The IRIS Vascular Viewer™

A new imaging technology to improve peripheral access success

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More than 260 million short peripheral I.V. catheters were sold in 2002 in the United States, representing the largest group of all vascular access devices.[1] One could conclude from this sizable number that healthcare professionals are proficient with their insertion technique, however, that is not always the case. Many factors contribute to make peripheral access for both veins and arteries quite challenging.

The number of patients with difficult venous access is increasing. There is increasing incidence of chronic diseases like diabetes, cancer and cardiovascular conditions. The population in the United States is aging, and neonatal and pediatric patients present challenging venous access due to their immaturity and changes in each stage of growth and development. Simultaneously, there is a lack of professionals with venipuncture skills adequate to manage these patient needs, due to the dual problem of a severe shortage of nurses and lack of consistent education for the nurses that are at the bedside.

Several studies document a decreasing level of patient satisfaction with hospital care. Most notably Press Ganey, a data collection company specializing in measurement of healthcare satisfaction, reports that from 1993 to 1997, venipuncture services suffered the most consistent and dramatic declines in patient ratings of care.[2]

These factors, in addition to the current high level of attention placed on patient safety and cost containment, highlight the need for a different approach to peripheral vascular access — an approach that better serves the needs and interests of both healthcare professionals and patients.

Table 1. Reported Insertion Success Rates for Peripheral IV Catheters

Patient Care Setting	Type of Nurse	Total # of patients	Results			
Medical-surgical units of community hospital[1]	I.V. nurses	650	83% "accuracy" rate for I.V. nurses vs. 50% "accuracy" rate for staff nurses. Accuracy rate was not defined			
	Staff nurses	75				
Urban pediatric teaching hospital[2]	Staff RN	197	86 (44%) successful; 111 (56%) unsuccessful			
	Physicians	416	95 (23% successful; 321 (77%) unsuccessful			
	I.V. nurses	43	42 (98%) successful; 1 (2%) unsuccessful			
2 large hospitals and 1 home infusion agency[3]	Infusion nurses	639	81.9% on one attempt	16.1% on two attempts	2% on three attempts	
	Generalist nurses	137	76.9% on one attempt	17.3% on two attempts	5.8% on three attempts	
Pediatric hospital[4]	In-patient medical-surgical staff nurses	249	53% on one attempt	14% on two attempts	24% within four attempts	9% more than four attempts
Large university-affiliated teaching hospital[5]	Staff nurses from in-patient medical, surgical, pediatrics, and intensive care units	371	Mean number of IV insertion attempts = 2.18, ranging from 1 to 14. 27% required 3 or more attempts 25% experienced treatment delays due to difficult access			

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Clinical and Administrative Issues of Vascular Access

Traditional methods to locate peripheral veins include distention, palpation, visualization, and knowledge of common vein anatomy. Recommendations focus on venous dilation techniques such as the appropriate use of tourniquets, fist clenching, tapping or milking the vein, application of warmth, and use of nitroglycerin ointment.[3-5] Peripheral arterial puncture depends on knowledge of common arterial anatomy and palpation for a pulse. Success rates for each of these procedures depend upon the skill of the operator and numerous patient related factors.

While studies reporting vascular peripheral success rates are limited, nevertheless, data from several studies reveal significant numbers of patients requiring more than one venipuncture attempt to establish access. (See Table 1.) One study reported that 9% of patients required more than four attempts[6], while another reported a mean number of 2.18 venipuncture attempts per patient.[7] A 1993 survey by the National Association of Children's Hospitals and Rehabilitation Institutions revealed that 44% of responding facilities permitted two insertion attempts for successful I.V. cannulation; 43% permited three or more attempts; and 13% had no restrictions allowing an unlimited number of attempts.[8] Another study conducted on arterial access in an in-patient pulmonary nursing unit reported 16 of 81 (19.75%) patients required more than one attempt.[9]

Reducing the number of puncture attempts reduces pain. The incidence of vasovagal reactions produced by the stress of venous cannulation increases with multiple attempts and prolonged duration of the procedure.[10]

Length of hospital stay can be directly impacted by the length of time required to administer the appropriate medication. In a study of patients with community-acquired pneumonia, the length of time from "door-to-needle" was assessed. The study did not delineate the reasons for the door-to-needle times but concluded that rapid delivery of appropriate antibiotics was associated with a shorter length of stay.[11]

Cost of multiple venipuncture attempts directly affects the financial viability of the facility. Capitated fee structures such as those in HMO's and Medicare, demand that excessive costs be eliminated. The operational cost for inserting a short peripheral catheter is reported to be $32.[12] Multiple attempts at venipuncture require more nursing time, multiple catheters and additional supplies for the procedure. Three attempts to establish a short peripheral I.V. catheter could cost the facility at least $96. These costs could drive the total patient expenditure beyond the amount of the capitated fee reimbursed to the facility.

