ENGLISH

WOUND CARE

APPLICATION OF SPARK WAVES® FOR WOUND HEALING DISORDERS

USER GUIDE - **DERMATOLOGY**

DERMAGOLD100®

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This manual is designed to accompany the dermagold100® Extracorporeal Spark Wave® Therapy (ESWT) device and to provide the user with practical information regarding its operation and application in medical practice. ESWT is not a new modality and has been widely used in human orthopedics for the last twenty years. There are currently more than two thousand ESWT devices being used worldwide in the field of medicine. Our understanding of ESWT is constantly expanding as more experience is gained. This manual puts forward our best recommendations at this time for the use of ESWT. These recommendations are based on current clinical experience and will be updated from time to time as more information becomes available.

Despite significant advances over the past decade, definitive closure of complex wounds remains a challenge. Wound size, location, etiology, and co-morbidities all impact the clinical management of complex and difficult to heal wounds. A current standard of care has evolved centered on topical negative pressure or vacuum assisted wound closure (VAWC) augmented by newer dressings with selective use of hyperbaric therapy. While the widespread adoption of VAWC has contributed to a decrease in the size of complex wounds, definitive closure still typically requires skin grafting or flap coverage. Additionally, complex wounds frequently require multiple operative debridements to achieve satisfactory results. Therefore, the ability to treat these wounds in an outpatient setting and achieve definitive closure in a timely and cost-effective fashion is highly desirable. Since the end of 2004, ESWT has been used for treating skin lesions in a few selected centers in Europe. Initial results were presented at the 8th Congress of the ISMST in 2005 in Vienna and follow-up results presented at subsequent ISMST congresses.

The results of a feasibility study for the use of ESWT for non-healing wounds were very promising and the authors concluded: "The ability to effectively achieve wound closure and implement shock wave technology as either an adjunct to standard therapy or as a stand-alone treatment for complex wounds needs to be evaluated in controlled trials that are currently underway. We are cautiously optimistic that this technology may advance wound care in a similar fashion as the introduction of vacuum assisted wound closure did a decade ago." See: [LIT 1]. Since 2006, several additional centers have begun using ESWT for skin lesions, e.g. the University of Zurich, Switzerland, University of Sao Paulo, Brazil and the University of Chieti, Italy amongst others. See: [LIT 2, 3]

Table 1 contains a list of the conditions currently being treated using ESWT. The dermatologic conditions will be covered in detail later in the manual.

DERMATOLOGY

- Non-healing, acute and chronic skin lesions
- Post-traumatic lesions
- Post-operative healing disorders
- Venous & arterial ulcers
- Decubitus ulcers
- Diabetic foot syndrome
- Burns

ORTHOPEDICS

Approved standard indications in orthopedics
- Tendinitis calcarea
- Radial epicondylopathy (tennis elbow)
- Greater trochanteric pain syndrome
- Patella tendon
- Achilles tendon
- Plantar fasciitis with or without heel spur
- Stress fractures
- Delayed bone healing
- Early stage of avascular bone necrosis (native X-ray without pathology)
- Early stage osteochondritis dissecans (OD) post-skeletal maturity

Common empirically tested clinical uses in orthopedics
- Ulnar epicondylopathy
- Adductor syndrome
- Pes anserinus syndrome
- Peroneal tendon syndrome
- Myofascial syndrome (fibromyalgia excluded)

Exceptional indications / expert indications
- Spasticity
- Apophysitis (Osgood Schlatter)

Tab. 1: Current ESWT indications

1.1 What are Spark Waves®?

Spark Waves® are high-energy acoustic waves that behave much like other sound waves except that they have much greater pressure and energy. As with sound waves, Spark Waves® can travel great distances with ease as long as the acoustic impedance stays the same. However, when the acoustic impedance changes, energy is released and the greater the change in impedance the greater the release of energy. There is a much higher release of energy at a soft tissue / bone interface than at a muscle / fascia interface.
The release of energy from the Spark Wave® within the region of the affected tissues and the resultant compression and tension of cells creates a positive physiological effect. Mechanotransduction is the physiological effect thought to be responsible for stimulating normal and injured cells to produce healing factors. See: [LIT 4]

1.2 What are the effects of Spark Waves®?

ESWT has been documented to have various effects on bone and soft tissue. Generally speaking, in sub-acute and chronic conditions, ESWT stimulates the re-initiation of stagnant healing processes, which causes re-modeling, and hence promotes healing, whereas in acute conditions, ESWT appears to initiate a more rapid and effective healing phase. ESWT also creates transient and incomplete analgesia. The mechanisms by which these effects are created are not completely understood, however they are thought to:

- Increase blood supply to the treated area by stimulation of neovascularization and growth factors;
- Influence on the expression of growth factors and -indicators such as e-NOS, TGF-ß, BMP, VEGF, PCNA;
- Re-initiate stagnant healing processes in chronic injuries;
- Decrease inflammatory processes;
- Stimulate osteoclasts and fibroblasts to rebuild injured tissues;
- Facilitate resorption of calcifications in tendons and ligaments; and
- Stimulate migration (differentiation) of stem cells.

