Vein Imaging: A New Method of Near Infrared Imaging, Where a Processed Image Is Projected onto the Skin for the Enhancement of Vein Treatment

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BACKGROUND A new noninvasive vein imaging device initially developed for phlebotomy has been tested for the first time for vein treatment. This unique device captures a near infrared vein image, processes it, and projects it onto the skin using green light.

OBJECTIVE To perform the first clinical tests of the device in phlebology.

METHODS AND MATERIALS A pilot study on 23 subjects with varicose veins and telangiectasias was performed. The VeinViewer prototype (V-V-P; Luminetx Corp., Memphis, TN) was tested in five situations: diagnosing feeder veins with the V-V-P, comparison between the V-V-P and ultrasound, marking varicose veins with or without the device, phlebectomy using the V-V-P, and the use of laser and sclerotherapy guided by the V-V-P.

RESULTS One hundred percent of subjects had feeder veins identified by the V-V-P. The ultrasound machine detected fewer feeder veins than the V-V-P, and the device identified more veins than the naked eye in all subjects. The V-V-P could help in finding feeder veins during phlebectomy and in guiding laser and sclerotherapy treatments.

CONCLUSIONS The device could identify veins that were invisible to the naked eye and too shallow for ultrasound detection. The V-V-P may help find feeder veins and may also help various types of vein treatments.

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Locating veins is critical for the treatment of varicose veins and telangiectasias. A subcutaneous vein that is invisible to the naked eye can be made easily discernible by the infrared imaging technology used in a new invention, the Luminetx VeinViewer (V-V; Luminetx Corp., Memphis, TN), which projects an enhanced image of subcutaneous veins onto the subject's skin.[1] The idea of a projector system that would acquire an image of an object and project an enhanced version of it back onto the object was conceived at the University of Tennessee Health Science Center, Department of Biomedical Engineering.[2]

The V-V operates by illuminating the subject's skin with near infrared (NIR) light. This NIR light penetrates skin and subcutaneous fat effectively because of the low absorption of these tissues in the NIR-wavelength range. NIR light is absorbed or scattered in the forward direction by blood, whereas it is scattered in all directions in skin and subcutaneous fat. Hence, blood reproduces as dark, whereas skin and fat appear lighter. The image reflected back from the subject is detected with a video camera. An IR filter prevents any visible light from reaching the video camera. The resulting NIR image is processed by a computer and then projected back onto the

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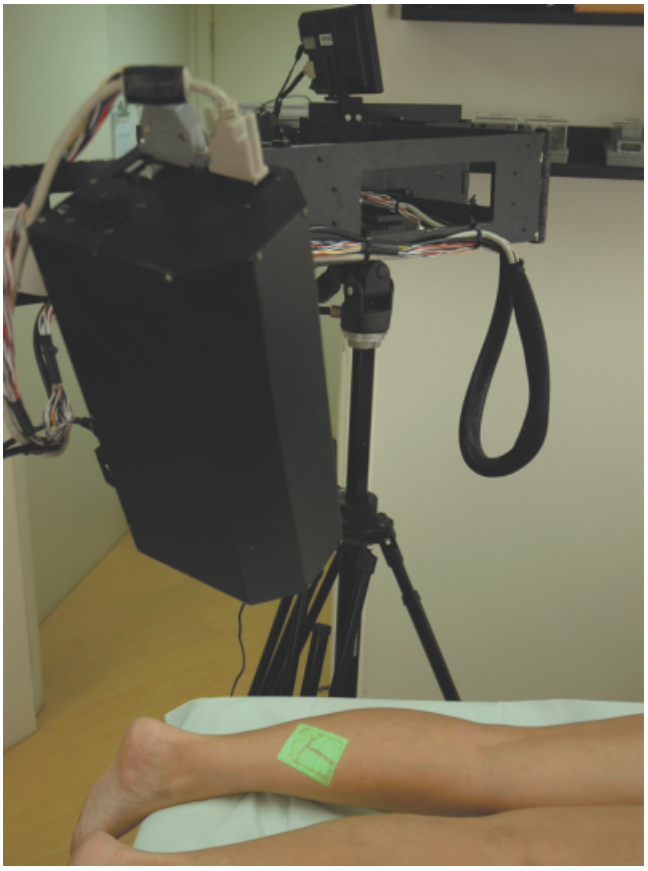

Figure 1. A photo of the VeinViewer prototype.

subject's skin with a projector using green light (Figure 1).

