

Wound Assessment: A Comparison between Digital Planimetry and Visitrak System Relative to Reliability and Validity

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Introduction

We are fifth year graduate students of the Daemen College, Doctorate of Physical Therapy program conducting our research on a wound measurement device called the Visitrak in our sixth year of study. This particular wound measurement device is a computerized tablet which uses acetate tracing (similar to a transparency) to assess the circumference, area, length, and width of wounds. The Visitrak method of measurement involves placing a sterile transparency over the wound, tracing the wound with a felt tip marker, removing the contaminated layer, placing the tracing on the Visitrak tablet, and retracing the wound using the Visitrak stylus. These tracing and calculated measurements can be saved in the Visitrak for future comparisons and healing rate can be calculated.

The purpose of our research is to further investigate the use of the Visitrak concerning intertester reliability and validity in a clinical outpatient setting. The research will be performed under the supervision of Dr. Michael Brogan, PT, DPT, PhD, CWS, Dean of Health and Human Services.

Background

Individuals with chronic wounds often suffer from a decrease in quality of life.¹ Elements that deter from quality of life include pain, cost of care, wound drainage, and the size of the wound. The intention of intervention is to decrease the size of the wound and increase the healing process. Proper measurement, documentation, and efficacy of treatment are key components of intervention. Clinicians use a variety of different wound measurement methods such as rulers, transparencies, photography, and/or computers.²⁻⁷ Although each method of measurement used in the clinic may have some degree of reliability and validity, the question of which method most appropriately approximates the size of wounds still remains. Further research is indicated relative to the various wound measurement tools, with the intent to validate these various methods, so that the best practice can be achieved. One recently developed measurement system, the Visitrak, does have some supporting literature lending to its credibility, reliability, and validity.⁸⁻¹³ Most of the literature conducted to validate this system, however, used simulated wounds.¹³⁻¹⁴

All wounds emerge within the acute stage of healing and occur by a variety of reasons including trauma, surgery, sickness, or bodily inadequacies, such as venous insufficiency.¹⁵ Acute wounds become chronic wounds when biological and environmental factors combine to create a wound environment that fails to support a natural and timely healing process.¹⁶ Whitney¹⁵ describes chronic wounds as failing to respond to treatments, possessing an unhealthy tissue quality, and failing to achieve proper closure, which leaves the wound susceptible to infection. Because of the various ways chronic wounds form, a variety of categories of chronic wounds exist. The main categories of chronic wounds include the following: venous stasis ulcers, diabetic ulcers, pressure ulcers, and any other wound that fails to heal properly.^{17,18} In order to properly monitor these chronic wounds and enhance typical healing, accurate

measurements of wound size must be collected in an effective and efficient manner to ensure that current treatment is efficacious.

Wound assessment is an important aspect of treatment for individuals with chronic wounds. Proper assessment is important for documentation in medical records because wound parametrics monitor the rate of healing. A variety of different wound assessment tools exist ranging from simple to elaborate and very cost efficient to expensive.¹ The different wound assessment tools currently implemented in various clinical settings today include rulers, transparencies, photography, and/or computers. Each category has a variety of different brands and methods of measurement. Although a wide variety of wound measurement tools exist, each measurement system estimates the wound length, width, and volume. Wound management depends on the objective and precise assessment of the wounds in question.¹⁹ When evaluated over time, wound measurement can predict the outcome of treatment, monitor the effect of treatment, identify infections, establish a diagnosis, and identify a patient's outcome.^{2,3} The Visitrak, a contemporary method of wound assessment, has been researched recently in regards to the reliability, validity, and utility on simulated wounds.

Smith & Nephew developed the Visitrak in 2003.¹¹ This measurement device consists of a digital tablet, a depth indicator, and a transparent tracing grid.³ The transparency consists of three layers. First, there is an outer layer. A wound contact layer follows and is sterile. The top layer consists of a grid and is placed on the tablet for tracing.^{3,11} The foam tip of the depth indicator is also sterile, and it was designed for one time use.³ The portable and lightweight tablet is perfect for transport and can be disinfected after each session with a patient.³ Besides being portable and user friendly, parametric measurements are accurate and reproducible when using the Visitrak system, which calculates area, length, width, and depth.³ To retrace the wound on the tablet, a clinician uses a stylus to follow the wound outline from the transparency.³ The Visitrak has the capability to store the parametric measurements and calculate the percentage reduction in the wound area compared to previous measurements.³

A meta-analysis of the current literature relative to the reliability and validity of the Visitrak suggests this tool is a valid method of wound assessment; however, reliability and validity when compared to other technologies may be questionable without further substantial investigation. Although some articles regarding the Visitrak exist, only one article concentrated on measuring human wounds to determine reliability and validity. Because of the lack of human subjects in the current research available, further investigation of these parametric measures using the Visitrak is necessary on human wounds.

