

European Experience with Pulsed Acoustic Cellular Expression (PACE™) Technology in the Treatment of Diabetic Foot Ulcers



Pulsed Acoustic Cellular Expression (PACE) Technology has been developed based on early scientific and clinical evidence of the beneficial wound healing effects of extracorporeal shock wave technology (ESWT). The dermaPACE® device has been developed specifically for PACE wave applications. SANUWAVE® received CE approval for the dermaPACE in March 2007. This approval is for treatment of acute and chronic defects of the skin and subcutaneous soft tissues - e.g. post-operative wound healing defects, post-traumatic wounds, deep partial thickness burns, decubitus ulcers, diabetic ulcers, and arterial mixed and venous ulcers.

Kristien Van Acker, MD, PhD
Sint Jozef Kliniek
Bornem, Belgium

Investigational Device. Not for Sale in the U.S.

Introduction

Extracorporeal shock wave technology (ESWT) was introduced to medical practice nearly 30 years ago for use in lithotripsy, and subsequently it became evident that ESWT also had bone and soft tissue healing effects. In the last decade this technology has been used to successfully treat tendinopathies, long bone fractures, non-union or delayed-union fractures, and avascular necrosis of the femoral head. Pulsed Acoustic Cellular Expression, known as PACE Technology was developed based on proprietary shock wave energy parameters and a specific defined protocol designed to optimize efficacy in the treatment of wounds.



The dermaPACE device utilizes an applicator to direct high-energy PACE waves into the wound bed. As the PACE waves penetrate the microcirculatory system, there is an immediate acute inflammatory and vascular system response. The response (cellular expression) effectively allows the wound to move through the inflammatory phase and into the proliferation phase of wound

healing. Multiple animal studies have reported the positive effect of PACE waves on soft tissue defects. Clinical publications have reported the biological response of initiation and acceleration of wound healing in burns,¹ traumatic wounds and reconstructive skin flaps,² and diabetic wounds.³ These reports give rise to hope that PACE will be a valuable treatment option for difficult to treat chronic wounds.

After receiving CE mark approval for dermaPACE, the reported data triggered the interest of many physicians and wound nurses, resulting in several smaller trials. Dr. van Acker et al, at Sint Jozef Kliniek, Bornem, Belgium, conducted one such trial. During this study, a protocol including standard of care in conjunction with PACE treatments was found to greatly improve wound closure. Patients received a total of 4 to 6 PACE treatments using a dermaPACE device. PACE treatments were conducted, on average, 2 times per week at the E2 setting using 500 impulses applied over 2 minutes.

Patient's Presentation Prior to PACE Treatment

	Age	Male/ Female	Diabetes Type 1/2	Type of Wound	Surgery	Prior Treatment	Medication (Antibiotics = AB)	Infection
Case 1	78	M	2	Neuropathic DFU	Tendon resection	Cadesorb™ Purilon® Intrasite™	AB	No
Case 2	71	M	2	Neuropathic DFU	revascularization >3 months before/ debridement	Allevyn™	No AB	No
Case 3	75	M	1	Neuropathic DFU	debridement	Isobetadine Dermicum® tulle	AB	No
Case 4	80	F	2	Neuropathic DFU	debridement	Allevyn™, Isobetadine Dermicum® tulle, Intrasite™	/	No
Case 5	86	F	2	Neuropathic DFU	debridement	Isobetadine Dermicum® tulle, Intrasite™, Flaminal®	/	No
Case 6	49	M	2	Neurovascular, Post- amputation DFU	debridement	Flaminal® Hydro	AB	No
Case 7	74	F	2	Neuropathic DFU	debridement	Isobetadine Dermicum® gel	/	No
Case 8	59	M	1	Neurovascular DFU	debridement	Isobetadine Dermicum® dermique	AB	No
Case 9	45	F	1	Neuropathic DFU	debridement	Silver dressing	AB	No
Case 10	78	F	2	Neuropathic DFU	debridement	Isobetadine Dermicum® gel, tulle, Flaminal®Hydro	No AB	No
Case 11	68	F	2	Neuropathic DFU	debridement	Allevyn™, Silver dressing	AB	No
Case 12	51	M	2	Neurovascular DFU	revascularization >3 months before/ debridement	Maggots, VAC®	AB	No



Patient 6
Before 4 PACE
treatments



Patient 6
After PACE
treatment

Results

Patient 1 is a 78 year old male with Type 2 diabetes that presented with a wound over the Achilles tendon that had persisted for more than 6 months. The patient received 4 PACE treatments and achieved complete reepithelialization of the wound within 12 weeks.

Patient 2, also a male Type 2 diabetic at age 71, had already undergone revascularization efforts for a chronic forefoot ulcer persisting for over 3 months. This patient also received 4 PACE treatments resulting in complete closure of the ulcer.