Failure with peripheral venous access leaves several choices including continuing to attempt peripheral venipuncture by other staff members, insertion of a central venous catheter, or changing the route of therapy to oral or intramuscular. Indications for central venous access include the pH and osmolarity of the therapy and the anticipated length of therapy. CVC use due to failed peripheral access alone increases the risk of other catheter-related complications. Changing the route of therapy could greatly affect the patient's response to therapy.

While a desirable goal is to achieve all arterial and venous punctures on a single attempt, this is an unrealistic target due to many patient-related factors. The outcomes of 789 consultations requested of an infusion resource nurse program in a Canadian hospital found that more than half of the patient's visible veins were rated as poor or worse.[13]

Patients at Risk for Multiple Attempts

Challenges with venous access are frequently seen in patients with multiple diseases, the very young, geriatrics, patients with certain skin characteristics, dehydration, and patients with lengthy and frequent infusion therapies.

Chronic Disease or Medical Diagnosis

Chronic diseases, such as diabetes, end-stage renal, cancer, cardiovascular, HIV/AIDS, multiple sclerosis and hemophilia, among others, require multiple hospitalizations and thus multiple courses of intravenous treatments. (See Table 2.) Puncture disrupts the endothelial lining of the vein or artery exposing the basement membrane between the layers of the blood vessel. Blood in contact with the basement membrane causes immediate clotting. When the clot is no longer required for hemostasis, the fibrinolytic system destroys it, however scar tissue remains making the vein more difficult to access in the future.[14]

Table 2. Chronic Diseases with the Potential for Difficult Venous Access

Medical Diagnosis	Comments
Diabetes	13 million people in US; >40% are over the age of 65; projected to be 39 million by 2050[1]
End-stage renal disease	>400,000 people in US; projected to be 2.2 million by 2030 with diabetes as the most common cause[1]
Cancer	New cases >1.4 million in 2004[1]
Cardiovascular diseases	64 million people in US; most common cause of death[1]
HIV/AIDS	>877,000 Americans diagnosed through 2002 (81% being men[1])
Multiple sclerosis	>350,000 in US
Sickle cell disease	50,000 people in US with 20% experiencing 30 to 40 painful crises annually[2]
Hemophilia	18,000 Americans with 400 babies born annually with the disease[3]; only 6% of patients reported to have a long-term vascular access device, leaving short peripheral catheters as the most common catheter[4]
Cystic fibrosis	30,000 children and adults in U.S.; about 1,000 new cases diagnosed annually; 80% diagnosed by age 3 but 10% are 18 years or older[5]; a 2-week course of infusion would require more than 5 catheter insertion procedures[6]
Rheumatoid arthritis	2.1 millions Americans[7]
Crohn's disease, ulceratice coliltis and other irritable bowel disease	1 million Americans, primarily affecting adolescents and young adults between 15 and 35[8]
Obesity	20% of all Americans, 20% of children ages 6 to 11, and 30% of children ages 12 to 19[9, 10]
Drug abuse and addiction	601,776 drug-related emergency department visits in 2000[11]
COPD	About 1.5 million emergency department visits by adults 25 and older were made for COPD in 2000 [12]

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In renal failure patients, collagen fibers invade the smooth muscle cells and reduce the elasticity of the vein wall.[15] Diabetes and hypertension causes changes in the endothelial and smooth muscle cells resulting in vasoconstriction and hypercoagulability.[16] Vein wall thickening increases the difficulty of cannulation procedures.

In patients with and without chronic disease, dehydration from simple gastrointestinal problems can lead to serious difficulties accessing a vein simply because there is not enough circulating fluid to distend otherwise healthy veins.

Age-related Changes & Skin Characteristics

Anatomical and physiological changes occur in skin, subcutaneous tissue and blood vessels as we age. The skin looses moisture and resilience. Finger-like projections that anchor the epidermis to the dermis flatten causing the skin to easily shear with venipuncture and dressing application. Subcutaneous fat surrounding superficial veins diminishes, increasing the risk of I.V. infiltration. Superficial veins become small and fragile as all three vein layers change with age. There is more connective tissue and less muscle causing the aging veins to become less resilient and have more scaring than younger veins.[17]

Neonates have smaller and more fragile veins, making their veins more difficult to cannulate. Preterm neonates have an increased risk for stress due to an immature neurological system. Reducing the number of venipunctures needed to deliver infusion therapy decreases the noxious stimuli that alters respiratory and cardiac status.[18]

Infants have similar challenges with smaller veins. Toddlers and prepubescent children have the highest percentage of subcutaneous fat making veins more difficult to locate.[19] Older children easily become less cooperative with repeated venipuncture attempts.[20]

The aging process results in changes in the skin causing it to become more rigid and less flexible. Photoaging resulting from excessive exposure to sun creates similar changes in the skin, making venipuncture more difficult.[13] Patients with highly pigmented skin have veins that are more difficult to see.

