

A Randomized Controlled Study Comparing Vacuum Assisted Closure to Standard Dressing Changes in the Development of Angiogenesis

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Hypothesis

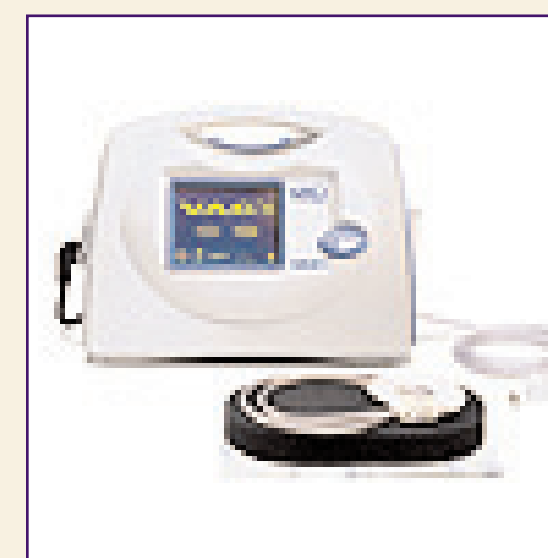
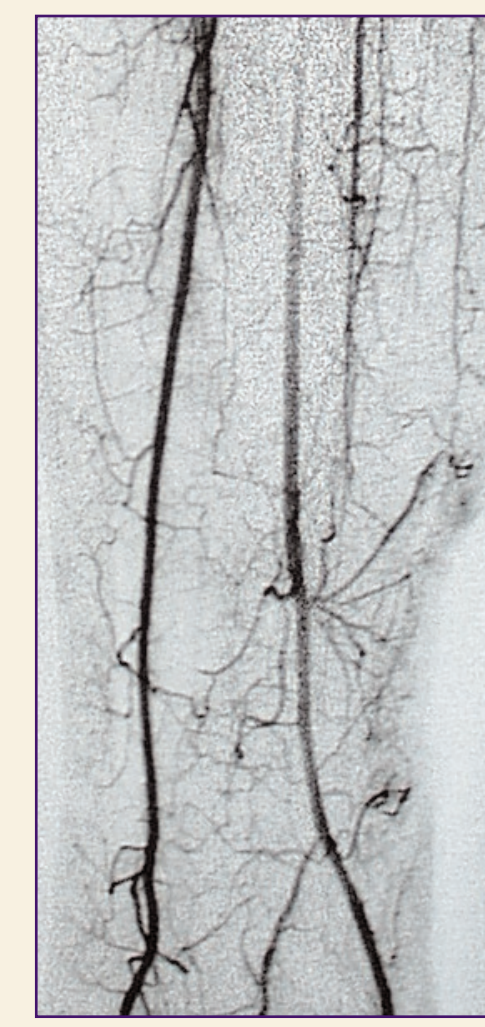
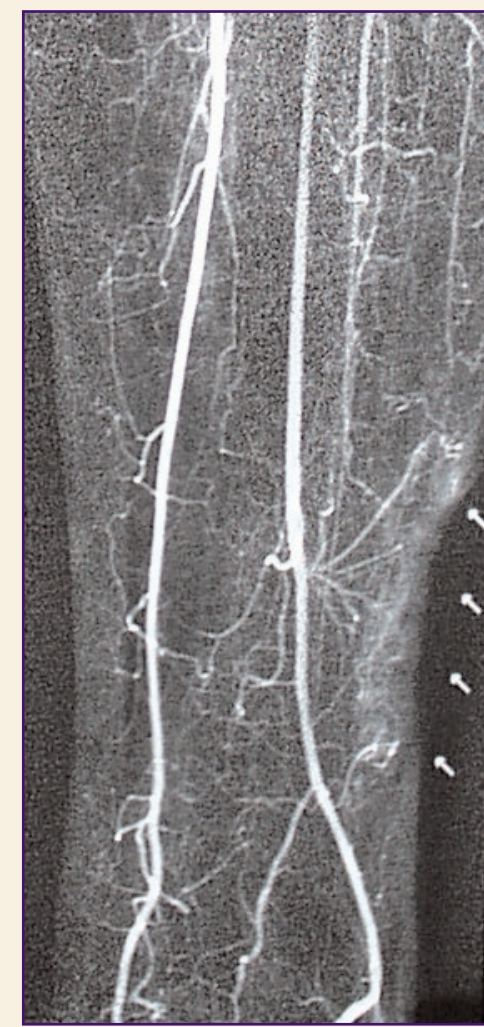
The use of Vacuum Assisted Closure (VAC) therapy will stimulate the development of angiogenesis in the subjacent tissues underlying and surrounding the wound base to a greater degree than can be achieved with standard wound healing efforts.