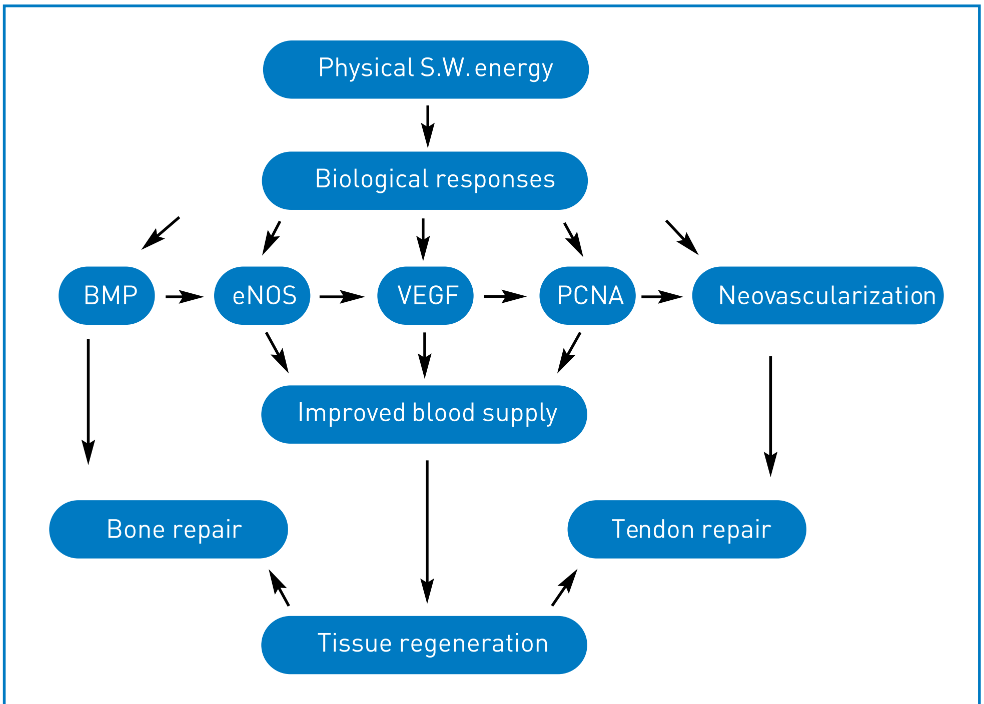


Fig. 1: Effects of Spark Waves® according to [Lit 5]

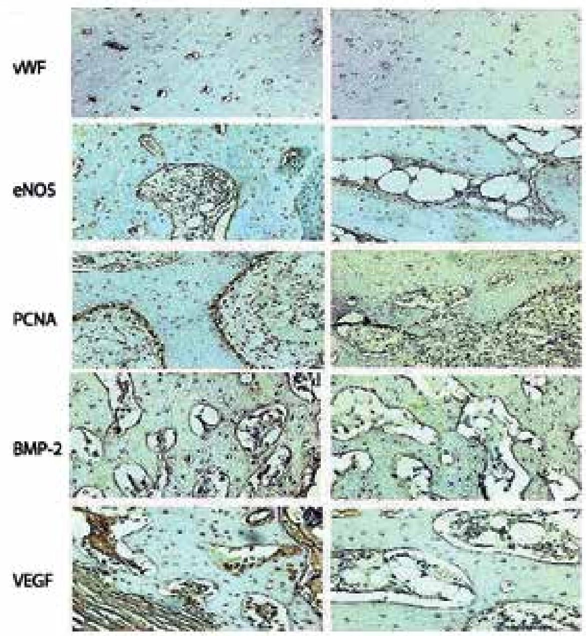


Fig. 2: The numbers of neo-vessels and cells with positive eNOS, BMP-2, VEGF and PCNA expressions are significantly higher in the high-energy shockwave group than the control and low-energy groups. Data from the low-energy group did not differ significantly from the control group. The biological effects of shockwaves appeared to be dose-dependent. See [Lit 5] Several other authors have investigated the basic working mechanisms of Spark Waves® in vivo. A selection can be found in [LIT 6].

1.3 Are there any side effects of ESWT?

No serious side effects have been reported by clinicians even when using highest energy settings; however the following minor side effects have been observed in isolated cases in orthopedics but almost never occurred in skin treatments:

- Minor petechial bleeding may occur if the coupling between the probe cushion and skin is not air exclusive;
- Occasional soft tissue swelling over treated tendons;
- Pulmonary tissue tearing and extra-systoles;
- Three to four-day period of incomplete and transient pain reduction after ESWT therapy; and
- Numbness over the treated area.

No correlation to outcome or future responses to therapy has been established in cases where soft tissue swelling occurs. Aiming at pulmonary tissues or the trachea should be avoided. Spark Waves® induce the healing process by stimulating various biological mechanisms including the release of growth factors and induction of new vessel growth.

