Development and clinical trial of a practical vessel imaging system for vessel punctures in children

Natascha J. Cuper, Rudolf M. Verdaasdonk, Rowland de Roode and Erica Septer
Dept. of Medical Technology & Clinical Physics and Clinical Haematological Laboratory
University Medical Center Utrecht, PO Box 85500, 3508 GA, Utrecht, The Netherlands
Correspondence: n.j.cuper@umcutrecht.nl

ABSTRACT
Venipunctures to draw blood for diagnostics can be cumbersome. Multiple puncture attempts are distressing, painful and traumatic, especially for small children. Drawing blood from babies, in particular, is a problem, due to the cutaneous baby fat, tiny veins and, worst case, a pigmented skin. We developed a practical vein viewing system based on IR transillumination that, contrary to commercial systems available, has the advantage of: a) low cost, b) easily implemented in routine practice, c) normal and IR image simultaneously available, d) small add-on, e) child friendly IR illuminator and f) efficient IR light coupling. Before introducing the vessel viewer for clinical application in the children’s department, parameters were measured in 194 patients (age 0-17 yrs): time to draw blood, number of attempts, skin characteristics, discomfort of patient, and experience of nurse. In this control group, time to draw blood increases significantly with decreasing age of the children. The instant feedback from the nurses has been valuable for the improvements of especially the illumination sources. A clinical trial has been performed in 125 patients (age 0-6 yrs) to prove effectivity of the system in the blood withdrawal procedure. There was a significant decrease from 13% to 2% in failure rate. Also time needed to search for a vein was significantly decreased. A practical and accessible vein viewing system has been developed and is being introduced for clinical application. Although the concept of patient friendliness is already accepted, measurements need to show the effectiveness for particular groups of patients.

Keywords: near-infrared, vessel imaging, vein, venipuncture, arterial lines, blood withdrawal, venous access, children

1. INTRODUCTION
Gaining access to a blood vessel is one of the most frequently performed procedures in the hospitals. It is experienced by patients as an uncomfortable and painful procedure and can be traumatic especially for children. Usually, blood drawing is performed to get insight in the patient’s health status. By means of a blood sample, a proper diagnosis can be set. Additionally, access to a blood vessel is needed for various purposes: intravenous sheet placement for administration of fluids and medication, and arterial sheet placement
for obtaining information about the patient’s status (e.g. blood pressure) during surgery. In some cases, gaining access can be quite difficult. The technician/nurse performing the procedure will have to be able to palpate (feel) the vessel or see it through the skin; otherwise a blind stick will be necessary, often with poor result. Patient features known to complicate the procedure are the presence of subdermal fat and/or tiny veins. Those features are especially seen in young children between 1 to 3 years. When a child has a dark skin, this will complicate the situation even more, because of the low contrast between blood vessels and skin color. In this situation, various puncture attempts are needed in combination with the assistance of more experienced personnel such as the anesthesiologists. Additionally, advanced techniques like ultrasound guidance can be applied. Sometimes it is necessary to fall back on more invasive procedures to gain venous or arterial access (especially in life-threatening issues as occurring on the ER) or to use other methods, with variable results. There are some complications that can occur during a venipuncture or arterial puncture procedure. The probability of complications increases with every extra puncture that is necessary. Complications associated with vessel puncture are bruising, phlebitis, infection, infiltration and in rare cases nerve injury by puncturing. In case of arterial lines placing before surgery, with the patient already under anesthesia, there is also the risk of complications due to longer anesthesia time when the procedure takes more time. Motivation and requirements for a practical vessel puncture system

Motivated by personal experience of one of the authors, a device was developed to make the procedure of blood drawing/vessel puncture more reliable and practical: a) fast identification of an optimal puncture position, b) successful blood drawing/vessel access at first attempt, c) minimize time of needle manipulation in the skin. Furthermore, the system has easy in use and well accepted: d) low cost, e) compact, f) minimal interference with daily practice, g) useful add-on for standard procedure h) easy to use. A system meeting these requirements is described in this paper with the first experience in clinical practice. DKMP BV de inspectie heeft uitgevoerd en het apparaat terug kan sturen.