The system is designed to maintain a constant contrast over the entire image. Hence, low-contrast objects are highly enhanced, whereas higher contrast ones are less so. The software allows image processing to be performed at the full video imaging rate. The green projector light is effectively removed by the IR filter on the camera, preventing feedback in the imaging system. An easy calibration procedure ensures the correct alignment of the projected image on top of the subject's anatomy. The V-V prototype (V-V-P) used in this study was developed in 2004 for blood collection and intravenous (IV) fluid administration, and the objective of this study was to determine whether it could help in the diagnosis and marking of feeder veins and supplement the existing methods used to treat them.

According to Redisch and Pelzer,[3] telangiectasias can be subdivided into four classifications based on their macroscopic aspect, namely, simple or linear, arborizing, spider, and papular. In addition, they can also be classified according to the presence or absence of a feeder vein (a vein with damaged valves that allows blood reflux into a smaller vein causing dilatation). For combined telangiectasias (CT) one or more feeder veins are present. For simple telangiectasias (ST), no feeder vein is present.[4] The CT are located on the dermis and have feeder veins with damaged valves with reflux. These veins can be connected to the superficial and/or the deep venous system. Lack of such a connection characterizes the lesion as an ST, no matter what its appearance may be.[5,6] Although both varicose veins and telangiectasias requiring treatment are clearly visible to the naked eye, feeder veins are often not apparent. The use of a device that enhances the ability to find feeder veins not visible to the naked eye may improve the treatment of telangiectasias.

The objective of this study is to evaluate the V-V-P on various vein treatment situations during diagnosis and treatment.

Materials and Methods

The V-V-P was brought to Brazil in May 2005. It was attached to a counterbalanced telescoping arm developed for research purposes. The telescoping arm was mounted on a tripod. Vertical positioning of the V-V-P was accomplished by raising and lowering the tripod using a built-in handle until the projection and camera lenses were in focus. Twenty-three consecutive subjects (the equipment was available for 1 week) with telangiectasias that did not respond

to laser and or sclerotherapy treatment were selected. Subjects with saphenous vein insufficiency and symptoms such as pain and/or edema were excluded from this study. Standard informed consent procedures were followed at all times. The study protocol conformed to the guidelines of the 1975 Declaration of Helsinki and was approved by our institutional review board. Documentation was done with digital photographs, as well as video filming both with and without the V-V-P, before the beginning of treatment.

The study was divided into five analyses: (1) diagnosing CT with the V-V-P (23 subjects); (2) comparison between the V-V-P and ultrasound (U-S; 2 subjects); (3) marking feeder veins with or without the V-V-P (7 subjects); (4) phlebectomy of feeder veins using the V-V-P (7 subjects); and (5) laser and sclerotherapy with skin cooling guided by the V-V-P [Quantum DL (Lumenis, Inc., New York, NY) 1,064-nm long-pulse laser treatments immediately followed by sclerotherapy, both techniques used with a cooler (Cryo5, Zimmer Elektromedizin, Neu-Ulm, Germany)[7] that uses a high-velocity stream of cold air to numb the skin; 15 subjects].

Diagnosing CT with the V-V-P

Subjects were initially placed in dorsal decubitus and moved if necessary. The V-V-P was placed at the appropriate focal distance from the projector lens to the skin. The equipment head was placed perpendicular to the skin surface to maximize performance.

Comparison between V-V-P and U-S

A comparison was performed between the V-V-P and two types of U-S machines, one portable (Pico, Medison, Sao Paulo, Brazil) and the other high resolution (Accuvix, Medison). First, subjects had their veins marked with ink dots using the V-V-P, and over each dot, U-S images were acquired. If the U-S was capable of detecting a vein, this mark was considered positive for U-S scanning. Positive and negative marks (where U-S detected no vein) were compared. The depth and diameter of feeder veins were measured with the U-S. Veins were also measured after removal.