2. GENERAL TREATMENT INFORMATION

ESWT involves using a hand held probe to couple Spark Waves® into the affected area and surrounding healthy tissue to induce a physiological response that will initiate healing.

2.1 Energy and numbers of shocks used

The number of shocks applied and the energy of each shock varies according to the size of the lesion (this is approximately a product of the surface area and cross sectional area of the lesion). The following general rules apply to the type and number of Spark Waves® required:

- The larger the size of the lesions – the greater the number of shocks required. Specific information about the energy and number of Spark Waves® required to treat specific conditions will be covered as the treatment of specific conditions is discussed.

However, it should be noted that the energy settings listed in the treatment tables are data from literature based on clinical experience, and they may vary as ESWT use progresses and develops.

2.2 Treatment area

When using the dermagold100® ESWT probe the objective is to traverse the Spark Waves® through the affected region as well as some of the adjacent healthy tissue. This will ensure delivery of maximum pressure and energy to the affected area. The probe is placed firmly onto the prepared skin lesion (see 3.2 Site Preparation). The probe handle is then slowly "pivoted" in a circular motion. The goal is to fan the Spark Wave® zone throughout the desired treatment region while maintaining firm contact with the skin to avoid an influx of air between the probe membrane and the skin. When treating large areas, it may be necessary to reposition the membrane to various areas or to slowly move or "walk" the probe along the treatment area e.g. around the wound area. The probe should always be moved smoothly and can be angled up to 20 degrees away from the perpendicular when being pivoted through a lesion. Throughout the treatment, care must be taken to ensure good coupling between the probe and the skin (see 3.2 Site Preparation).

2.3 Applicators

The dermagold100® is available with an unfocused therapy head which emits unique, mainly unfocused Spark Waves® that are specially designed for skin indications.

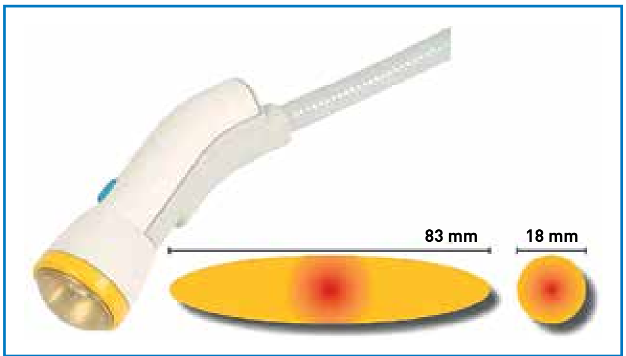


Fig. 3: Applicator and typical dimension of the -6dB zone of the unfocused probe OP155 with a length of up to 83 mm and a diameter up to 18 mm. A full description of the probe and its functions can be found in the dermagold100® User Manual.

2.4 Staging of treatments

The therapy of wound healing disorders requires 4 to 5 treatments on average. However, some wounds react very well with fewer treatments while others require more treatments. The number of treatments is very case specific and depends on the type of wound healing disorder. Based on the current knowledge a prediction for the required number of treatments cannot be made. As long as the wound improves, Spark Wave® therapy should be continued.

3 PATIENT PREPARATION







3.1 Regional anesthetics or sedation

For wound treatment usually no anesthetics are necessary because patients tend to tolerate the therapy very well. If necessary (e.g. for a highly sensitive patient) the energy level and frequency can be reduced for the initial impulses and then incrementally increased to the desired level.

3.2 Site preparation for wound treatment

The following steps should be followed:

- Shave hair, if necessary, to avoid air bubbles in the coupling area around the wound.
- If necessary, perform a debridement of the wound (debridement is also possible after the therapy).
- Measure wound size to calculate desired number of pulses.
- Apply sterile ultrasound gel to the wound.
- Cover the wound with sterile OP-site foil and make sure that no air bubbles are in the area to be treated.
- Apply liberal amounts of ultrasound gel to the foil. Gel can be reapplied as required to ensure good probe/skin contact.
- Perform treatment. Refer to the following chapter in order to estimate the desired number of pulses and energy levels.

3.3 Post-therapy recommendations

After Spark Wave® therapy for skin lesions, remove ultrasound gel and clean the wound. A wound dressing according to current standards in wound care should be used. No special instructions are necessary other than normal instructions to patients after Spark Wave® therapy.

4 TREATMENT PROTOCOLS

For Spark Wave® application on wounds the number of pulses depends on the wound size. The currently accepted standard is to use 350 pulses (regardless of the wound size) plus an additional 20 pulses per square centimeter of wound area.