Proposed Work for Fall 2008

Purpose of the Study

This research study investigates the intertester reliability and validity of the Visitrak, a wound measurement system, on human subjects in a clinical setting. Subjects of the study will be receiving wound treatment by a licensed Physical Therapist, Dr. Michael Brogan, PT, DPT, PhD, CWS at a Western New York outpatient clinic. The Visitrak will be applied to wounds as a means of collecting data on wound circumference, area, and depth. Visitrak measurements will be compared to data collected through digital planimetry, which is considered the gold standard of wound measurement. Following the collection of data, intertester reliability and the validity of the Visitrak will be assessed.

Hypothesis

Ho1: The Visitrak has high intertester reliability when used to measure patients with chronic wounds in a clinical setting.

Ho2: The Visitrak has a high intraclass correlation coefficient when compared to the gold standard of wound measurement, which is digital planimetry.

Ha1: The Visitrak does not have high intertester reliability when used to measure patients with chronic wounds in a clinical setting.

Ha2: The Visitrak does not have a high intraclass correlation coefficient when compared to the gold standard of wound measurement, which is digital planimetry.

Design of the Study

The design of this study is that of methodological research. This type of research, as described by Portney²⁰ (1993), involves the evaluation and comparison of measurement tools in a clinical setting for the purpose of establishing reliability and validity.

Setting

This study will take place at two physical therapy outpatient chronic wound clinics in the Buffalo community (St. Joseph's Hospital of the Catholic Health System and the Center for Skin Integrity, which are both located in Cheektowaga, NY).

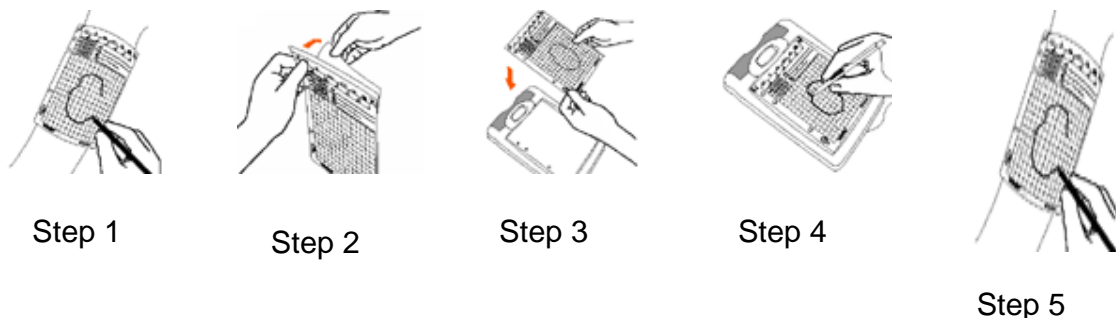
Subjects/Sample

Subjects who participate in this study will be introduced to purpose and nature of this study and will voluntarily sign and informed consent prior to participation. Subjects must meet all inclusion criteria and be at least 18 years of age with at least one open chronic wound. Subjects will be seen as outpatients by a licensed physical therapist under the direct referral of a physician. Measurement of the wounds will be part of their treatment plan. Participation in this study will not require anything beyond that which they would receive as part of their treatment. Our target sample will consist of approximately 30-35 lower quarter chronic wounds, which are not compromised by infection. Wounds will be measured individually; in cases where a subject has multiple wounds, each wound will be measured separately and included in the overall data set. Wounds that have been measured previously may be re-measured at a later date following significant change for the purpose of reliability and validity.

Methods

The student researchers will exercise and master the skills associated with using the Visitrak prior to collection of data to ensure that a consistent method of Visitrak application and measurement is achieved. Mastery will be achieved through experiential learning and practical application of the system on simulated wounds. Prior to using the device, researchers will read

the manual regarding the Visitrak and will be familiar with the technological aspects on how to use the Visitrak. Consistent methods of use will include the following:



- placing sterile standard tracing transparency for Visitrak on the wound
- tracing the wound using a Sharpie marker
- removing the transparency layer in contact with wound
- placing the final layer of transparency on the Visitrak,
- retracing the wound on the Visitrak tablet using the Visitrak stylus.
- Calculate desired measurements.¹⁻³

Data Gathering

Three student researchers will measure chronic wounds on subjects at outpatient wound clinics under the direction of Dr. Michael Brogan. The three researchers, Kaitlyn Kester, Rebecca Martel, and Holly Wood Brown, are students at Daemen College who are enrolled in their sixth year of the Doctorate of Physical Therapy Program. Additionally, digital planimetry measurements will be taken by a wound care specialist, Dr. Michael Brogan, prior to the measurements being taken by the three researchers. Digital planimetry measurements will be kept confidential until the completion of all data collection.

