
VeinViewer[®]

by Luminetx

Innovations in Vascular Access:

**Accidental Needlestick Injuries
Decreased via Utilization of the
VeinViewer[®]**

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Introduction

One of the most serious concerns in healthcare today is the occurrence of accidental needlesticks. According to the Centers for Disease Control (CDC), there are over 250,000 reported accidental needlesticks per year in the United States. Surveys administered in healthcare settings have further indicated that less than half of all accidental needlesticks are properly reported. In fact, some estimates state that there could be as many as 600,000 to 1 million accidental needlestick injuries that occur in the U. S. every year¹.

The problems associated with an accidental needlestick cover a myriad of issues. Needlestick injuries are associated with the occupational transmission of more than 20 pathogens. Between 1985 and 1999, cumulative totals of 55 documented cases and 135 possible cases of occupational HIV transmission were reported to the CDC. Other possible pathogen transmissions involve Hepatitis C and Hepatitis B². The negative effects are not just confined to physical problems. In a study of 20 health care workers with an HIV exposure, 11 reported acute severe distress, 7 had persistent moderate distress, and 6 even quit their jobs as a result of the exposure³. As is the case with many medical problems, colleagues and family members might suffer emotionally as well.

The epidemic of accidental needlesticks has become so acute that many government standards have been adapted to attempt a curbing of the problem. In 1991, OSHA published the Bloodborne Pathogens Standard, Title 29 Code of Federal Regulations, Part 1910.1030, to protect workers from exposures to bloodborne illnesses. This plan requires healthcare organizations to have an exposure control plan and perform annual documentation of consideration and/or implementation of safer medical devices.



In 1999, OSHA issued a compliance directive to enforce bloodborne pathogen (BBP) standard procedures. In 2002, the Needlestick Safety and Prevention Act was passed to amend the BBP standard. This act added needleless systems and required that exposure control plans reflected changes in technology.

The larger problem is the patient population with difficult venous access which directly correlates with an increased number of needlestick attempts. The Infusion Nursing Society has shown that more than 90% of all hospitalized patients require some form of peripheral vascular access during their stay, and many continue these procedures long after their discharge. Of these patients, a significant number have superficial vessels that are not only difficult to visualize and palpate by traditional clinical methods, but also difficult to access as well. In fact, although peripheral vascular access is the most frequently performed procedure among clinicians today, the inability to locate a patient's vein can quickly deteriorate into a very stressful, painful, and a sometimes traumatic situation requiring the patient to endure "multiple needlesticks" before one successful cannulation can be achieved. Patients who suffer from difficult venous access (DVA) are an ongoing challenge in healthcare. DVA as a clinical condition has yet to be defined and is not typically identified in a patient's medical record; however, clinicians are made painfully aware of the condition of DVA in patients as they struggle to gain venous access. It should also be noted that although lack of clinician skill and experience may play a huge role in the plight of multiple needlesticks, the patient significantly contributes by introducing risk factors including: age, obesity, dehydration, ethnicity, a compromised peripheral circulation, psychological stress/fear/trauma, damaged veins or developing scar tissue from repeat needle insertions, and chronic illnesses such as cancer, hypertension and diabetes. In many cases, patients who suffer from DVA must undergo an external jugular intravenous line placement or in the worst cases, require the insertion of a central venous catheter.

Potential Solutions

Medical devices that utilize visible light, near infrared light, or ultrasound to enhance a technician's ability to visualize and successfully access a vein are commercially available. Many of these types of devices have emerged in recent years. There are a number of healthcare practitioners that have adapted one or more of these technologies to attempt to decrease the number of needlesticks necessary to initiate intravenous therapy. Ultrasound is consistently utilized for venous access, specifically for PICC line insertions. Ultrasound generally is not as effective for superficial vessels, requires messy gels, and is not a hands free unit. Transilluminators have demonstrated effectiveness in specific environments; however, they require direct contact with the patient and also require that a room be darkened before imaging is performed. Many forms of transillumination, near-infrared technology and ultrasound have been introduced to the market, yet none of the available devices to date has demonstrated to be ideal for **all** clinical applications.