Length and Frequency of Therapy

Infusion therapy may be required for several days, weeks, months or even years. Sporadic exacerbation of illness or planned courses of therapy may necessitate venipuncture and infusion therapy for a few hours or a few days. Patients with intermittent infusion needs may be unwilling to have a long-term vascular access device placed, preferring to rely on peripheral venipuncture for each course of therapy.

Nursing Staff Skill

Hospitals are now essentially large intensive care units because of the increasing numbers of patients with chronic diseases and the rapidly rising acuity of patients.[21] While the demand for qualified, skilled nurses is increasing, the supply is decreasing. In June 2001, the American Hospital Association reported that 126,000 nurses were needed to fill vacant positions. The U.S. Bureau of Labor Statistics reported in February 2004 that one million new and replacement nurses would be required by 2012.[22]

One aspect of hospital re-engineering over the past decade has been to disband I.V. teams, thus removing the most proficient nurses from the patient. The idea is that any nurse should be proficient at these infusion tasks. Productivity, efficiency, and organizational profitability directly flow from a high level of quality and reliability.[23] Press Ganey sites the disbanding of centralized I.V. teams as a major reason for their documented decline in patient satisfaction with venipuncture.[2] Numerous studies have demonstrated that I.V. teams reduce complications and improve quality. These studies have culminated in the highest recommendation from the Centers for Disease Control for all hospitals to have an I.V. team.[24]

The Infusion Nurses Society (INS) Standards of Practice clearly delineate the scope of infusion nursing practice and outline a specific course of study in infusion nursing.[25] The availability of such courses for registered nurses (RN) depends upon what may be offered by their employer; however, most hospital administrators expect new graduates to be capable of all job responsibilities when hired.[23]

Licensed practical/vocational nurses (LP/VN) in many states are required to take an I.V. therapy course before they assume responsibility for infusion therapy. Such courses are not mandated for registered nurses, even though they have had very little or no instruction about infusion therapy.

Many healthcare settings have tried to delegate responsibility for insertion of short peripheral catheters to unlicensed assistive personnel (UAP) implying that this task does not require advanced knowledge and skill. Delegating the task of inserting a short peripheral catheters to UAPs depends upon the policies established by each employer; however, this practice is not advisable. The task requires patient-specific judgments derived from nursing knowledge and skill not found in a UAP. The RN remains responsible for clinical outcomes of the patient.[26]

Infrared Imaging Technology

Until recently, it was believed that using infrared light (IR) to illuminate vascular structures would be no more successful than the use of visible illumination.[27,28] Given the strong evidence presented by leaders of the biomedical optics field that transillumination of tissue yields only diffuse or muddy images, no research was performed to investigate the utility of this technique. However, in 1994, several Air Force researchers discovered[29] to the contrary that it is indeed possible to transilluminate rather thick portions of human anatomy or to reflect from near surface anatomy with IR light. This significant invention is the basis of an Air Force patent that is being commercialized for clinical use.

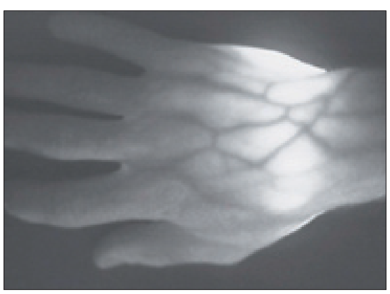

Figure 1. Transillumination of the hand.

Figure 2. Transillumination of the ante cubital fossa

The IRIS Vascular Viewer™, a unique system providing real time imaging, is the first product built upon this patented technology. It provides the practitioner with a precise and direct image of blood vessels. The clinician intuitively recognizes the veins, arteries, skin and catheter and uses the image to accurately guide the catheter into the exact vein. An example of the types of images that this technology provides is shown in Figures 1 & 2.

Principles of Operation

Components of the Vascular Viewer™ include the light or illumination source, the detector, and the display. The illumination source is a matrix of diodes emitting infrared light which is light we cannot see. The light source may be directed to the surface of the limb from a distance or applied directly. If applied directly, the light passes through the limb. If applied from a distance, it is reflected from the near surface back to the detector. These two modes of operation are transillumination and reflection, both of which generate images of vessels.

The IR light must be amplified and shifted in wavelength so that the operator may see the image. Once the IR light has made its way through the tissue or is reflected at the near surface, it travels in a straight line to the detector. Inside the detector, the IR light is converted into an electrical signal. The electrical signal is then converted to a visible image. This electronic wizardry is accomplished in a small cylindrical tube. The IR light enters at one end, and bright, high resolution, monochromatic images are seen at the other end in the eyepiece. Since this process is instantaneous, the operator sees a real time image of the subcutaneous vasculature.

