

Advanced Wound Care

INCREASE BLOOD FLOW

INCREASE TISSUE PERFUSION

INCREASE TISSUE OXYGENATION

MicroVascular Therapy

FOR

Diabetic Ulcers, Decubitus Ulcers

Any chronic, Non-healing Wound

"Adequate local cutaneous perfusion and oxygenation are the most influential

*Pecoraro, R.E., Ahroni, J.H., Boyko, E.J., Stensel, V.L. Chronology and determinants of tissue repair in diabetic lower-extremity ulcers, Diabetes, 1991

Of all the possible mechanisms in the pathogenesis of wounds, ischemia and the resultant hypoxia it causes, is the largest obstacle to healing. The medical profession has been battling ischemia/hypoxia with vasodilators, growth factors, heating modalities, infrared light, and hyperbaric oxygen.

MicroVascular Therapy (MVT) is a physical medicine modality which addresses the problem from a different perspective: working directly and mechanically to elevate blood flow through neuromuscular stimulation of the venous muscle pump.

In MVT, a MicroVas Vascular Treatment System generates ionic impulses which pass through the body, or an extremity, using strategically placed carbon emitter pads. The pads are positioned 180° from each other in groups of up to 8 pairs. The ionic impulses pass completely through the limb or body, creating circulation in the treated area through neuromuscular stimulation of the venous muscle pump, and by upregulating the metabolic process.

While little information exists concerning the MVT mechanism of action or efficacy, one study of 25 diabetics 1 shows encouraging results (Chart 1).

While the 48% increase for the average patient after one 45 minute treatment is dramatic, the 157% increase in baseline for patient number 4, suggests that the benefits of treatment are cumulative and perhaps long-lasting. It is postulated that this is the result of angiogenesis, or perhaps the reversal of stenosis brought about through the repeated pulsations of increased blood flow at increased hydrostatic pressures.

In terms of limb salvage, patient number 2 may be the single most dramatic example. In week one, with a TcPO₂ reading of 0 before treatment and 2 after treatment, he represented an unsalvageable limb. After four weeks of treatment, he still reads only 3 before treatment and 8 after treatment: quite an improvement, but still not a salvageable limb. Following treatment in the eighth week, however, he reached a reading of 35—very likely a salvageable limb!

CHART 1

Patient	Day 1		Week 4		Week 8	
	Baseline	End TX	Baseline	End TX	Baseline	End TX
1. RH	1	3	3	8	-	-
2. EH	0	2	3	8	5	35
3. MM	12	24	18	29	-	-
4. VW	21	36	32	48	54	63
5. SB	27	27	-	-	-	-
6. ED	7	21	24	36	-	-
7. JF	40	46	48	52	-	-
8. WG	1	6	2	14	-	-
9. RG	35	45	-	-	-	-
10. BH	47	56	-	-	48	60
11. KH	28	46	-	-	-	-
12. DH	53	60	-	-	-	-
13. RJ	3	31	-	-	-	-
14. BK	60	65	-	-	-	-
15. JR	13	21	-	-	-	-
16. HL	21	23	-	-	-	-
17. JM	36	46	-	-	46	51
18. RM	15	32	-	-	-	-
19. MN	1	1	-	-	-	-
20. JN	28	37	-	-	-	-
21. AO	30	34	-	-	-	-
22. AS	23	25	-	-	-	-
23. WT	4	16	-	-	-	-
24. DW	40	47	-	-	-	-
25. NW	22	62	-	-	-	-

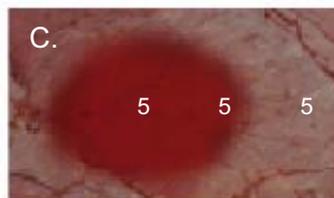
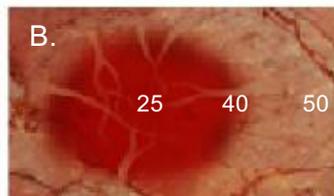
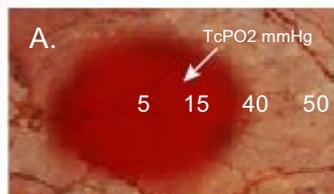
TcPO₂ readings were taken:

1. At the beginning of treatment 2. After treatment
3. Pre and post treatment at four weeks 4. Pre and post treatment at eight weeks

48%
Average tissue oxygen tension improvement in one treatment

58%
Average tissue oxygen tension improvement in baseline in 4 weeks

157%
Largest tissue oxygen tension improvement in baseline, 8 weeks



* A hypothesis

Ischemic Pressure Gradients And Angiogenesis*

A. The body senses an ischemic gradient and responds with an attempt to "level" the gradient through angiogenic factors which begin the process of neovascularization.

B. As new capillaries begin to bud and develop, the TcOP₂ in the wound begins to rise.

Collagen synthesis will occur only when the TcOP₂ rises above 20.

C. In the hypoxic patient, the body sees no ischemic gradient localized to the wound, does not begin the angiogenic response and the wound becomes chronic.