During the data collection, subjects will continue to receive their prescribed current treatment within the outpatient wound clinic. At no time will data collection interfere with the course of wound treatment. Chronic wounds will be measured using the Visitrak while the subject is positioned in the most optimal position for measuring and most comfortable position for the subject. The data collection will take approximately 30 minutes per wound and will be recorded confidentially on a private data sheet labeled with the subject's individual and confidential number. Data will be transferred later to Microsoft Excel, respecting confidentiality. The sheets will be in the possession of Kaitlyn Kester, Rebecca Martel, Holly Wood Brown and will be reviewed by Dr. Michael Brogan. All collected data will be analyzed using appropriate statistical procedures.

With regard to digital planimetry, wounds will be photographed using a Polaroid, health cam, which is a camera that uses two lasers to assure a distance of exactly 10 cm from the lens to the wound. This camera, and subsequent photographs, allow for reliable measurements secondary to the constant relative to distance. Dr. Michael Brogan will calculate wound measurements using the digital planimetry images. The wound dimensions recorded by Dr. Michael Brogan will remain unknown to the researchers until the completion of data collection. Additionally,

measurements recorded by each researcher will remain unknown to the other researchers until all measurements have been recorded.

Outpatient clinic staff will be present at all times while researchers collect measurements to ensure the safety of subjects in the study.

Data Analysis Method

All data will be analyzed using appropriate statistical procedures under the guidance and direction of Professor Cathy Buyea, who is a statistician. Statistical analysis will include a power of analysis calculation, paired t-test calculation, and intraclass correlation coefficient calculation.

Daemen College Human Subjects Research Review Committee Informed Consent

Title of Research Project:

Wound Assessment: A Comparison between Digital Planimetry and the Visitrak System Relative to Reliability and Validity

Description of the Research Project:

This research study investigates the intertester reliability and validity of the Visitrak, wound measurement system, on human patients in a clinical setting. The Visitrak will be compared to digital planimetry for validity purposes. According to Portney²¹ (2000), interrater reliability refers to the ability for multiple testers to achieve the same results for a given variable. Validity, also according to Portney²¹ (2000) refers to the extent an instrument is able to measure what it is intended to measure.

Description of Participants' Role:

The subjects will be asked to have their wounds measured using a camera and sterile grid paper. Prior to measurements, a verbal description of the study will be given to a potential subject. If the subject remains interested in participating, an informed consent form will be given and verbally explained to the subject and, if willing, signed by the subject. The total time required to perform the measurement is subject dependent but should not exceed 30 minutes. Researchers will exercise standard safety precautions during the wound tracing process and only sterile materials will contact the participant's wound(s). Outpatient clinic staff will be present for supervision during measurements.

Benefits:

There are no direct benefits to the subjects. However, the value of research data collected has potential benefit to society in regards to wound assessment.

Risks:

There are no risks beyond what is incurred with standard wound management.

Inclusion Criteria:

Inclusion criteria for the subjects in this study are that they possess an uninfected chronic wound of the lower quarter less than 40cm². The subjects must be 18 years of age or older. The subject will understand and be able to speak English. The nature of wounds must be chronic, and be due to one or more of the following etiologies: venous, arterial, pressure, metabolic, neuropathic, traumatic, and surgical.

Confidentiality:

Data collection will take place at an outpatient clinic. The evaluation and results will be recorded on the subject's private data sheet with personal identification number provided by the researchers, Kaitlyn Kester, Rebecca Martel, and Holly Wood Brown. Upon completion of the data collection for each session, the researchers will collect the sheets for data analysis, which will be completed upon collection of all wound measurements for the entire study.

All information will be published in its aggregate form and there will be no publication that could link your participation with the data. Confidentiality of each participant will be maintained. Any identifying information, such as this consent form, will be stored in a secure location separate from other data.

Researcher(s)

This research project is being conducted by:

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Researchers Qualifications :

The researchers are currently working toward their Doctorate of Physical Therapy degree. They are matriculating in the last professional phase semester of the physical therapy program at Daemen College. Data collection, documentation, and analysis will be overseen by Dr. Michael Brogan (Physical Therapist), Associate professor and Dean of Health Sciences at Daemen College, who has supervised numerous research studies throughout his career and is well published in his area of expertise, Chronic Wound Management.

Budget: \$2,200

A budget of \$2,200 is requested to financially support the research.

Description	
Visitrak Device including tablet shipping and handling	\$800.00
Visitrak Tracing Grids (3 boxes of 50)	\$300.00
Visitrak Depth Probes (3 boxes of 50)	\$300.00
Professional Development Funds (conventions, conferences, or symposiums)	\$800.00
Total	\$2,200

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