Independent evaluation of

BEMER® PHYSICAL VASCULAR REGULATION THERAPY

Liezl Naudé

Advanced nurse specialist: wound management Advanced lower limb and wound management centre, Pretoria

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Introduction

Lower limb wounds have always been a challenge not only due to the complexity of the trauma, but also because of the nature of chronic ulceration. In wound management we can utilise the best possible first world dressings we can get our hands on, but if we do not treat the cause of chronic ulceration, we will not be able to heal the wounds completely.

The pivotal point within wound management remains wound bed preparation (WBD) and we still regard moist wound healing techniques as the cornerstone of modern wound healing.^{1,2} WBD was first proposed in 2000^{3,4,5} and is now regarded as the prerequisite for a successful outcome in wound management globally.⁶

The difference with this module is that we have to treat the cause first before we even try to deal with the wound bed. Macro-circulation is essential for life but without adequate micro-circulation we will not be able to facilitate the exchange of nutrients and waste products between the blood and surrounding tissue. Circulatory disorders and the resulting oxygen deprivation leads to a serious shortage of adenosinetriphosphate (ATP), the universal biological energy generated at cellular level.

Improved circulation, especially an improved micro-circulation, increases the manufacture of sufficient biological energy in the form of ATP, improves cellular metabolism, provides a better supply of nutrients and removal of toxins in tissue and organs and hence results in a better functioning of the self-regulating mechanisms. This also ensures the organism's ability to adapt and to optimise all biological processes.

It is the protein bio-synthesis which is of paramount importance for human life and health. As a reproducing process, it is highly dependent on sufficiency of oxygen supply in the oxygen-driven ATP energy production process.

As a wound management specialist working

in an advanced wound management centre, our patient profile consists of patients having several pathologies such as venous insufficiency, arterial insufficiency, lymphoedema, diabetes, malignancy, immune deficiency, arthritis, pain syndrome and many others.

Aim

The purpose of this independent evaluation is to document the impact of physical vascular BEMER therapy as a patented broadspectrum low-intensity pulsed electromagnetic field therapy on these patients' wound healing, overall well-being and specifically their microvascular status.

By increasing cellular energy, BEMER treatment has been shown to improve cellular performance which facilitates the body's inherent ability to self-regulate its important physiological parameters and heal itself by:

- Improving blood circulation (micro and macro circulation)
- Strengthening the immune system through increased t-cell release
- Increase in oxygen partial pressure
- Improving blood viscosity
- Improving cell metabolism and ion pumping.

Method

In 2012 and 2013 a series of case studies were conducted on a range of different chronic wounds including foot ulcers and mixed lower leg ulcers. In this evaluation several cases will be discussed where BEMER formed part of the treatment regime. The cornerstone of this treatment was also the application of the wound bed preparation guideline enabling moist wound healing.⁶

Cases had varying medical pre-conditions, which included prior sharp debridement of devitalised tissue and different levels of bacterial load. A range of wound dressings were used according to the phase of wound healing.

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Standard BEMER protocol for all advanced lower limb and wound management centre patients

- Patient was started on initial treatment on the body mat (BM), intensity 3 (10.5 µT), which is thereafter increased at one level for the first four treatments up until a level six intensity (21µT), which is then maintained when using the BM.
- 2. After the BM session (eight minutes) mini-mat (MM Large intense applicator) is applied directly on affected area at level 10 intensity (35 μ T) for eight minutes. After MM session (eight minutes) the special light applicator (SLA Small LED light applicator)

is applied directly on the wound surface at level 10 intensity (35 µT) for eight minutes.

Patient SHO001: diabetic arterial foot ulcer right maleoli

Patient history

Mr S is a 59-year old male with a history of arterial insufficiency and diabetes. Patient had angioplasty and bypass surgery, small ulceration still remained for longer than one year. BEMER therapy was started with moist wound healing.

Photo 1

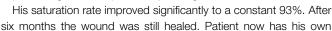


Photo 2



Evaluation

Patient intially experienced severe claudication, he had no quality of life and could not even go shopping with his wife. Within two weeks of using the BEMER, the wound healed and the patient was able to walk without pain. He was also able to start swimming again without experiencing calf cramps halfway through his exercises.