Marking Veins with or without the V-V-P

Usually, feeder veins are marked before surgery with dots or dashes along their visible course (Figures 2 and 3). The ink usually used to indicate veins ("marks anything" style that is resistant to antiseptic) was found to alter the V-V-P images in preliminary tests before the beginning of the pilot study. Other markers were tested, and a thin-point black one that was soluble in alcohol was used. After veins were marked, the V-V-P was turned off, and other marks resistant to the antiseptic were put over the previous ones.

To improve the naked-eye view, many recommend using a combination of incandescent light, fluorescent light, and light from the sun (it is preferable to have large windows and schedule the procedure near noon). In contrast, use of the V-V-P requires less light to enhance the green image projected onto the skin (Figure 2). The number of marks without the V-V-P was counted. The machine was then turned on and veins were remarked. The number of marks before and after V-V-P use were compared.

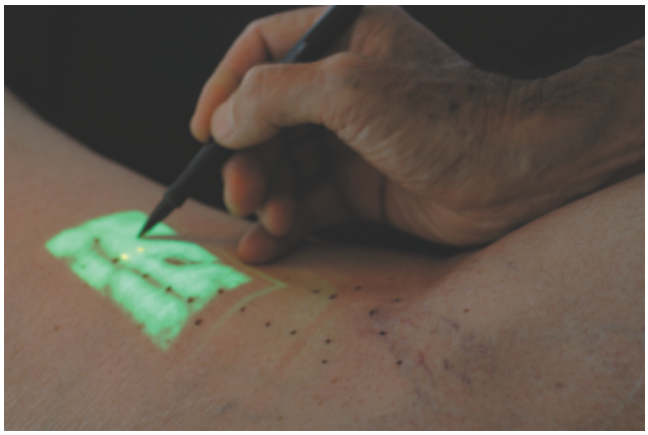

Figure 2. Detecting and marking feeder veins with the VeinViewer prototype.

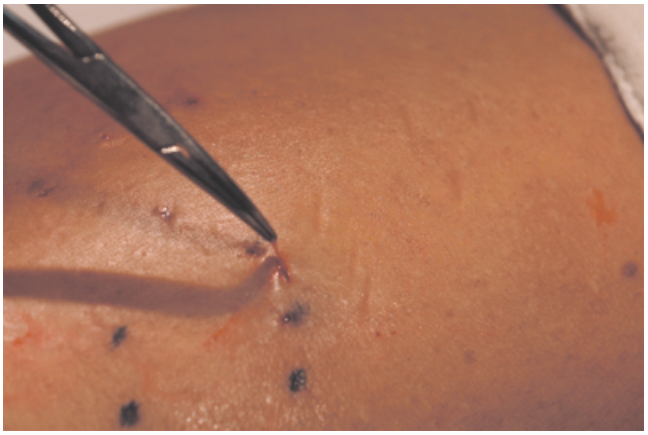

Figure 3. Phlebectomy of a feeder vein.

Phlebectomy of the Feeder Veins Using the V-V-P

Procedures were performed in the standard manner[2,4] with the subject in a decubitus position and with antisepsis, placement of sterile surgical drapes, and anesthetic infiltration (2% lidocaine) performed. A local anesthesia technique device [The Wand (Milestone Scientific, Livingston, NJ)] was used, the same that we have been using the past 3 years. A future study testing the tumescent anesthesia is advisable. No IV sedation was used. After anesthesia, removal of feeder veins was initiated through successive mini-incisions employing a 40/12 needle, a No. 12 crochet hook for searching and catching, and delicate nippers (Figure 3). All the marked veins were laid on a table, an assistant measured the approximate vein size using a pachymeter, and the number of marks where the surgeon could not find a vein were counted. After that, sclerotherapy was performed to treat the telangiectasias and to test whether the veins were disconnected. The sclerosant solution used for all cases was 75% hypertonic dextrose. During sclerotherapy, lack of profuse leakage indicated a negative disconnection test. In this situation, the V-V-P was again employed in an attempt to find the remaining veins. Use of the V-V-P as a guide to finding veins was also analyzed.