The following table lists the number of pulses for different wound sizes as an example.

wound size	wound area	number of pulses	
1 x 1 cm	1 cm^2	350 + 20	= 370
2 x 2 cm	4 cm^2	350 + 4*20	= 430
2 x 4 cm	8 cm^2	350 + 8*20	= 510
4 x 5 cm	20 cm^2	350 + 20*20	= 750
6 x 8 cm	48 cm^2	350 + 48*20	= 1310
10 x 12 cm	120 cm^2	350 + 120*20	= 2750

Tab. 2: Calculation example for number of pulses for different wound sizes

The following table shows the number of pulses required for the corresponding wound size. To calculate the required number of pulses, identify the wound area in square centimeters, multiply it by 20 and add 350.

WOUND SIZE, WIDTH (CM)

WOUND SIZE, LENGTH (CM)

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	size in cm^2
	370	390	410	430	450	470	490	510	530	550	570	590	610	630	650	number of pulses
2	2	4	6	8	10	12	14	16	18	20	11	24	26	28	30	size in cm^2
	390	430	470	510	550	590	630	670	710	750	790	830	870	910	950	number of pulses
3	3	6	9	12	15	18	21	24	27	20	33	36	39	42	45	size in cm^2
	410	470	530	590	650	710	770	830	890	950	1010	1070	1130	1190	1250	number of pulses
4	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	size in cm^2
	430	510	590	670	750	830	910	990	1070	1150	1230	1310	1390	1470	1550	number of pulses
5	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	size in cm^2
	450	550	650	750	850	950	1050	1150	1250	1350	1450	1550	1650	1750	1850	number of pulses
6	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90	size in cm^2
	470	590	710	830	950	1070	1190	1310	1430	1550	1670	1790	1910	2030	2150	number of pulses
7	7	14	21	28	35	42	49	56	63	70	77	84	91	98	105	size in cm^2
	490	630	770	910	1050	1190	1330	1470	1610	1750	1890	2030	2170	2310	2450	number of pulses
8	8	16	24	32	40	48	56	64	72	80	88	96	104	112	120	size in cm^2
	510	670	830	990	1150	1310	1470	1630	1790	1950	2110	2270	2430	2590	2750	number of pulses
9	9	18	27	36	45	54	63	72	81	90	99	108	117	126	135	size in cm^2
	530	710	890	1070	1250	1430	1610	1790	1970	2150	2330	2510	2690	2870	3050	number of pulses
10	10	20	30	40	50	60	70	80	90	100	110	120	130	140	150	size in cm^2
	550	750	950	1150	1350	1550	1750	1950	2150	2350	2550	2750	2950	3150	3350	number of pulses
11	11	22	33	44	55	66	77	88	99	110	121	132	143	154	165	size in cm^2
	570	790	1010	1230	1450	1670	1890	2110	2330	2550	2770	2990	3210	3430	3650	number of pulses
12	12	24	36	48	60	72	84	95	108	120	132	144	156	168	180	size in cm^2
	590	830	1070	1310	1550	1790	2030	2270	2510	2750	2990	3230	3470	3710	3950	number of pulses
13	13	26	39	52	65	78	91	104	117	130	143	156	169	182	195	size in cm^2
	610	870	1130	1390	1650	1910	2170	2430	2690	2950	3210	3470	3730	3990	4250	number of pulses
14	14	28	42	56	70	84	98	112	126	140	154	168	182	196	210	size in cm^2
	630	910	1190	1470	1750	2030	2310	2590	2870	3150	3430	3710	3990	4270	4550	number of pulses
15	15	30	45	60	75	90	105	120	135	150	165	180	195	210	225	size in cm^2
	650	950	1250	1550	1850	2150	2450	2750	3050	3350	3650	3950	4250	4550	4850	number of pulses
16	16	32	48	64	80	96	112	128	144	160	176	192	208	224	240	size in cm^2
	670	990	1310	1630	1950	2270	2590	2910	3230	3550	3870	4190	4510	4830	5150	number of pulses
17	17	34	51	68	85	102	119	136	153	170	187	204	221	238	255	size in cm^2
	690	1030	1370	1710	2050	2390	2730	3070	3410	3750	4090	4430	4770	5110	5450	number of pulses
18	18	36	54	72	90	108	126	144	162	180	198	216	234	252	270	size in cm^2
	710	1070	1430	1790	2150	2510	2870	3230	3590	3950	4310	4670	5030	5390	5750	number of pulses

Table 3: Number of pulses depends on size of the wound area

The following pages contain specific protocols for treating the dermatologic conditions listed in Table 1.

4.1 POST-OPERATIVE HEALING DISORDER

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
Post-operative healing disorder is defined as partial or complete failure to heal after primary closure of a surgical wound.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Before, 2 weeks and 17 weeks after 2 sessions of Spark Wave® therapy, a total of 1400 impulses were applied in 4 minutes and 40 seconds.

4.2 POST-TRAUMATIC LESION

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
Soft tissue wounds resulting from direct penetrating or blunt trauma associated with necrosis of epithelial and non-epithelial extra-skeletal structures (e.g., fibrous and adipose tissue, skeletal muscle, vasculature, etc.) should be categorized as posttraumatic.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Dog bite, before, 3 weeks and 11 weeks after 4 sessions of Spark Wave® therapy, a total of 3400 impulses were applied in 11 minutes and 20 seconds.

