided.
Patch application employed a simple procedure requiring less than 3 minutes to complete. Patch applications and removals were always to be accomplished by the authorized professional. First, the area of the skin selected for patch application was cleansed with a standard 70 percent alcohol wipe to remove all residual skin oils. An area of approximately 6 inches in diameter was alcohol wiped. This is important to promote patch adhesion to the skin. The alcohol was allowed 30 to 60 seconds to dry completely. The patch was removed from its sterile envelope, the protective liner materials removed, and the patch carefully placed on the selected, cleansed, dry skin site. The adhesive area of the patch was gently but firmly smoothed to remove wrinkles or channels from the center to the periphery. It was then pressed to the skin to promote adhesion. A Polaroid camera with closeup lens attachment was used to make a permanent photographic record of the patch, confirming its integrity at the time of removal. The photograph was labeled and data sheets completed. The photographs were taken in this study as a matter of record keeping and reporting. In practical application, a photograph of the patch would not be taken.

At the assigned date for subsequent testing, a second urine specimen was collected and the patch photographed again and then removed. The absorption pad component of the collected patch was carefully placed in a clear plastic bag along with chain of custody documentation and sealed. The adhesive portion of the patch was simply discarded. All photographs and data sheets were stored along with the patch specimen, sheets were stored along with the patch specimen, and data sheets completed. The photographs were taken in this study as a matter of record keeping and reporting. In practical application, a photograph of the patch would not be taken.

For example, should one or more of a participant’s urine specimens be positive for cocaine, then the patch was analyzed for cocaine. This was done following a simple elution procedure which reconstitutes the collected substances contained in the patch into a 2.5 mL buffered solution. Thus, the concentration(s) of drug(s) found in the patch is expressed in the amount per mL of the elution solution.

Results of the Study

A total of 127 subjects participated in this study. Table 1 provides a summary of this participant population by sex, race, and age. None of the subjects had a drug positive (cocaine, opiate, amphetamine, marijuana, or phencyclidine) urine sample at either the time of patch application or removal. These results were not surprising, considering the limitations of the program to strictly voluntary participation and comparisons to percentages of positive urine tests in mandatory drug testing programs.

A random selection of approximately 10 percent of the patches was analyzed for the presence of each of the five drugs. The cutoffs established by the National Institute on Drug Abuse for “positive” in urine for the five identified drugs of abuse cannot be employed for the sweat specimens. Sweat is a qualitatively and quantitatively different bodily fluid, and, therefore, it is subject to different sensitivities and cutoff levels. The rationale behind the arbitrary decision points or cutoffs employed for drugs of abuse in the patches was three standard deviations above the values found in control patches. These values specific for each individual drug would mitigate the potential for false positives.

Of the urine specimens analyzed patches, only one participant was found to have a cocaine positive patch. The sensitivity level for cocaine being positive in patches was 15 ng/mL. Six of the 12 amphetamine analyzed patches were found to be positive for amphetamines at a cutoff of 20 ng/mL by GC/MS. Of the opiate analyzed patches, none of the 12 were found to be positive for opiates using a 10 ng/mL cutoff. None of the 12 marijuana analyzed patches were found positive for marijuana with a cutoff at 0.5 ng/mL. Of the 10 percent of the patches analyzed for the presence of phencyclidine, none of these were positive for the drug.

Of the 127 volunteer participants, only five individuals (<5 percent) reported any indications of skin irritations resulting from wearing the patch. And as was expected, several participants (approximately 14 percent) claimed that the patch "fell off."

Discussion

Based upon the findings from the study conducted with the U.S. probation office and the U.S. pretrial services office, as well as other product evaluation programs in the criminal justice system, there are clear indications that the patch has some distinct advantages in illicit drug testing. The patch is gender neutral and can be easily, conveniently, and quickly
applied and removed by male or female officers for male or female offenders. This overcomes the objection many urine collectors have to the necessity of observing the urine being voided into the collection container.

Urine specimen collection requires special handling procedures. Concern about handling urine and fear of contamination or infection have increased. The patch eliminates these issues and concerns. The urine test is also subject to manipulation by flushing the kidneys with excessive water or by consuming acidic beverages to mask certain drugs in the test. Sweat constituents cannot be manipulated with excessive water intake or by consumption of acidic beverages.

The patch allows for a 7-day or longer period of continuous monitoring for illicit drug use. Under conditions where close supervision is employed, the patch serves this purpose well and may be cost effective in eliminating the multiple urine tests which would otherwise be necessary over the same period of time.

During the course of these studies, most volunteer participants were asked for their opinion of the patch as a means for drug testing or an alternative to urine specimen collection. A vast majority (>90 percent) of the responses were in favor of the patch as an alternative to urine testing. Many stated their preference for the patch because of the discomfort of being subjected to observed urine collection and the inconvenience when a specimen cannot be provided in a timely fashion. Many found the convenience of the patch a significant plus. The patch allows for some degree of flexibility in scheduling appointments for patch removal. Many offenders preferred the patch, as it was perceived to be a more effective deterrent to drug use and proof of abstinence than urinalysis.

At this time, one cannot state exact costs of the patch and subsequent analysis. It can be projected that the patch system may cost slightly more than the standard urine test. However, the significant differences are that a single patch test may cover the same period of surveillance as two or three urine tests. There is significant savings in patch use under these conditions as well as improved detection. The difference in shipping costs between 60 mL urine specimens, which require extensive packaging, and patches, which can be sent in conventional mailing envelopes, is a further consideration.

**Summary**

The intent of this article is to report the results of a substantial field trial of a new alternative to urine collection for drug abuse testing. Studies conducted in the criminal justice system demonstrated some significant advantages of the sweat patch over conventional urinalysis.

The patch was conclusively preferred by the offender population participating in this program. Advantages related by probation officers and parole agents documented their preference for the patch in terms of its gender neutral convenience and elimination of the need for observed urine specimen collection. It further eliminates the need to handle collected urine specimens. These observations were echoed consistently along with other positive responses.

The fact that the patch provides continuous monitoring for a few days or as long as 14 days allows significantly improved management of subjects in a closely supervised drug testing program. In this respect, the patch can be cost effective in reducing the costs for the multiple urine tests during the same time period which would otherwise be necessary. The inherent difficulties, complications, costs, and fears involved in handling urine specimens and shipping containers of urine specimens to a clinical laboratory for analysis would be greatly reduced. The patch can be shipped at room temperature in conventional envelopes.

The fact that the field trial described here was voluntary on the part of the defendants and offenders helps explain the low number of urine and patch tests which were positive for illicit drugs. Nevertheless, the primary objective of the evaluation was to experience and test the utility of the patch in the actual environment in which it is intended for use. Under these conditions, there was wide acceptance for its use as soon as possible. Once the patch receives Food and Drug Administration market approval and successfully responds to legal challenges, the authors believe it will prove to be a valuable alternative to urine

**TABLE 1. SELECT VARIABLES OF PARTICIPANT POPULATION**

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Once the patch receives Food and Drug Administration market approval and success­fully responds to legal challenges, the authors believe it will prove to be a valuable alternative to urine
specimen collection for drug testing in the criminal justice system.

REFERENCES