Laser and Sclerotherapy Guided by the V-V-P

Some subjects seen during the V-V-P's pilot study week could not be scheduled for surgery due to the short period of time and so were treated with the less invasive method of laser and sclerotherapy guided by the V-V-P. Results were analyzed by comparing before and after photos, as well as by soliciting subject opinions. The sclerosant used was one of the most used in Brazil: 75% hypertonic dextrose. It is similar to the IV solutions commonly used at hospitals (5% and 25% but in a higher concentration).

Results

None of the subjects incurred an infection, and none showed any signs of being affected by the V-V-P. Physicians were able to identify feeder and varicose veins easily, with normal, dimmed, or no illumination in the room.

Diagnosing CT with the V-V-P

All 23 subjects were submitted to diagnosing CT with V-V-P. No subjects were excluded from the study because of failure to find feeder veins with the V-V-P. Photos taken with and without the V-V-P documented the presence and location of these veins (Figures 4 and 5). It was found that the V-V-P could also show the refilling process after decompression of CT in all of them. Physicians and subjects were able to see and discuss the treatment.

Comparison between the V-V-P and U-S

A total of 75 marks were made by the V-V-P in two subjects. Of these 75 marks, 13 (17%) were also visualized by high-resolution U-S, and 9 (13%) by portable U-S, when placed over the marks. The deepest vein identified by the V-V-P was 0.8 mm in diameter and 7.8 mm deep. The V-V-P continued to visualize increasingly tiny veins until one 0.2 mm in diameter and 8.2 mm deep could not be identified. The smallest vein detected by the U-S measured 0.4 mm, and it could not find those shallower

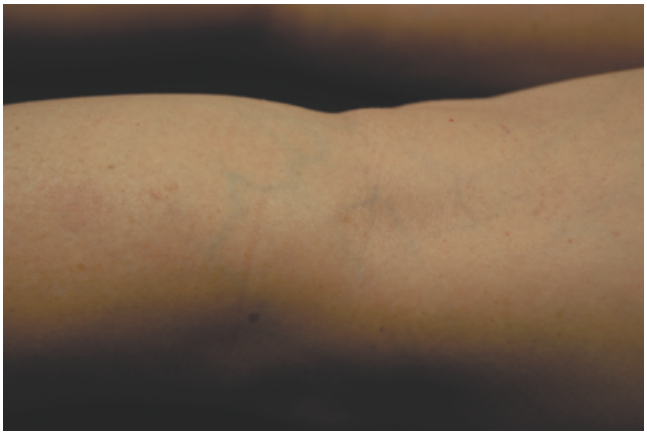

Figure 4. Combined telangiectasias. Appearance before treatment, photographed with the VeinViewer prototype turned off.

than 2.7 mm.These were of course easily visualized by the V-V-P.

Marking Veins with or without the V-V-P

Seven subjects who were scheduled for phlebectomy were marked with the naked eye. Adding them all, 103 marks were made. Employing the V-V-P, an additional 211 marks were added. Of this total of 314 marks, 67% were done only through the use of the V-V-P. In these 7 subjects, the V-V-P identified three times as many locations for marks as the naked eye. Because these subjects were CT, naked-eye visualization of feeder veins was either difficult or impossible (Table 1).

Phlebectomy of the Feeder Veins Using the V-V-P during the Procedure

Seven subjects were submitted to phlebectomy, some of them in more than one area (a total of 16 areas). The marked feeder veins measured after removal averaged 0.96 mm.The smallest and biggest ones were 0.15 and 3 mm, respectively. After feeder vein phlebectomy, 13 areas tested positive for the disconnection test. Three of the 16 had a negative test. The V-V-P was then activated, and the remaining feeder veins identified by it were removed. The disconnection test immediately became positive in all three areas. On postoperative evaluation, the results for operated areas were considered good or excellent in all cases.