Recently, the VeinViewer imaging system has been manufactured to illuminate the superficial, peripheral vasculature. This innovative technology is produced by a Memphis-based biotech company called Luminetx Corporation. Through various trials and consumer utilization, the VeinViewer imaging system has seemingly demonstrated to be efficient in many clinical applications and scenarios.

VeinViewer Technology

The VeinViewer was developed in 2005-2006 and allows the capture and projection of an image of subcutaneous veins. The device was approved as a class I exempt medical device by the FDA and is the primary device manufactured by Luminetx Corporation, Inc. The VeinViewer utilizes near-infrared light to create an image that is captured by a charge-coupled digital camera. The image file is transmitted to the device's on-board computer. A proprietary algorithm is applied to the file to enhance contrast and assure alignment for projection of the image onto the surface of the subject's skin. The device uses DLP technology to

display the image within 0.06mm of the capture location, allowing precise mapping of the subcutaneous venous pattern onto the skin surface. Time from image capture to display is less than 0.01 second.

In laymen's terms, the VeinViewer bathes a patient's skin with harmless near-infrared light, the hemoglobin in the bloodstream absorbs that light and a reflection of the resulting image is captured by a digital camera in the VeinViewer head. This image is then processed, contrast is added and with the aid of DLP technology, the image is placed back down on the skin in the exact same anatomical location in real-time.

Significance

The VeinViewer imaging system by Luminetx has demonstrated the ability to significantly increase the rate at which difficult venous access (DVA) patients undergo successful peripheral intravenous cannulation. This system has also exhibited the ability to lower the number of attempts required to achieve successful intravenous access. By effectively and consistently improving peripheral vascular access, the VeinViewer can provide numerous positive implications with regard to patient care and satisfaction.

Clinical Benefits

Due to the sheer accuracy of the VeinViewer Imaging System, there are many implications that could potentially result in an amazing contribution to healthcare overall. First, this technology has proven to increase the efficiency of healthcare workers when attempting to initiate intravenous therapy or obtain a blood sample for testing. This efficiency has been realized with regard to a decrease in the number of attempts required to obtain venous access; in turn, increasing the first stick success rate results in several positive outcomes. Additionally, the time needed to obtain venous access has been decreased as well. The VeinViewer image allows healthcare workers to find accessible veins in a timelier manner; rather than the practice of "looking" for several minutes before deciding which vein is most suitable for an attempt.

Another clinical benefit is the ability to assist the practitioner in achieving that ever-elusive first-stick success. One of the most dreaded medical practices of today is either intravenous insertion or venipuncture for the testing of blood samples. In particular, children are victimized by numerous attempts due mostly to smaller veins that aren't as visible with the naked eye. One researcher concluded that "venipuncture and IV insertions are the two most common sources of pain in hospitalized children. In fact, IV insertions and blood draws were the most frequently reported painful events in hospitalized children."

Finally, as a result of demonstrating that the VeinViewer decreases the number of attempts needed to initiate intravenous therapy, a very positive side effect is a decreased number of sharp needles in the hands of practitioners. As the number of sharps in the hands of practitioners is decreased, the correlated result is a decrease in the chances of sustaining an accidental needlestick injury. Accidental needlesticks among healthcare workers is a major problem in hospitals and clinics everywhere. According to one published journal article, the average number of accidental needlesticks was 2 for every 1,000 needles utilized in that particular healthcare scenario³. If the number of overall needles in the hands of practitioners were to decrease in number, one could only assume that the number of accidental needlestick incidents would decrease as well based on percentages alone. Although the VeinViewer has primarily been demonstrated as an aid to access venous structures for medication therapy and/or phlebotomy, the device also acts as a safety device via vascular visualization.