4.3 VENOUS ULCER

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm² level 10 membrane 8-10	350 pulses plus 20 pulses per cm²	7 - 14 days	not limited

1. General information
Venous ulcers are non-healing sores or wounds (shallow, exuding ulcer with diffuse edges, brown pigmentation, surrounding skin scaling) of the lower leg often located near the medial malleolus in patients with known incompetence of the perforating draining veins of the leg (with generalized affected limb edema) apparent by duplex ultrasound.

Spark Wave® therapy stimulates vessel ingrowth and production of growth factors but has no significant influence on the venous back flow. Usually venous ulcers do not respond as well as the other indications.

2. Site preparation
See 3.2 Site preparation for wound treatment.

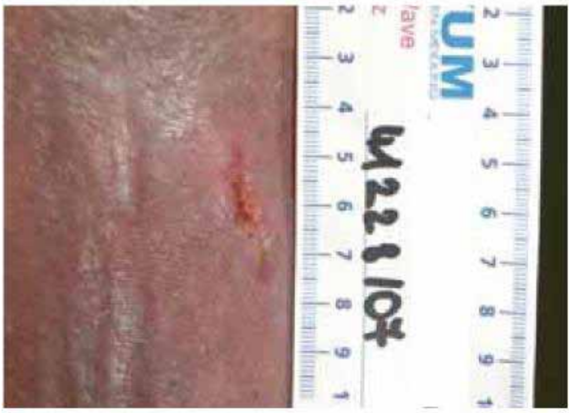
3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
A venous ulcer at the lower limb persisting for many years before, 236 days and 1.5 years after 14 sessions of Spark Wave® therapy with a total of 5500 impulses applied in 18 minutes and 20 seconds.



4.4 DECUBITUS ULCER

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
Decubitus ulcers are defined here as sores resulting from pressure exerted on the skin, soft tissue, muscle and bone by the weight of the patient against a surface beneath them.

Decubitus ulcers demonstrating partial-thickness loss of skin involving epidermis and dermis, or full-thickness loss of skin with extension into subcutaneous tissue, but not through the underlying fascia can be included.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Before, after 14 weeks and 2 years after Spark Wave® therapy. Weekly sessions were performed over a period of 6 months.

4.5 DIABETIC FOOT SYNDROME				
Applicator	**Energy flux density Energy level Membrane pressure**	**Number of pulses**	**Treatment interval**	**Total number of treatments**
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
Diabetic foot syndrome here is characterized as any diabetic related wound healing disturbance or delay.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Before, after 6 weeks and after 12 weeks and 6 sessions of Spark Wave® therapy using a total of 2300 impulses applied in 7 minutes and 40 seconds.

4.6 ARTERIAL ULCER

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
An arterial ulcer (deep with localized edema and shiny, hairless surrounding skin) is defined here by chronic, non-healing, distal limb ulceration in patients with known atherosclerotic peripheral vascular disease unable to receive revascularization due to medical co-morbidity or lack of suitable outflow artery in the affected extremity with ankle/brachial indices < 0.80 or toe pressure <50 mmHg.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Before, after 1 and after 2 sessions of Spark Wave® therapy using a total of 900 impulses applied in 3 minutes.

4.7 BURNS

Applicator	Energy flux density Energy level Membrane pressure	Number of pulses	Treatment interval	Total number of treatments
OP155	0,10 mJ/mm^2 level 10 membrane 8-10	350 pulses plus 20 pulses per cm^2	7 - 14 days	not limited

1. General information
Burn wounds are defined here as non-circumferential, deep, second-degree burns typically characterized by presence of blisters, mottled/patchy appearance, and diminished or no sensation.

2. Site preparation
See 3.2 Site preparation for wound treatment.

3. Treatment protocol
Spark Waves® should be applied to wound area and surrounding tissue.

4. Post-therapy care
Application of wound dressing according to current standards.

5. Monitoring / Follow-up therapy
Changes in wound size should be monitored. If no improvement in the wound size or appearance becomes visible after several sessions, consider alternative therapy.

6. Additional Information
See also [Lit 1, 2]

7. Case example
Before, after 4 weeks and after 7 weeks and 4 times Spark Wave® therapy with a total of 3000 impulses applied in 10 minutes of total treatment time.

5. ABSTRACTS

ESWT in Chronic Decubitus Ulceration in Complex Neurological Disability

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Device and producing company

DermaGold (USA), Tissue Regeneration Technologies (TRT),orthowave180 C (Outside USA), MTS Europe GmbH

Introduction

Skin ulceration in complex neurological disabilities is often chronic causing pain, risk of septicaemia and limitation of activities leading to a decreased quality of life. Chronic ulcers are also expensive in terms of nursing time and financial cost of treatment. We have previously described provisional findings of a study of ESWT on chronic ulceration. This paper presents the final findings of the study.

