

IMPROVED LOWER LIMB CIRCULATION AND WOUND HEALING DUE TO CYCLOIDAL VIBRATION THERAPY (VIBRO-PULSE®). DOPPLER COMPARISON OF THE TREATED AND UN-TREATED DIABETIC LIMB.



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Introduction

Reduced circulation can exacerbate tissue ischemia and prolong wound healing (1), this in particular applies to diabetics with neuro-ischemic ulceration or wounds following surgical intervention. Many diabetics suffer with various levels of either macro or micro angiopathy. Vascular surgical intervention can improve blood flow from occlusion above the knee, however this becomes more difficult for below the knee peripheral vascular disease.

Vibro-Pulse® (**Fig1**) is a medical device that applies low frequency oscillation vibration to the lower limb. The frequency range of vibration has been shown to increase skin and soft tissue blood flow (2) including in diabetics (3). Vibration results in mechanotransduction, cells convert mechanical forces in to chemical activity, in this instance stimulating the production of nitric oxide a vaso-dilator by means of eNOS synthase which controls vascular tone. (4) Vasodilation also increases cellular shear stress against the blood vessel wall (5), this has been shown to stimulate angiogenesis that would aid effective wound healing. In diabetics arterial intimal thickening can impede diffusion of nitric oxide from the endothelial to the smooth vascular muscle. The relationship between poor wound healing and low shear stress of endothelial cells or turbulent flow due to reduced blood flow as a result of vascular disease has been shown (6). In particular with diabetes it has been shown to effect angiogenic growth factors and inhibitors reducing angiogenesis activity (7) impairing such as collateral vessel growth. The following is a record of wound healing and change in blood flow between the treated and un-treated lower limb of a diabetic self applying Vibro-Pulse at home 3 x a day for 30 minutes.

Method

The patient met the indications and contraindications for use and consented to use the product. Continuing with standard treatment a Vibro-Pulse unit was allocated to the patient to self apply at home for 3 x a day for 30 minutes to treat his right lower limb wound only.



Fig 1. Vibro-Pulse

Patient: Male. 72 years old diabetic with angiopathy in the lower limbs. A right leg non-healing transverse metatarsal surgical wound following amputation due to tissue necrosis. Wound dressing Hydrosorb gel + Iodine. Wound duration 6 months prior to commencing Vibro-Pulse. The patient was assessed at clinic every 2 weeks and the following recorded..

- Wound status • Wound area • Photograph • Pain score. 0 no pain to 5 excruciating
- visual analogue scale. The patient also had a Doppler measurement (Dopplex Assist, Huntleigh Healthcare) of both the right leg (Vibro-Pulse treated) and the left untreated leg. This occurred at
- Start • Week 8 • Week 16.

Results: Wound healing

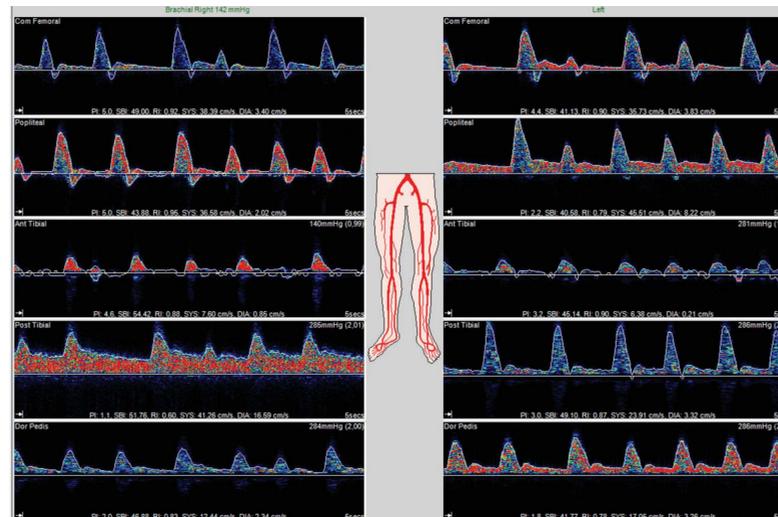
	Wound Size	Exudate	Wound bed	Peri-wound	Pain 0-5
START	30 cm ² shallow	Moderate	90% sloughy	Inflamed	Medium (3)
Week 2	22.5 cm ²	Moderate	70% sloughy Signs of epithelialisation	Healthy	Slight (2)
Week 4	22.5 cm ²	Clear	100% sloughy	Healthy	Slight (2)
Week 6	18.75 cm ²	Clear	50% sloughy 20% granulation 30% pink epithelialisation	Healthy	None (0)
Week 8	7.5 cm ²	Clear	1% slough 25% granulation 74% pink epithelialisation	Healthy	None (0)
Week 10	4 cm ²	Moderate	1% slough 9% granulation 90% epithelialisation	Healthy	None (0)
Week 12	2 cm ²	Moderate	1% slough 8% granulation 91% epithelialisation	Healthy	None (0)
Week 14	0.3 cm ²	Moderate	100% epithelialisation	Healthy	None (0)
Week 16	0.03 cm ²	None	100% epithelialisation	Healthy	None (0)
Week 17	Healed	None	Fully epithelialised	Healthy	None (0)

RESULTS: Measurement / Observations

Start (**Fig 4**). Progressive changes in the arterial system caused by diabetic micro and macro-angiopathy especially bilaterally in the popliteal artery, predominance in the right limb.