Patient 3 is a 75 year old Type 2 diabetic male that presented with an infected wound covering most of the big toe persisting 1 month that had already undergone debridement protocols without success. Using the standard protocol of 4 PACE treatments the wound completely healed within 3 weeks. Patient 4, an 80 year old female patient with a chronic heel wound, had undergone nearly all intervention techniques without success over 2 years. This patient received 6 PACE treatments and achieved full closure within 13 weeks.

Patient 5, also a female Type 2 diabetic with a chronic heel wound persisting for 2 months, achieved full wound closure within 9 weeks after 4 PACE treatments. This patient's wound had been very painful, but after 2 weeks of treatment the pain resolved.

Patient 6 is a 49 year old male with Type 2 diabetes that presented with osteomyelitis in his big toe. Following amputation of the toe the amputation area did not improve and threatened further amputation. The patient was treated with 4 PACE treatments and achieved complete wound closure within 5 weeks and avoided further amputation.

Patient's Results After PACE Treatment

	Number of Treatments	Reaction of the Wound	Change in Pain After Treatment	Weeks to Wound Closure	Existence of Wound Prior to PACE	Patient Compliance
Case 1	4	Positive	No prior pain	12	>6 months	Good
Case 2	4	Positive	No prior pain	8	3 months	Bad
Case 3	4	Positive	No prior pain	3	1 month	Good
Case 4	6	Positive	No prior pain	13	>2 years	Good
Case 5	4	Positive	Yes, less pain after 2 weeks of PACE	9	2 months	Good
Case 6	4	Positive	No prior pain	5	1 month	Good
Case 7	4	Positive	No prior pain	15	>6 months	Good
Case 8	4	No resolution	Pain due to poor circulation resolved after treatment	No	>3 months	Good
Case 9	6	Partial resolution	No prior pain	No	>2 years	Good
Case 10	4	Positive	No prior pain	4	>3 months	Good
Case 11	6	No resolution	No prior pain	No	>6 months	Bad
Case 12	6	Positive	No prior pain	10	>3 months	Good

Patient 12
Before 6 PACE
treatments



Patient 12
After PACE
treatment



Patient 7 is a 74 year old type 2 diabetic female patient with a proximal wound to the big toe that had existed for over 6 months. After 4 PACE treatments, the ulcer closed within 15 weeks.

Patient 8, a 59 year old male patient with Type 1 diabetes and poor vascularization, presented with a wound persisting for over 3 months on his big toe that caused the patient debilitating pain. Following PACE treatment, the wound did not immediately close; however, the patient reported that his pain was gone.

Patient 9, a 45 year old female with Type 1 diabetes, underwent 6 PACE treatments for a foot wound, but it did not achieve full closure. The patient was later re-diagnosed for an underlying healing issue that must be addressed surgically.

Patient 10, a 78 year old female patient with Type 2 diabetes, achieved complete closure of her foot wound within 4 weeks following 4 PACE treatments.

Patient 11, a 68 year old female Type 2 diabetic post-forefoot amputee, was treated with 6 PACE treatments for her 6 months old persisting forefoot wounds. Following a period of poor compliance and no improvement, the patient is now improving as her compliance improves.

Patient 12, a 51 year old male with Type 2 diabetes, presented with an extremely deep heel wound already treated through revascularization efforts, maggot therapy and VAC therapy without resolution. He underwent 6 PACE treatments, and his wound rapidly closed within 10 weeks at a rate that surprised clinicians.

Conclusions

These early European results indicated that Pulsed Acoustic Cellular Expression offers an improved standard of care that may shorten a lengthy conservative therapy healing process. Further, PACE made later operative measures, such as amputation, unnecessary for most of the patients described providing additional cost savings. PACE was shown to reduce wound size, increase the rate of wound closure, and heal chronic persisting DFUs. In many cases, PACE treatment successfully closed ulcers that other modalities such as advanced dressings, revascularization efforts and additional surgeries could not heal. PACE treatment provided an improved quality of life for the patients by decreasing the time needed to heal most wounds. This also provided a cost savings to the facility because treatment time was decreased by earlier wound closure.

References:

- ¹ R. Meirer et al., Shock Wave Therapy: An innovative treatment method for partial thickness burns. Burns 31; 921-922, 2005.
- ² R. Meirer et al., Extracorporeal shock wave may enhance skin flap survival in an animal model. JBJS, 58; 53-57, 2005.
- ³ Kamelger FS. et al., Extracorporeal Shock Wave Therapy in the Treatment of Chronic Diabetic Lower Leg Ulcers. Poster presentation, Wound Care Congress, Colorado Springs, Colorado, Nov. 12-13, 2006.

SANUWAVE AG

Kreuzlingerstrasse 5

CH - 8574 Lengwil

Switzerland

Phone : +41 (0)71 6868 900

Fax : +41 (0)71 6868 901

Email : info@sanuwave.com

www.sanuwave.eu