Methods

A randomised double-blind cross-over study, with washout period, of ESWT and a placebo ESWT was used. All patients in a large long-stay hospital specialising in chronic neurological conditions were eligible for inclusion in the study. Patients were randomised into treatment with ESWT first or with the placebo ESWT head first. Treatment periods were weekly for four weeks. There was a two week washout period between the two forms of 'treatment'. After six weeks the treatment methods crossed over. The machine used was the Orthowave 180c with two heads - one active and one inactive. The machine fired for both the ESWT and the placebo treatments thus the noise was the same for both treatment groups. The area and depth of the ulceration was recorded by tracing the outline of the ulcer onto an acetate sheet and measuring the area using a computerised grid System (Visitrak™ [Smith & Nephew]). For each observation the average of three measurements were taken.

Results

Fifteen ulcers (in 13 patients) were included in the study; eight were on the buttocks/sacrum/trochanter and seven were on the feet/ankles. Where there was some healing prior to the study (5) there was no evidence that the ESWT increased the rate of healing. Where there was small surface area ulceration but with a sinus present (3) there was no evidence of healing; but for those with static chronic ulcers all showed improved healing after the start of ESWT. Where the placebo head was used first there was no healing until after the ESWT treatment started. After the research period those with sinuses were treated using a different technique of ESWT and there was some evidence that healing began to occur though this needs further study under research conditions. Some patients showed deterioration in the size of the ulceration on starting ESWT. These were patients with undermined ulcers with vulnerable ischemic skin. There was then improved healing - thus the ESWT assisted debridement of the ulcers.

Discussion

It is uncertain why there was no effect of ESWT on those ulcers already showing healing, and this needs further study. The non-healing of the sinuses was probably due to the technique being used, and this needs further research. The main finding was that those ulcers that had not been healing prior to the study all improved, with some healing completely. Considering that some of these ulcers had been present for many months, or even years, this indicates that ESWT has a potential place in the treatment of chronic ulceration in people with complex neurological disabilities.

Conclusion

We were unable to demonstrate any benefit of ESWT on ulcers that were already healing or where there was a sinus present. In the latter case this was probably due to the technique being used. ESWT had a significant effect on healing of those ulcers that had not been showing any healing prior to the study.

Shock wave therapy to improve wound healing after vein harvesting for CABG

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Introduction
Wound healing disorders after vein harvesting for CABG are an evident clinical problem. Extracorporeal shock wave therapy (SWT) has been shown to improve wound healing in patients with diabetic and vascular ulcers. It remains uncertain if prophylactic application of SWT can improve wound healing after vein harvesting.

Methods
In order to study the effect of prophylactic SWT we performed a prospective randomized trial. Eighty consecutive patients undergoing isolated CABG were randomized to either prophylactic SWT (n=40) or no treatment as control (n=40). SWT was applied after wound closure at the end of the operation under sterile conditions. A total of 25 impulses (0.1mJ/mm^2; 5Hz) were applied per centimeter wound length. Wound healing was evaluated using the ASEPSIS Score on postoperative days 3-7. Patient demographics, operative data and postoperative adverse events were monitored.

Results
Both groups were comparable with regard to patient characteristics, operative data and postoperative adverse events. Wound length (SWT: 41±13 vs. control: 37±11) was comparable between the two groups (p=0.110). The asepsis score showed improved wound healing in the SWT group (SWT: 5.1 ± 5.6 vs. control: 9.7 ± 8.1, p=0.009). We observed no difference in use of antibiotics or in hospital stay. No adverse events were observed in the treatment group.

Conclusion
As shown in this prospective randomized study, prophylactic application of low energy extracorporeal shock wave therapy improves wound healing after vein harvesting for CABG.

Clinical Experience with ESWT in Sub Acute and Chronic Wounds

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Introduction
Sub-acute or chronic wounds of different aetiology represent a major problem not only for the patient but also for the social system. The Trauma Centre Meidling started treating wounds non-respondent to Standard care with ESWT in August 2004. An update from the clinical ESWT experience between 2004 and 2007 is given.

Methods
Patient study enrolment was done during routine clinical work between August 2004 and December 2007. Patients of both sexes with soft tissue wounds of different aetiology persistent longer than 1 month were included. The primary outcome measure was rate of wound closure. Secondary different correlation analyses (e.g. defect size, age, aetiology) were also done.

Results
As of December 2007, 350 patients had been treated with unfocused extracorporeal shock waves (male: 56%, female: 44%), primarily in an outpatient clinical setting. Mean age was 50.4 (SD 18.0) in males and 71.7 (SD 16.2) in females. Main wound location was the lower extremity, followed by the upper extremity. Aetiologically, wound healing disturbances (38.8%) and post-traumatic necrosis (28.9%) were most common. The overall complete healing rate was 69.2%. In addition, 5% of patients showed a healing rate greater than 50% and 2.1% of the patients a healing rate lower than 50% of initial wound size. The percentage of wounds that remained unchanged during ESWT (=non-healed) was 5.9%. The percentage of patients who missed follow-up was 23.7%. A correlation between greater wound size and non-healing wounds was found in the aetiology of disturbed wound healing, whereas in the venous ulcers this was not found. A correlation was also found between age of the patient and therapy responsiveness.