BEMER at home and his overall health has improved significantly. He is able to exercise and have an active lifestyle for the first time in more than a year. He also got a clean bill of health from the vascular surgeon and no further vascular interventions were indicated at this point in time.



Patient CRO005: arterial foot ulcer

Patient history

A 25-year old male patient with a history of ulceration for more than three months. Patient has a history of intermittent claudication over the past two years. Capillary refill count five. Poor pulse quality with severe pain 9/10.

Photo 1



Photo 2



Evaluation

Patient's wound improved significantly even though basic wound dressings were used. Within the first four BEMER sessions capillary refil changed to three and stayed at three for the last month. Pulses are now bounding and overall condition of the foot improved. No oedema present. Patient had a computer topograph angiogram and the vascular surgeon decided not to do any surgery due to the significant improvement without any intervention at this stage. BEMER therapy is the main focus of treatment and wound dressings are used to facilitate autolytic debridement. Patient is able to sleep better and mobility has improved. Pain now 6/10. This patient benefited significantly from the BEMER units at the centre as part of the evaluation. He is undergoing as many sessions of BEMER as possible.

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Patient DEA001:chronic venous leg ulcer

Patient history

Patient is a 70-year old male with a history of chronic venous ulceration. He also had localised infection and severe arthritis. At the start of his treatment the ulcer was very painful 8/10.



Photo 1

Photo 2



Evaluation

BEMER therapy is combined with compression therapy and advanced wound care products. A significant increase in vascular flow and oxygen levels are seen after each BEMER session.





Patient BRI002: Reynaud's syndrome and connective tissue disorder

Photo 1

Patient history

A 57-year old female patient with auto-immune disorder, Reynaud's syndrome, arterial insufficiency, arthrosclerosis and connective tissue disorder. Pain 9/10 at start of treatment.





Photo 2

Evaluation

Improved circulation within two weeks of using the BEMER. All digit wounds healed with no new ulcerations for the first time in one year. Patient has had no new wounds for the past five months since using the BEMER three times per week as maintenance treatment. Saturation improved from 85% to 92% after BEMER sessions. Patient experienced better mobility as well. Whilst using the BEMER once a week patient had no recurrence of ulceration. Patient stopped coming to the centre for three months. Pain started flaring up again and small ulceration occurred. Patient is now using the BEMER once a week in a maintenance programme and for the last two months and had no recurrence.

Patient KHA001: diabetes, severe oedema, pain and heart failure

Patient history

A 76-year old female diabetic patient with a history of pressure sores after hospitalisation for heart failure. Patient could not mobilise at all and had severe pitting oedema bilateral. Wound slow to heal and pain 8/10. Biphasic pulses with doppler evaluation.





Photo 2

Evaluation

Decrease in oedema within one week of BEMER therapy three times per week. Only very light crepe bandages were applied below the knees to assist with managing the oedema in between BEMER sessions. Both the ulcers demarcated well and overall condition improved significantly. Pain decreased to 4/10 and patient is now able to stand on her own with minimal assistance.

WOUNDCARE

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Patient POT003: venous ulceration

Patient history

Photo 1

Photo 2

A 72-year old female diabetic patient with a history of ulceration after falling and creating a degloving injury one month ago. Wound slow to heal and pain 8/10. ABPI = 0.9





Evaluation

Wound healing improved significantly with better perfusion after application of BEMER therapy. Patient's pain decreased and oedema also decreased. Wound healed in less than two months with good epithelial skin requiring weekly dressings with light compression and weekly BEMER sessions.

Patient DEB003: burn wound diabetic patient

Patient history

Photo 1

Photo 2

A 44-year old type 1 diabetic patient with a history of a nonhealing deep partial thickness burn wound. Pain 8/10. Bounding pulses. Wound present for two months. Patient was not able to walk on the foot at all.





Evaluation

Patient had an immediate decrease in pain with the first BEMER session. After one week pain levels were experienced as 2/10 and after two weeks the patient was able to go back to work. He was also able to walk normally without crutches. To his delight some pigmentation also returned as can be seen in the photographs.