MicroVascular Therapy raises the periwound TcOP₂ to instigate and accelerate the process of angiogenesis through the proliferation phase of healing.

"An average periwound TcPO₂ of less than 20 mmHg was associated with a 39-fold

*Pecoraro, R.E., Ahroni, J.H., Boyko, E.J., Stensel, V.L. Chronology and determinants of tissue repair in diabetic lower-extremity ulcers, Diabetes, 1991

Vascular Impairments Complicate Treatment

Effects of vascular disease occur in both the larger macrovascular and the smaller microvascular arteries, which supply local cellular nutritive flow. Equally important is the fact that the disease is multifocal and can be found in the peripheral, cerebrovascular, and cardiovascular systems at the same time. Progression of neuropathy leads to autonomic denervation (loss of sympathetic nerve innervation) with resultant arteriovenous shunting and microvascular thermoregulatory dysfunction. This in turn results in abnormalities in the microvascular response to injury, with attendant reduced tissue perfusion. That lack of oxygen keeps the ulcer from healing. In cases of infection, the impaired blood flow reduces the delivery of oxygen to the affected tissues, making

aggressive treatment of ischemia a priority.*
*Miller, M.S., Vascular Impairments Complicate Treatment, Biomechanics, 2003

RSD and Pressure Ulcers-A Real Challenge!



The patient, a 57 year old woman, suffered a minor fracture of her tibia and was given a plaster cast as part of her treatment. The pressure of the cast coupled with the patient's poor circulation, combined to create a pressure ulcer that ran down the side of her ankle, wrapped around the heel and up the other side of her ankle.

To compound the situation, or perhaps triggered by the series of events, the patient also developed Reflex Sympathetic Dystrophy (also known as Complex Regional Pain Syndrome) marked by a heightened sensitivity to dermal contact. She was unable to undergo debridement, or tolerate the use of topical dressings.

At the MicroVas Treatment Center, the patient received MVT three times a week which did not cause her pain. At one point, the therapist tried a simple saline gel and the patient reacted with extreme pain (10/10) and it had to be washed off immediately.

Subsequently, the treatment regimen consisted of MicroVas treatments and sterile gauze dressings only. The photos at left show her remarkable progress over a 60 day time period.

ISCHEMIA:

...inadequate vascular supply fails to provide the inducers, substrates, and oxygen necessary for wound healing.

Problem Wounds: How to Promote Healing, Prevent Recurrence.
Consultant, 11/01/2000 Strauss, M.B.

HYPOXIA

Hypoxia plays a critical role in wound healing since it impairs collagen synthesis and prevents fibroblast proliferation and migration.

Harkless, et al, Podiatry Today, 2000, 1045-7860



In the time it takes you to read this brochure, five people in America will

One

experience amputation 87,000 annually, billion every 2 minutes amputatio

*Vinik, A.I. et al, Diabetic Neuropathy: A Small-Fiber Disease, MedScape Today, 2003



Two Year Old Ulcer Healed In 60 Days

A 63 year old male diabetic was suffering from a non-healing foot ulcer which had persisted for two years despite a vigorous program of traditional wound care. He had already lost two toes and was facing the possibility of foot amputation within a relatively short time.

After MicroVascular Therapy (MVT) five times a week for ten weeks at HealthSouth Rehabilitation Hospital of Tulsa, Oklahoma, the ulcer was completely healed and his foot was pain free.

Examined several months after treatment, it appeared the same as in photo three, at left.

Post-Surgery Non-Healing Wound

The patient is a 53 year old female diabetic who slipped and fell on some stairs. The fall resulted in a compound fracture of the leg with significant trauma to the surrounding tissue. She was transported to St. Francis hospital in Tulsa where the orthopedic surgeon on call, used plates attached with screws to stabilize the break. Four months later, because of poor circulation, the incision was showing no signs of healing, as shown in the top photo at right. The patient was fearful of an amputation since the wound was growing worse.

After the patient began MicroVas treatments, the effects were quickly apparent. Not only was the wound healing, but a fracture in the tibia was also healing. After more MicroVas treatments, the patient was examined by her doctor who was surprised to see the extent of healing that had occurred.



GRADIENTS

...the pressure gradient between normal and stenotic regions is known to be the most important factor for collateral vessel development.

NON-SURGICAL REVASCULARIZATION ?

Revascularization has been growing in popularity for a number of reasons, but the operation addresses only the macrovasculature and achieves results in a limited area, while the ischemic problems may be of a more general nature. Surgical revascularization is less than a perfect answer. A recent study of amputations at a major VA hospital* reported that 26% of the amputees had undergone prior revascularization with 48% of those having early failure.

MicroVascular Therapy (MVT) dramatically raises the wound/periwound pressure gradient in most patients (see OU study inside). The increases in baseline indicate the process of angiogenesis. We postulate that MVT forces the development of collateral circulation to such an extent that it could be considered "non-surgical (micro)revascularization" and is the basis for our clinical successes.



Phycon Medical, Inc. 13325 North 56th Street,
Tampa, Fl. 33617

813-985-5818 Fax 813-985-1571

pck1@phyconmed.com