2. DEVELOPMENT OF A VESSEL VIEWING SYSTEM

The vessel viewing system has been developed by the dept. of Clinical Physics of the University Medical Center of Utrecht (UMCU). It consists of a compact infrared sensitive CCD camera with SVHS resolution with a zoom lens. An infrared filter is used to block all visible light below 850 nm. The camera is attached to the back of an 8 inch LCD monitor and supported by articulated arm that can easily be clamped onto any surface. The IR light source consists of 1 W power LEDs of 850 nm. The LEDs are attached to a neoprene bandage which can be wrapped around the arm of the patient and provide a good contact with the skin for optimal light transfer. The neoprene bandage has an opening on the puncture side and shields light outside the region of interest. Depending of the thickness of the body part, one or more LEDs are used. For transillumination of the hand, the illuminator can optionally be packed in a small animal figure like a frog to make it more child friendly during clinical application (fig. 2). The power of the LEDs can be varied and is limited to prevent too high temperatures during skin contact. The transilluminated near-infrared light scatters through the skin and is absorbed by blood vessels. The infrared light that passes through is captured by the camera. The resulting real-time image is presented on the LCD monitor that is placed at an ergonomically position for the nurse. This way, the use of the system does not interfere with the normal routine/procedure of blood drawing and the nurse can use the system as diagnostic tool for guidance but can instantly fall back on her/his normal vision.
In figure 1, a schematic view of the system is presented. Figure 2 illustrates the UMCU vessel viewing system in clinical action during a blood withdrawal in a child with a dark skin color. Vessel viewing systems have also been developed and commercialized by others\textsuperscript{6,7}. However, the UMCU vessel viewing system distinguishes itself from other systems in various areas: practical use, low cost, compact, suitable for various applications and it does minimally interfere with the standard procedure of vessel puncture (patent pending).

3 BACKGROUND AND FEASIBILITY STUDIES

3.1 The optimal wavelength for visualization of blood vessels in the near IR

Near infrared light is well known for its properties of deep tissue penetration. Due to its longer wavelength, scattering is minimized and absorption by chromophores in skin, such as melanin, is decreased. Lower scattering and absorption enable near infrared to travel several centimeters through tissue before being absorbed. Absorption by blood is also decreased, but relatively less compared to other chromophores in the skin. The combination of those two properties, i.e. low scattering and a difference in absorption between blood and surrounding tissue, enables to use near-infrared light to visualize blood vessels underneath the skin. In figure 3, the optical density (OD) is shown of a standard subsurface vein compared to optical density of epidermis of different skin types. Since the epidermis is thin, scattering can be ignored and the optical path length is assumed to be comparable with the actual thickness of the epidermis. This can be expressed in the following equation:

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OD = \frac{R_1}{\ln 10}
\]

\( \mu_a = \text{absorption (cm}^{-1}) \)

\( l = \text{thickness of epidermis or path length (cm)} \)
3.2 Estimation of depth range for vessel visualization

Although near infrared light is able to penetrate tissue for several centimeters, only vessels up to a certain depth are visible. Due to scattering, the image of vessels located deeper is blurred and ‘erased’ as calculated by Sharp et al.\textsuperscript{10} To gain more insight in the maximum depth that could be reached with our system, a study was performed in a tissue phantom to determine up to which depth an artificial vessel could be discriminated. The phantom was based on a bath of Intralipid 20%. To obtain a scattering coefficient $\mu_s (1-g)$ comparable to tissue (i.e. 1 mm$^{-1}$), the Intralipid 20% was diluted into 18 parts of distilled water, according to literature\textsuperscript{11}. Two “blood vessels” were made of infrared absorbing material (black neoprene) with a thickness of 2 mm and a thickness of 5 mm, respectively, to simulate a vein and an artery. The “blood vessels” were submerged in a container with a 2 cm layer of Intralipid underneath to provide a sufficient scattering layer creating a diffuse background from the IR LED light source positioned at the bottom of the container. On top of the “blood vessels”, layers of Intralipid were added with steps of 1 mm Intralipid and images were registered with the viewing system from the top. In figure 5, a sequence of images is presented with an increasing Intralipid layer up to 20 mm. In the visible spectrum (naked eye view), the “blood vessels” were not visible anymore at 5 mm. Using the UMCU vessel viewing system, the 2 mm vessel was hardly visible at 9 mm. The bigger 5 mm vessel was visible enough to perform a guided puncture up to 15 mm. At a depth of 19 mm, no vessel could be discriminated anymore. In this model, absorption was not taken into consideration, for the test was about the maximum depth to which a vessel was be visible depending on diffused scattering in tissue, assuming the infrared light intense enough to penetrate the tissue. In clinical practice, the tissues will be perfused by the microvasculature with blood.
cells. This will decrease the overall contrast. Taken this into account, it can be assumed that veins can be discriminated up to 5 mm and arteries up to 10 mm depending on the diameter. This range should be sufficient in clinical practice to reach most puncture sites of interest. However, the diameter and blood filling vessel is of major influence.