Conclusion

ESWT for sub-acute and chronic wounds that are partly non-responsive to standard of care shows clearly beneficial effects in terms of entire wound closure.

Accelerated Healing of IIa-Burns Under the Influence of ESWT

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Introduction

Musculoskeletal shockwave therapy increases blood flow in tissues and results in neoangiogenesis. In a study carried out on animals, enhanced tissue regeneration was observed in adipocutaneous flaps. The aim of our conducted clinical study was to demonstrate reduced duration of healing after shockwave therapy on IIa° burn wounds.

Methods

Material and Methods: We carried out a prospective, randomized non-blinded clinical study. Musculoskeletal shockwave therapy was applied within 24 hours post-trauma. Shockwaves with an energy level of 0.1-0.14 mJ/mm^2 were used. Fifty patients with superficial second degree thermal lesions (burns and scalds) were selected, twenty-five patients from this group received ESWT treatment, twenty-five patients served as the control group. All participating patients, i.e. patients given ESWT as well as those of the control group, received identical dressings made of perforated silicon layer (Mepitel®) in combination with polyhexanid. Main objective criterion was the time to complete re-epithelization, secondary objective criterion was the incidence of side effects. Results: Results: The group treated with ESWT resulted in a significantly shortened time of re-epithelization (minus 2.48 days) compared to the control group. No side effects were observed.

Discussion

The presently available publications discussing the positive effects of ESWT, especially on skin/soft tissue, underscore the results of our own study, in which a highly significant shortened period of re-epithelization of skin donor sites via ESWT could be verified. Because ESWT is still in its early stages as a treatment for chronic wounds and skin lesions, the actual mechanism is purely hypothetical.

Conclusion

Extracorporeal shock wave therapy is a new treatment option in terms of a supplementary method in the therapy of superficial second degree burn wounds (IIa°).

Blood flow perfusion and molecular response after ESWT in chronic skin ulcers

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Introduction

This prospective study evaluated the efficacy of extracorporeal shockwave treatment (ESWT) in chronic skin ulcers and compared with hyperbaric oxygen therapy (HBO), and investigated the antibacterial and regeneration effects.

Methods

105 patients with 112 chronic skin ulcers were randomly divided into two groups. There were 60 patients with 67 ulcers in the ESWT group and 45 patients with 45 ulcers in the HBO group. Both groups showed similar demographic characteristics. Patients in ESWT group received shockwave treatment, whereas patients in HBO group received HBO therapy. Blood flow perfusion culture and sensitivity and biopsy were performed before and after treatment. The evaluations included clinical assessment, blood flow perfusion scan bacteriological study, histomorphological examination, and immunohistochemical analysis.

Results

The overall results showed: completely healed in 39%, improved in 51% and unchanged in 10% for the ESWT group; and 18% completely healed, 51% improved and 31% unchanged for HBO group (P = 0.007). ESWT group showed significantly better blood flow perfusion and considerably more active cell proliferation and concentration than HBO. On immunohistochemical analysis, ESWT group showed significant increases of eNOS, VEGF and PCNA expressions and decreases of TUNEL expression over the HBO group. The culture results revealed significant decreases in bacteria growth after treatment, but no difference was noted between the two groups.

Discussion

ESWT is more effective than HBO in treating chronic diabetic skin ulcers. ESWT significantly improves blood flow perfusion associated with increased angiogenesis, increasescell proliferation and decreases cell apoptosis.

Conclusion

ESWT is effective for treating chronic diabetic ulcers. The application of ESWT results in increased angiogenesis with improved blood flow perfusion molecular responses and tissue regeneration in chronic skin ulcers.

How many shockwaves are enough? Dose-response relationship in ischemic challenged tissue.

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Introduction

Recently, we showed beneficial effects of extracorporeal shock wave therapy (ESWT) on ischemic challenged tissue. We were able to show that ESWT improved flap outcome irrespective of application time (elective treatment 24h preoperatively, 1h postoperatively or treating manifest ischemic tissue 24h postoperatively). In the current study we investigated flap outcome in respond to various total amounts of impulses.

Methods

In the ischemic area of a rodent epigastric flap, different amounts of total shock wave impulses were applied (30, 300, and 1,000) which corresponds to 1.4, 14, and 47 pulses/cm2, respectively. Parameter of effectiveness included planimetry (necrosis, shrinkage), flap perfusion (assessed by 2-D laser Doppler imaging), and immuno-histochemistry over a 7 day follow-up period.

Results

All shock wave treated groups showed substantial reduced tissue necrosis compared to control. Looking at the total amount of pulses within treatment groups, animals receiving 300 impulses showed the best results (less necrosis). Neither lower nor higher amounts (30 and 1,000, respectively) further improved flap outcome. No significant differences were found in the perfusion and immuno-histochemical parameters.