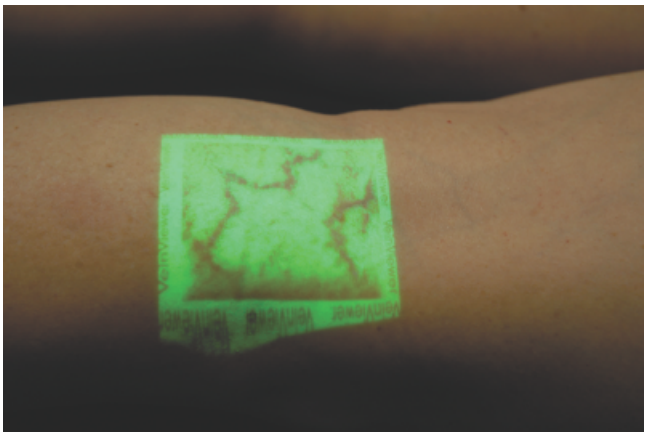

Figure 5. Combined telangiectasias. Appearance before treatment, photographed with the VeinViewer prototype turned on.

Laser and Sclerotherapy Guided by the V-V-P

A total of 15 subjects with CT lesions were treated with laser and sclerotherapy guided by the V-V-P. Of these, 9 reported a total or partial improvement of the lesion, 4 had no improvement, and 2, so far, reported that the problem became worse. One was later treated by phlebectomy, with good results. The V-V-P was capable of guiding the laser treatments and also showing the effect of the laser (e.g., the vein collapsed partially and the V-V-P vein image became shorter and thinner) minutes after the laser shots (Figures 6 and 7).

Discussion

Treating telangiectasias that have feeder veins is tricky. Up until now, physician experience was the best tool for finding and treating feeder veins, regardless of the technique chosen. These veins are normally too deep for naked-eye visualization and too shallow for

TABLE 1. A Comparison of the Number of Marks Made by Naked-Eye Visualization and Palpation and Those Made with the Aid of the VeinViewer Prototype (V-V-P)

Subject File Number	*Naked-Eye Marks*	*V-V-P Marks*	*Total Number of Marks*	*Improvement Factor*	*Percentage of Marks Done with the V-V-P Only*
19655	15	15	30	2	50
25245	18	78	96	5.3	81
25849	7	16	23	3.3	70
26186	10	42	52	5.2	81
26187	9	26	35	3.9	74
26453	4	10	14	3.5	71
26488	40	24	64	1.6	38
Total	103	211	314	3.0	67

U-S detection. When U-S is used for feeder vein detection, merely positioning the U-S's gel and probe can collapse a small feeder vein entirely. Even if the vein is located, its image only appears on the machine's monitor, and it is difficult to tell precisely where it actually is. In addition, the necessary gel makes it highly problematic to mark the skin with a pen.

The V-V-P was initially developed as an aid to collecting blood and injecting IV medications, but it seems to have excellent visualization at exactly the depth and diameter of the feeder veins. As seen in this study, the feeder veins were diagnosed in all 23 subjects. One unique feature of the V-V-P is the fact that the processed image is projected directly over the vein, onto the skin, enabling easy marking and transoperative checking. Moreover, the room illumination does not need to be special and can even be turned off.

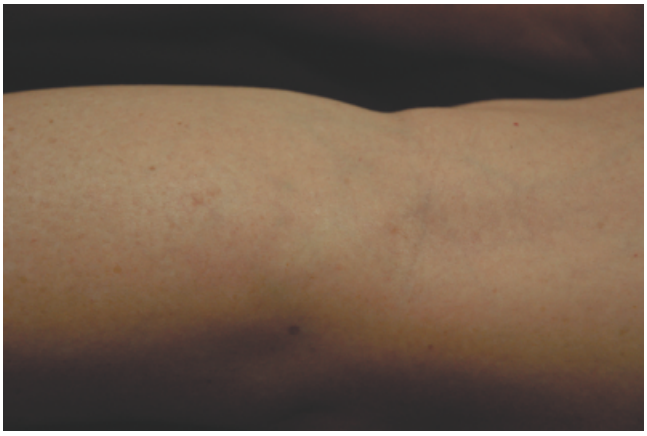

Figure 6. Combined telangiectasias. Appearance after 1 month and one session of laser combined with 75% dextrose, photographed with the VeinViewer prototype turned off.

In the two cases where the V-V-P and the U-S machine were compared, the U-S had the advantage of being used after the veins were marked with the V-V-P. Even so, the smallest vein detected by the U-S measured at 0.4 mm, whereas the smallest one marked by the V-V-P measured 0.15 mm, indicating much greater sensitivity.