3.3 Practical feasibility testing for imaging vessels

The UMCU vessel viewing system was tested for imaging a large range of locations of the human body on volunteers of different ages, skin types and subcutaneous fat content. The images were capture in real time from the camera. It must be expressed there has been no enhancement on the images presented in the figures: the same resolution/contrast can be seen on the LCD screen.

Figures 6 and 7 show transillumination of the hand and the wrist: the branches of superficial veins in the hand become clearly visible. In the wrist, the arteries can be perceived as more diffuse dark lines in the depth. Because the arteries are situated deeper, the edges look hazier than the edges of the superficial veins due to scattering. In the real time image, pulsation can even be observed. Figure 8 shows transillumination of a hand prepared with Iodine used to disinfect the skin before surgery. In visible light, the yellow color of Iodine makes visualization of veins difficult, however, the IR view is not influenced and shows the vessels clearly. Using transillumination on the fingers, the small capillary vessels become visible as illustrated in figure 9. One preferred position for vessel puncture to obtain larger quantities of blood is the inner elbow (antecubital fossa). This position is much thicker and the presence of bone structures makes transillumination more difficult. However, using a special design of light applicator, the light can scatter around the bone with sufficient intensity to visualize the arteries in both children and adults. Figure 10 shows the vessel in the antecubital fossa in a child and figure 11 shows of the same position in an adult.
Figure 6. Superficial veins in the hand
Figure 7. Superficial veins and the arteria radialis and ulnaris in the wrist
Figure 8. Veins in a hand disinfected with Iodin
Figure 9. Capillary vessels becoming visible in the fingers
Figure 10. Veins in the antecubital fossa of a 6 year old child
Figure 11. Veins in the antecubital fossa of an adult
4. CLINICAL STUDY
To determine effectiveness of the system in the clinical situation, a study was performed applying the system during the procedure of blood withdrawal in children. The study population consisted of patients attending the Wilhelmina Children’s Hospital and had to undergo a blood withdrawal for diagnostics. For reference, a preliminary study (n = 194) was performed during venipunctures to obtain statistically validated numbers of the parameters of interest e.g.: time to identify the puncture position, time of needle penetration, time to obtain blood, number of puncture failures. In children from 0 to 17 years of age (mean 8.1 ± 5.0), it was found that the failure rate (i.e. the rate one puncture did not lead to the appearance of blood in the tube) of the procedure decreases with age. In children of 6 years old and younger, the average failure rate is 12.5%. In children over 6 years old, the average failure rate is 3%. There was correlation between presence of sub dermal fat and failure rate. Due to the higher failure rate, this study focused on children in the age range of 0 to 6 years old (2.75, ± 2.1). The population size n consisted of 80 controls and 45 cases. Controls were defined as the children undergoing a blood withdrawal without help of the system. Cases were the children undergoing the procedure with help of the system.