Conclusion

ESWT in soft tissue complications such as ischemia has clear beneficial effects. A dose response relationship was found in reducing tissue necrosis.

ESWT to improve the outcome of complex non-healing leg and foot ulcers

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Introduction Unfocused, low energy Extracorporeal Shock Wave Therapy (ESWT) has been shown to be a feasible treatment option in acute and chronic non-healing wounds with complete healing rates of up to 75%. We report our preliminary experience with soft-focused low energy ESWT in complex non-healing leg and foot ulcer patients.

Methods

Retrospective analysis of 22 patients (mean age 73±13.6 years) with 30 complex non-healing (mean 104 weeks; max 1,382 weeks) leg or foot ulcers treated by ESWT from July 2007 to February 2008. Etiologies were: arterial (n=11), venous (n=5), mixed arterio-venous (n=4) and other (n=9) such as rheumatic, postoperative, posttraumatic and of unknown etiology. Seven of 30 wounds were infected, 11 of 30 associated with diabetes and 5 of 30 with immunosuppressive therapy. Twenty-nine of 30 wounds were chronic and non-healing despite adequate local therapy and treatment of underlying disease. One diabetic patient suffered from subacute osteomyelitis. The device was used at an energy level of 0.09 mJ/mm^2, 4 pulses/sec. Chosen treatment dose was 100 pulses/cm2. Accordingly, 300 to 3,000 pulses were applied based on wound size initially weekly, then every one to three weeks according to the clinical response. Thorough debridement was carried out either before or after ESWT and the wounds were treated after the principles of phase adapted moist wound healing.

Results

Nineteen of 22 patients (26 of 30 wounds) completed all proposed sessions. Three patients (13.6%; 4 of 30 wounds) withdrew because of pain, inflammatory reaction of periwound tissue or unknown reasons, respectively. Of the remaining 26 wounds, 7 (29%) were completely healed, 14 (58%) improved and 5 (13%) were non-responding to ESWT. Possible reasons for non-responding were: 2 skin cancers (1 proved, 1 unproved due to patient denial of biopsy), 1 gadolinium associated nephrogenic dermatofibrosis, 1 lymphedema, and 1 infection of Achilles tendon. Average wound size in the 21 (87%) responding wounds decreased from 4.2 ± 5.07 cm2 to 1.6 ± 3.09 cm^2.

Discussion

Healing was induced in 21 of 26 (87%) non-healing wounds after treatment with ESWT.

Conclusion

ESWT is a valuable treatment tool for complex non-healing wounds with a high responder rate. However, RCTs are needed to definitely prove its efficacy.

Summation of the Experiences Using Defocused ESWT for Chronic Skin Lesions in the Trauma Center Meidling

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Introduction

Treating complicated soft tissue wound conditions (delayed/non-healing wounds) is extremely challenging but extracorporeal shock wave therapy seems to have great potential in this field. We present the annual, almost traditional, update from our clinical ESWT experience between 2004 and 2008.

Methods

Patient study enrollment was done during routine clinical work between August 2004 and December 2008. Patients of both sexes with soft tissue wounds of different etiology persistent longer than 1 month were included. The primary outcome measure was rate of wound closure. Secondarily, different correlation analyses (e.g. defect size, age, etiology) were performed.

Results

Through December 2008, 390 patients were treated with unfocused extracorporeal shock waves (male: 57%, female: 43%), primarily in an outpatient clinical setting. Mean age was 57.8±20.2 (2008: 50.4±18.0) in males and 61.6±19.2 (2008: 71.7±16.2) in females. As found in the analysis of 2008, the main wound location was the lower extremities (lower leg: 44.6%; foot: 13.9%) followed by the upper extremities. Patients who were treated due to wound healing disturbances (39.5%) and posttraumatic necrosis (31.3%) were most common, as they were last year, but percentages showed a slight increase over last year. In total 72% of the wounds treated with ESWT healed completely (2008: 69%). We were also able to see a slight decrease in non-respondent wounds (5.3% in 2009 vs. 5.9% in 2008). Fortunately, the percentage of patients who missed follow-up also decreased to 15.4% (23.7%

in 2008). The mean of ESWT sessions was 2.9 times with a range from 1 to 15 sessions in total. The mean of total amount of applied pulses was 1,483 (range from 100 to 44,700). The healing time for wounds successfully treated with ESW was a mean of 43.8 days (±45). In recent analysis a correlation was found between greater wound size and non-healing wounds, as was found in 2008. Again, a correlation was also found between age and therapy responsiveness. The older the patient, the worse the prognosis of outcome with ESWT. First experiences (long term follow-up) with wounds which are healed in response to ESWT show smooth, good relocatable scars. In addition, in treating hypertrophic, algetic scars with shock waves we observed scar reduction concomitant with quality improvement and patient report of pain reduction.

Conclusion
ESWT shows consistently excellent results in treating sub-acute and chronic wounds which are partly non-responsive to standard care.

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