Marking veins with a V-V-P was a simple procedure: the veins were just marked where they were made visible with the V-V-P. Optimal performance was obtained when the image was in focus and when the optical axis of the V-V-P was perpendicular to the surface of the skin. Instant and easy to understand imaging over the lesion helped the subjects to understand the necessity of treating the feeder veins.

The V-V-P could also help in determining the direction of venous flux or reflux by projecting the image of refilling after compression of the telangiectasias. These

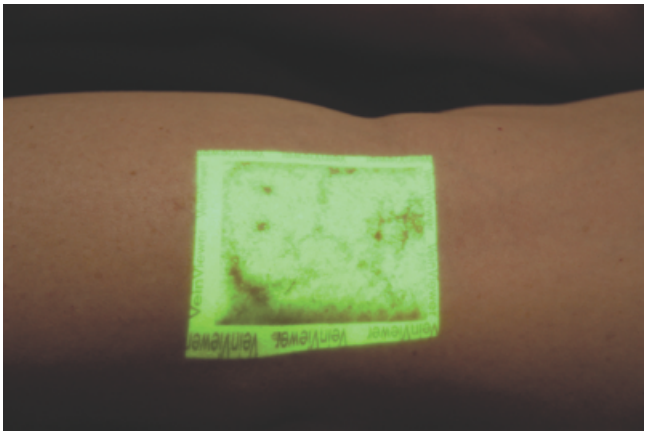

Figure 7. Combined telangiectasias. Appearance after 1 month and one session of laser and sclerotherapy with skin cooling, photographed with the VeinViewer prototype (V-V-P) turned on. The V-V-P image also shows two black dots (image of two 1-mm-diameter clots).

images corroborate the hypothesis of valve insufficiency in the feeder vein(s), and this observation should stimulate new studies.

In some cases where the V-V-P was used, the difference between the number of marks obtained with it and without it was larger than in other cases. The V-V-P lead to three times more marks than with the naked eye, as seen in Table 1 (on a small sample). This variability probably resulted from the fact that some CT subjects had more veins that were invisible to the naked eye.

Seven subjects were submitted to phlebectomy using the V-V-P, all under local anesthesia. Another future interesting study to be done could analyze the influence of the tumescent anesthesia on the V-V image.

Employed during the procedure, the V-V-P was able to visualize hematomas after vein removal, as well as the remaining veins. The image of a hematoma caused by phlebectomy is like a diffuse dark stain, differing from the image of a vein, which is more distinct. This ability to visualize veins while a procedure goes on is very useful, because blood can wash away marks applied beforehand. Also, if during a phlebectomy, there is a hypothesis of remaining feeder vein(s) (negative disconnection test described under Materials and Methods), the only possible way to detect a feeder vein without the V-V-P is by palpation or visualization. And regardless of the study size, postoperative evaluations appeared to show fewer hematomas with the use of the V-V-P, clearly the result of improved ability to find feeder veins.

In the past, in our clinic, telangiectasias that had feeder veins (CT) were generally treated by surgically removing the feeder veins. It had been found that the combination of laser treatment and sclerotherapy was rarely effective in treating CT. Now that the V-V-P is available, however, laser/sclerotherapy treatment of CT has been reassessed. It was hypothesized that the failure of the laser/sclerotherapy treatments in the past may have been due to missing invisible feeder veins rather than being due to any inherent weakness in the laser/sclerotherapy technique. Our present results show that laser/sclerotherapy treatments of CT could be more effective than we expected when the V-V-P is used for guidance. A new prospective clinical study with a larger number of subjects comparing the results with or without the V-V-P is now ongoing.

Another study to be performed to evaluate the use of this device is the avoidance of undesirable vein perforations during local anesthesia, as well as dermatologic procedures such as botulinum toxin injection for facial treatment. In such situations, perforation can cause hematomas greatly interfering with the procedure and the recovery.

Conclusion

In our evaluation, the V-V-P has a great potential as a tool for phlebologic diagnosis and treatment. As soon as a commercial version of the machine is available, we believe that a prospective

clinical study with a larger number of subjects should certainly be done to corroborate our findings and to demonstrate the system's capabilities to the clinical community.

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