The standard procedure of blood withdrawal from a vein takes places as follows: the nurse applies a tourniquet around an arm or wrist of the patient. The arm or hand is then searched for a suitable vein by palpation and looking. A vein that is palpable (with or without being visible) is mostly preferred above a vein that is only visible. If nothing is palpable or visible, a “blind stick” is necessary, performed by knowledge about anatomy. This is very difficult, for vessel anatomy can differ a lot between individuals. After two non-successful punctures, a more experienced nurse/technician is called in or a physician is contacted. The preferred site for a venipuncture is in the antecubital fossa (the inside of the elbow), for this spot is less painful and often has bigger veins. If no vein is palpated there, the hand is searched for veins. Those veins are often quite thin and the spot is more painful. In this age category of patients, often an assistant is used to hold the arm or hand of the patient. The blood is collected with a vacuum system, in which a tube is attached to the needle via a vacutainer[tm] system. Sometimes an open system is used, in which blood drips from the needle into the tube. The only difference in the procedure between the cases and the controls is the use of the system. The system is placed in a way not hindering the nurse in his or her working manner. The screen with the image of the veins and the limb of the patient itself are both visible at the same time. The nurse can use the system the way he or she wants and can choose which LED holder to use (a band strapped around the arm with use of the puncture hole or having an assistant to hold the LEDs underneath the patient’s limb).

Firstly, data without use of the system was collected. After this, data was collected with the system in use. To obtain a random population, every incoming patient at the laboratory within the right age category was selected for the study in both cases and controls. This was the closest approach to a random population as possible in the clinical situation. With the system in use, parents of the child were asked for their consent to cooperate with the study. The fact that the procedure of venipuncture as usual is not changed with the use of the system was explained. The nurses in the study are all trained and skilled in the venipuncture procedure with children. One important parameter of the study was the failure rate. For every case and control, it was registered if at the first puncture blood flows into the tube. Every time more than one puncture was necessary was considered a failure. A second important parameter was the time the needle was underneath the skin, while searching for the vein. This is the most painful action during the procedure. It is expected that this time will decrease with the system in use. Other parameters registered were age, skin color (light,
Mediterranean and dark), body fat (normal, chubby, baby fat). Stress endured by the child is noted, being normal, tense/ light stress and very stressed/ wrestling, before, during and after the procedure. The measurements are registered by an observer present at the procedure without an active role. The age distribution in the study population was described by mean and standard deviation. The failure rate among cases and controls was statistically weighed by means of a one-tailed z-test. A one-tailed test was applied since it was not expected that the procedure with the viewing system would take longer or have a higher failure rate, due to the fact the normal procedure was not changed with the system in use.

The time needed to search for a vein was not normally distributed and therefore described with median and interquartile range. The difference is statistically weighed by means of a one-tailed Wilcoxon W test. Next to this, the searching time was divided in groups below and above 15 seconds because normally an easy puncture procedure should take no longer than 15 seconds. This the time is longer than 15 seconds, it can be assumed that the discomfort and pain of the presence of the needle moving underneath the skin would increase substantially. A one-tailed z-test was applied to compare the difference between the two groups. The p-value should be below 0.05 to conclude the difference is significant.

5. RESULTS
The study population consisted of 80 controls, age 0-6 years (mean 3.1 ± 2.0), and 45 cases, age 0-6 years (mean 2.2 ± 2.1) attending the Clinical Laboratory to have blood withdrawal performed. The only difference between cases and controls was the use of the system while performing the blood withdrawal. The failure rate among controls (10 controls, 12.5%) and cases (1 case, 2.2%) shows a significant difference with a p-value of 0.026. There was also a significant difference between time in seconds needed to search for the vein among cases (median 1 ± 3) and controls (median 2 ± 9) with a p-value of 0.034 Figure 12 shows the box plot of the distribution of searching time among cases and controls. As one can see, there are many outliers and the data is not normally distributed. In the control group, there are a lot of outliers in the upper range, compared to the case group. When we divide the data of searching time in two groups (above and below 15 seconds), there is a significant difference in the number of controls (17) and cases (3) with a searching time above 15 seconds with a p-value of 0.016. The system was able to visualize veins in all cases. In ten cases were no palpable or visible veins could be detected, the system was still able to visualize the veins successfully. Since the study population was of relative young age, many patients (65/80 controls and 40/45 cases) had still some amount of baby fat. Therefore, no statistical conclusions can be drawn for the presence of baby fat on failure rate. Although there seemed to be an association between having a dark skin and failure rate among controls, the amount of dark-skinned patients in the study group (7/80 controls and 2/45 cases) was too small to draw statistical conclusions. The system was also used on special request of the nurses for patients not included in the study population. This occurred in 11 patients, age varying from 0 to 2 years old and one of 11 years old (mean 1.6 ± 3.2). The group of patients was notorious of being ‘difficult to puncture’, where the nurse was not able to find a vein by sight or palpation. In 3 of those cases (27.3%), the procedure failed even with the viewing system. However, in the other 8 patients the procedure was expected to have failed without the use of the viewing system.
6. DISCUSSION