As IR light travels through or is reflected from tissue, it is intensely scattered by many cellular components. Because hemoglobin absorbs some of this light more strongly than the surrounding tissue, the operator sees its presence as dark lines (Figures 1 & 2) contrasted against the surrounding tissue. The depths at which images can be clearly seen are dependent upon the amount of light emitted by the light source, the scattering of the light by overlying tissue, and the extraneous IR light that may be present. Fluorescent lighting at normal levels does not interfere with imaging; therefore, the Vascular Viewer™ may be utilized in typical hospital and other clinical settings.

Skin color has no affect on imaging. Bone, cartilage, tendon, adipose tissue and to a large extent muscle are translucent and therefore are not visible. Blood in subcutaneous spaces however is easily seen, and this aids in the detection of vein trauma and infiltration. Additionally, vessels in extremities with reduced blood flow can be seen. Moreover, infusates that infiltrate or extravasate can be detected as bright contrasts against the surrounding vessels and tissue. Consequently, the monitoring of I.V. sites can be performed readily.

Direct transillumination is not required to achieve a useful image. The operator may choose to illuminate at nearly any angle from where an image is desired. For instance, vessels near the dorsal surface of the forearm could be seen by placing the light source on the medial or lateral side of the arm.

Other Imaging Technology

There have been many attempts to use light to illuminate the vascular network as an aid to various diagnostic and infusion procedures.[18, 30-33] Currently there are several visible light technologies on the market to aid in the cannulation of both pediatric and adult patients (e.g., Venoscope®[34], Pediascan, & VeinLite). Other available devices use sound to create an image of the vascular structure being accessed. Table 3 compares many characteristics of IR, visible light, and ultrasound.

Table 3. Comparison of Bedside Vascular Imaging Devices

Advantages	Vascular Viewer™	Visible Light Devices	Ultrasound
Real-time image	Yes	Yes	Yes
Intuitive imaging, easy to recognize vessels	Yes	Yes	No
Hands-free operation	Yes	No	Depends on brand
Precise image	Yes	No	Depends on skill of operator
Use in typical lighting in healthcare settings	Yes	No	Yes
Traditional venipuncture procedure	Yes	No	No
Less experience required for successful use	Yes	No	No
Short learning curve to master the device	Yes	No	No
VAD visible outside patient	Yes	Yes	No
VAD visible inside vessel	Yes	No	Yes
Simple, rapid setup	Yes	Yes	No
Superficial vein visualization	Yes	Yes	No
Deeper vein visualization	Yes	No	Yes
Artery visualization	Yes	No	Yes
Cost	$15,000	$300 to $600	>$15,000

Clinical Applications of the Vascular Viewer™

The IRIS Vascular Viewer™ can be used for vein and arterial puncture and catheter insertion. The actual location of the vein is seen through the eyepiece, so that the operator is looking at a real-time image.

During 2004, a randomized study of arterial punctures in the emergency department of a large teaching medical center compared the Vascular Viewer to traditional blind technique. The study group had more than 40% fewer punctures and corresponding reductions in supplies and procedure time.[35]

Table 4. Peripheral Arterial Access for ABG analysis using the Vascular Viewer™

	Group Mean Values		
	Control Group using traditional methods (n=28)	Study Group using Vascular Viewer (n=30)	p Value
Procedure time	16 minutes	8.73 minutes	0.001
Skin sticks	2.93	1.70	0.000
Arterial sites used	1.43	1.10	0.004
ABG kits used	1.71	1.14	0.001

Benefits of the Vascular Viewer™

The Vascular Viewer™ quickly reveals the precise location and orientation of veins and arteries in a real-time image. Bifurcations, venous valves, and vasospasm are also visible. The image shows the close proximity of other veins or arteries to prevent unintended puncture of additional vessels. The light source can be moved until the best site is found, then secured into place for the procedure. A disposable cover separates the light source from the patient's skin to enable infection control measures.

The Vascular Viewer™ allows for hands-free viewing. The operator can see the catheter, the skin surface and the intended vein. The Vascular Viewer™ permits the use of standard I.V. insertion technique. Once inside the vein, the catheter can be seen along with any extravascular blood or fluid that may indicate an unsuccessful cannulation. After cannulation, the Vascular Viewer™ easily moves out of the field so that the site can be secured and dressed.

Learning to use the Vascular Viewer™ is easier than other imaging technology. During initial studies, many nurses have immediate success while others have required five or six procedures to feel comfortable with the device. Nurses that have been concerned about attempting venipuncture on patients with difficult veins may no longer have to wait on a more skillful colleague. Faster, more successful venous and arterial cannulation means more satisfied patients, better clinical outcomes and reduced costs.

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