Study Background

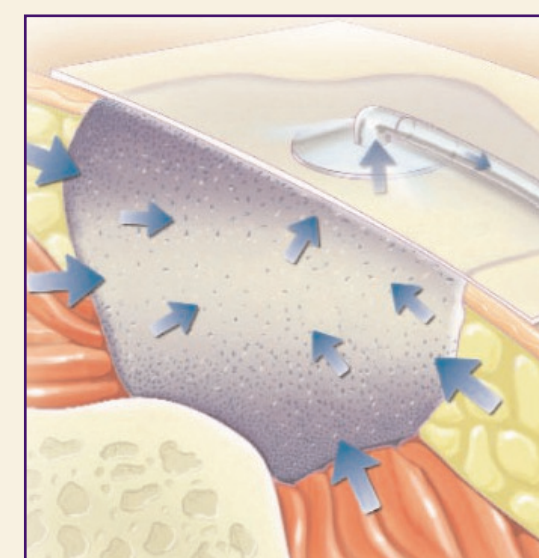
The presence of tissue ischemia and hypoxia due to compromised arterial blood flow is a primary factor compromising wound healing. Angiogenesis or the development of new blood vessels begins very early after wounding and is visually manifested in the proliferative phase of wound healing as granulation tissue. The lack of neoangiogenesis or development of granulation tissue is a poor prognostic indicator of normal wound healing. An adequate blood supply is required to deliver oxygen, nutrients and energy substrates to maintain the phases of wound healing. The proliferation of fibroblasts and the production of collagen, as well as the replication of epithelial cells necessary for wound closure are energy and oxygen dependent processes. A 20 fold increase in the metabolic demands of healing tissue has been reported. Wounds that are compromised by impaired angiogenesis will have poor blood supply and are unlikely to progress through the stages of healing in an orderly and timely fashion.

The VAC is a subatmospheric pressure system utilizing medical grade polyurethane foam wound dressing that is fitted at the bedside to the appropriate size for each patient's wound, and then covered with an adhesive drape to create an airtight seal. An evacuation tube is embedded in the foam and then contacted to a vacuum device which creates a negative pressure therapy that is delivered to the wound. The application of subatmospheric pressure provides an environment that is conducive to wound healing.

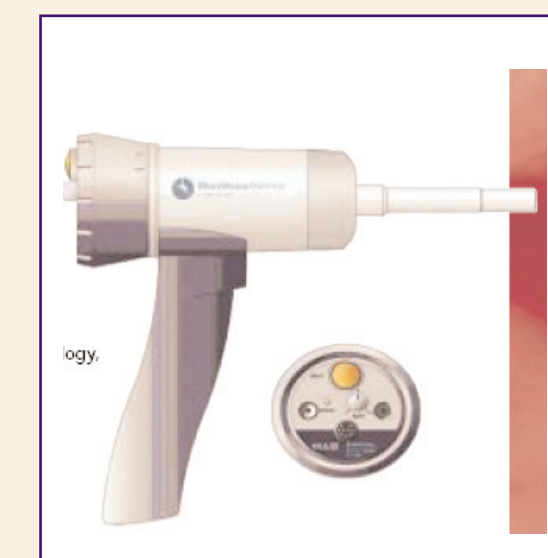
The VAC enhances wound healing by stimulating granulation tissue. The etiology of this granulation is thought to be increased blood flow to the wound base and stimulation of angiogenesis, but the physiologic tissue changes due to VAC therapy that lead to the development of angiogenesis has not been proven or documented. A recent clinical observation demonstrated angiographic evidence of subjacent angiogenesis in a patient with a wound that was managed successfully with VAC therapy (see photos). However, to date no randomized controlled trials have been performed to document wound angiogenesis. We propose that subatmospheric pressure dressings applied to lower extremity ulcers will promote angiogenesis more effectively than moist wound therapy dressings.



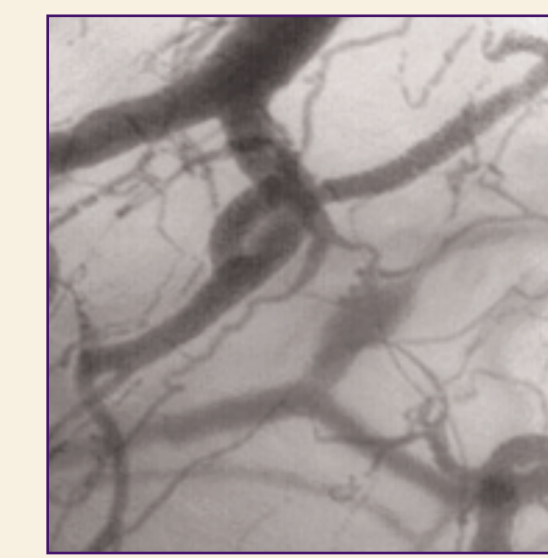
VAC



VAC Effect



Cytoscan



Cytoscan Image

Study Design

Selected patients will be randomized into either a control group (treated with moist dressings alone) or a treatment group (treated with VAC® therapy). During the eight week study period, tissue biopsies will be collected at regular intervals. These tissue specimens will be analyzed using digital measurements, Western blot immunoelectrophoresis, and histopathology. In addition, the wound area will be visualized for the development of neoangiogenesis using orthogonal spectral imaging (Microscan®) which will non-invasively capture images of the microcirculation. These parameters will be used to assess and compare the development granulation tissue and neoangiogenesis.

Inclusion Criteria

1. Subject has a post surgical dehisced wound of the lower extremity (greater than two weeks and less than one month duration).
2. The subject (age > 18) or subject's legal representative is willing to sign informed consent.
3. Transcutaneous Oximetry (TCPO2) evaluation which demonstrated tissue hypoxia in the periwound region (10-40mmHg).
4. An ankle brachial index (ABI) less than or equal to 0.85.

Exclusion Criteria

1. Presence of osteomyelitis, untreated cellulitis, or other active uncontrolled soft tissue infection.
2. Malignancy in the wound base or in the margin of the wound.
3. Presence of necrotic tissue with eschar present.
4. Presence of sickle-cell disease, connective tissue disease, or any systemic hematologic disorder.
5. History of radiation or frostbite to the wound area.
6. Prior VAC therapy to the same wound.
7. Current or prior treatment with HBO.