Pathological brachial crural - indices of 0.99 of the anterior and posterior tibial artery and a mediocalcineal dorsalis pedis artery. (mediocalcinea - the sclerotic vessel is not compressible under the inflated cuff. This pressure does not relate to the actual pressure.) Posterior and anterior tibial show a characteristic stenotic curve. The indices of the pulse index (PI standard 14 to 16) are pathological. The resistance index is also pathological (The norm is from 0.96 to 1.0). On the posterior tibial artery the flow has changed, showing signs of turbulence and post-stenotic acceleration of systole of 41.26 cm / sec.

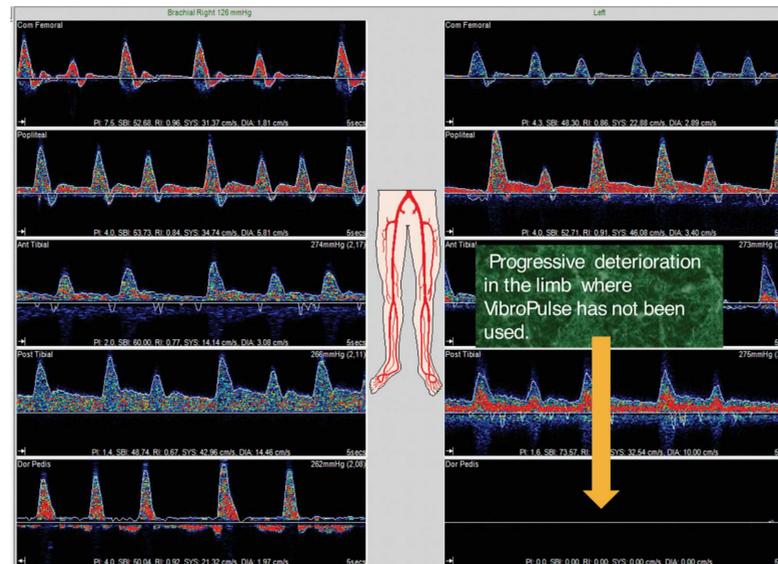
FIG 4. START



RIGHT LEG / WOUND

LEFT LEG UN-TREATED

FIG 5. WEEK 16 of VIBRO-PULSE



RIGHT LEG / WOUND

LEFT LEG UN-TREATED

	Right Leg (Vibro-Pulse) treated	Left leg no intervention
Week 8	Stenotic changes with a moderate improvement in hemodynamics	No change
Week 16	(FIG 5) An improvement in hemodynamics in the area under the right trifurcation. An increase in the brachial-crural index on the anterior tibial artery, increased blood flow velocity also on the dorsalis pedis artery and an increase in the pulsation index and resistance index. Systolic velocity increased from the original 12.44 to 21.32 cm / s.	(FIG 5). A gradual progression of the vascular disease with the occlusion of the dorsalis pedis artery and a stenotic curve of the posterior tibial artery.

Discussion

Improvement in wound healing had been slow to date with a duration of 6 months following transverse metatarsal amputation. Applying Vibro-Pulse 75% healing occurred in the first 8 weeks, the rate of healing then slowed with full healing by week 16.

The patient recorded a reduction in pain from 3 medium to 0 none by week 6. Doppler readings showed that at the start both lower limbs had diabetic macro and micro angiopathy at an advancing stage of morbidity. However at week 8 and at week 16 there was a clear improvement in blood flow in the Vibro-Pulse treated right lower limb, this compared to a further deterioration in blood flow in the untreated left lower limb.

The non-invasive application of vibration therapy results in the stimulation of endothelial nitric oxide synthase resulting in vasodilation and changes in vascular tone. As shown in the changes in blood flow noted between the left and right lower limbs.

Conclusion

Vibration therapy (Vibro-Pulse) was effective in stimulating the healing of this diabetic lower limb wound.

Improving blood flow was noted in the treated lower limb compared to the untreated lower limb. Further blood flow comparative studies on lower limb macro and micro angiopathy patients is recommended.

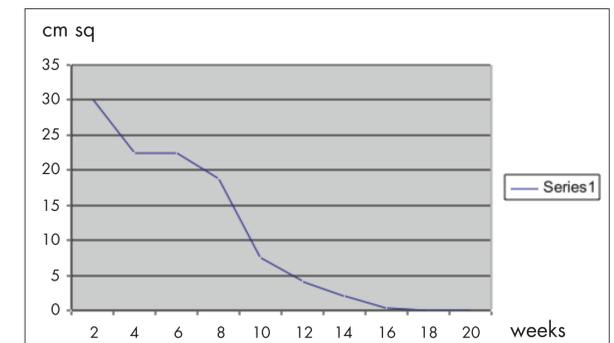


Fig 2 START 30cm sq wound 6 month duration



Fig 3 Week 14 of Vibro-Pulse.

Wound healing



References

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