Discussion

Intravenous access is something that is required of over 90% of patients who walk into a hospital for treatment. Many of these patients suffer from DVA and as a result, endure multiple sticks in order to receive the treatment they so desperately need in a time of illness. Additionally, these patients also routinely need their blood drawn for testing.

By depicting an accurate image of subcutaneous vasculature directly on the surface of the skin, the VeinViewer is able to enhance a clinician's ability to obtain venous access in patients with or without DVA. There have been attempts by other technologies to provide assistance with difficult venous access. To date, none of the technologies have proven to definitively solve the problems associated with DVA on every attempt.

In a demonstrative study performed at Lifeblood Biological Services in Memphis, Tennessee in early 2005, the VeinViewer was tested for utilization in patients with known difficult-to-find and difficult-to-access veins. Thirty patients, previously screened and rejected as blood donors, were chosen for clinical evaluation to determine the effectiveness of the VeinViewer to locate veins for access. Over a 20 day period, these patients were re-screened and imaged with the VeinViewer in order to locate a viable vein and attempt venous access of that vein for blood collection purposes. The VeinViewer located a viable vein in 100% of this sample of patients. Additionally, the blood center staff members had a 100% blood collection success rate with these same patients that had previously been rejected as donors due to DVA. Incidentally, all 30 patients were successfully cannulated on the first attempt. Given the current national average of anywhere from 2.4 to 6 sticks per IV access, gaining venous access on the first attempt in DVA patients who were previously rejected as blood donors is quite impressive.

In another more recent study (2007-2008) performed at Wolfson Children's Medical Center in Jacksonville, Florida, preliminary results demonstrated that the VeinViewer increases the first stick success rate, decreases the number of attempts required to successfully gain venous access, and decreases the amount of time needed to achieve said venous access⁴. The following table depicts the preliminary results from the study:

Table 1 - Wolfson Study Preliminary Results

	Age Category	First Attempt Success Rate	Mean # Attempts/Patient
Baseline	Pediatrics 1-9 years	49.3%	1.97
Study	Pediatrics 1-9 years	80%	1.29

There were zero incidents of accidental needlesticks in the study as well. The VeinViewer successfully decreased the number of attempts needed for venous access by 65%.

Considering the national average can range anywhere from 2.4 to over 6 attempts per intravenous line, 1.29 attempts in a pediatric population is astounding⁵. In many cases, the VeinViewer could decrease the number of sharps needed for venous access by 1 or more needles per IV. The implications of this kind of technology could be felt not only among healthcare workers concerning their safety, but also among the financial departments of healthcare organizations. Direct quantified costs of an accidental needlestick injury range anywhere from \$2,234 to well over \$3,832 just for screening and initial treatment. The unquantified costs include emotional costs, drug toxicities, lost time from work, and societal costs associated with an HIV or HCV seroconversion. A technology that has the potential to decrease the quantified and unquantified costs of accidental needlestick injuries is well justified.

Conclusion

The current approach to peripheral venous access is unsatisfying on many levels and results in too many sticks in order to achieve successful venous access. The VeinViewer by Luminetx displays an accurate “vascular map” to aid healthcare providers in locating viable veins. The VeinViewer has also demonstrated the ability to increase the odds of gaining venous access with a lower number of attempts, thereby

decreasing the number of needles utilized for IV therapy. Furthermore, the technology has proven to be helpful in gaining venous access during the first attempt. It stands to reason that if fewer needles are needed for the purpose of achieving venous access, there will be a drop in the odds of healthcare workers having an accidental needlestick injury. If the VeinViewer can prove to drastically reduce the number of “sticks” needed to gain access, there should be a drop in these incidents which will most certainly lead to financial and emotional effects of these injuries – No needle, No needlestick.

The VeinViewer by Luminetx is truly innovative in its design and approach to modern healthcare. Based on all the advantages the technology provides, it is quickly becoming the standard of care for venous access.

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