The first clinical testing to prove the effectiveness of the vessel viewing system developed in our hospital show promising results. Although, everybody has an intuitive feeling that the vessel viewing system will improve the blood vessel puncture procedure, clinical studies have to performed to obtain objective statistically significant data. Indeed a significant difference in failure rate was found, with a decrease of 13 to only 2% when using the our viewing system. The statistical strength can be improved with increasing number of patients included in the study especially for the other parameters registered. It also has to be considered that the study is performed in a specialized children’s hospital were the nurses performing the procedure are highly experienced venipunctures in children. It can be expected that for nurses/technicians with less experience on venipunctures in children, the difference between cases and controls will be larger.

It was also important to observe that the UMCU vessel viewing system was easily accepted by the nurses/technicians working with the system. This can be illustrated with the special requests for the viewing system: they were prepared to wait for arrival of the viewing system for about 15 minutes before a puncture attempt. The viewing system was found to be easy to handle and the learning curve was short. In none of the cases, the system was found to interfere or complicate the procedure, even when the child was considered to be easy to puncture since the vein was visible by eye. The system was able to visualize veins successfully in 10 cases with no palpable or visible veins and in those cases, the technicians often reported the procedure would probably have failed without the system. Next to those cases, there were also cases where the vein was only slightly palpable and the system was able to give more information about the size and orientation of the vein. This was most often the case in very young children with a lot of baby fat and tiny veins. In every case, the system was able to provide confirmation, even if a vein was palpated. From the patient’s perspective (and parents) it is an enormous advantage that the blood draw procedure is less traumatic in view of less pain, less stress and short procedure time. Especially, for child-
ren who need to be punctured for blood drawing structurally, could easily development fear of needles and struggle during the next procedure making it even more difficult. It was observed that the use of the vessel imaging system distracted the children undergoing the procedure and they felt less uncomfortable. There are many other fields where application of the UMCU vessel imaging system can be helpful. Various small feasibility studies have already started: e.g. placement of intravenous sheets. This procedure is considered to be more difficult and painful than a venipuncture, and can also be difficult in adults. Especially, patients with a history such as rheumatic illness, diabetes or chemotherapy are known to be difficult to puncture. Visualization for vascular abnormalities can be very useful for example for placing lower arm shunts in dialysis patients (dilatations or stenosis). The imaging system can be useful in vessel surgery, e.g. for placing shunts or removing of varicose veins. It has potentials for diagnosis and evaluation of the effectiveness of particular therapies: e.g. the presence and growth of the capillaries in fingers and toes after stem cell therapy in diabetes patients can be examined. Recently, a new study has been started for the placement of arterial sheets. Arterial lines are often placed preliminary to surgeries and are mostly applied at the arteries in the wrist. In small children (i.e. 0-3 years of age) this can be difficult due to the amount of sub dermal fat and tiny arteries. Since the child is already under anesthesia, time loss should be reduced as much as possible in view of complications. Also from a financial perspective the viewing system is promising. Expensive OR time loss can be prevented in complex arterial placing using the vessel imaging system. The UMCU vessel imaging system is already used successfully and the anesthesiologists are eager to work with the vessel viewing system routinely.

7. CONCLUSIONS
The effectiveness of the UMCU vessel viewing system in the clinical situation was proven statically significant in young children undergoing blood withdrawal procedures. The system can be of great help to reduce pain and trauma and in lowering the chance of complications. The practical usability and benefits are well appreciated by the nurses working with the viewing system. The field of applications will be further expanded supported with clinical feasibility studies.

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