Patient BEY002: spider bite left hand

Patient history

Photo 1

Photo 2

A 32-year old male patient bitten by a spider on his hand resulting in severe oedema and discomfort. Pain 8/10. Patient immediately started with antibiotics and BEMER standard protocol.





Evaluation

Initial swelling was severe, but decreased within 30 minutes after the first session. Patient was able to utilise the BEMER initially for three times per day. By day three he had no discomfort and swelling was gone. Two weeks after the incident he had no pain and no complications.

The pivotal point within wound management remains wound bed preparation and we still regard moist wound healing techniques as the cornerstone of modern wound healing

Independent evaluation of BEMER[®] physical vascular regulation therapy utilisation

Comparison photographs before and after BEMER therapy sessions

Standard protocol for all wound management patients:

Patient starts on initial treatment on the Body Mat (BM) intensity three (10.5 μ T), which is thereafter increased at one level for the first four treatments up until a level six intensity (21 μ T), which is then maintained when using the Body Mat.

After the BM session (eight minutes) Mini-mat (MM large intense applicator) is applied directly on affected area at level 10 intensity (35 μ T) for eight minutes. After MM session (eight minutes) the small LED light applicator is applied directly on the wound surface at level 10 intensity (35 μ T) for eight minutes.

Before treatment session	After treatment session	Wound photograph before BEMER therapy	Wound photograph before BEMER therapy
SpO2 = 87% Pulse = 84 BP = 142/88mmHg Pain = 7/10	SpO2 = 92% Pulse = 78 BP = 135/78mmHg Pain = 6/10 Improvement in tissue colour and perfusion	#System	
SpO2 = 92% Pulse = 85 BP = 130/85mmHg Pain = 5/10	SpO2 = 94% Pulse = 78 BP = 125/80mmHg Pain = 4/10 Long term improvement in oedema and suppleness of the skin		
SpO2 = 85% Pulse = 80 BP = 137/82mmHg Pain = 8/10	SpO2 = 92% Pulse = 76 BP = 125/78mmHg Pain = 7/10 Drastic improvement in wound bed colour and perfusion	9/	
SpO2 = 90% Pulse = 70 BP = mmHg Pain = 0/10	SpO2 = 96% Pulse = 68 BP = mmHg Pain = 0/10 Increased sensation, patient experiencing heat sensation at wound site	- Junija	-2+4] ² /h
	Showed in these photograhs is the immediate effect of using the BEMER therapy. Keeping in mind the effects of the pulsating physical vascular regulation therapy on all the cells in the body, we can see an improved perfusion which also means increased oxygenation. This resulted in every patient having an improvement in their oxygen		

Results

At the Advanced Lower Limb and Wound Management Centre in Pretoria, treatment is based on the standard BEMER protocol described on the previous page. We have seen significant results with regards to improved vascularisation, improved granulation tissue as well as tissue oxygenation (as can be seen from the before and after comparison photographs).

Overall improvement in patient well-being was significant especially with mobilisation and reduced pain levels. We have also been using the therapy in treating patients with sleep disorders and 60% of patients reported an improvement in their sleep patterns, which resulted in an overall better quality of life.

Conclusion

The cases seen in this evaluation showed a significant improvement with the use of BEMER therapy. This technology is invaluable in patients with microvascular disorders or insufficiency and has been shown to assist in saving limbs.

This technology enables me to provide the best possible care for the compromised patients that we treat. Significant to our centre is also the improvement in sensation that some of our diabetic patients experience with regards to their neuropathy, this is still very early in the studies that we do and more data need to be collected in this regard.

Overall the decrease in pain is the most significant result when dealing with patients that have wounds. We also see a remarkable difference in athletes with muscle injuries as well as bruising. Athletes recover faster from injury and have less swelling and bruising after therapy.

Improved vascular flow cannot be ignored and the value of this treatment modality is hugely underestimated in the medical fraternity. I am excited about the results so far and can't wait to improve more patient's quality of life, allowing them to take their rightfull place in society.

References available on request

saturation percentage.