

Extracorporeal Shock Wave Technology - New Approach to Treating Diabetic Ulcers: 18 - Month Follow Up



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Purpose & Hypothesis:

For musculoskeletal indications, the mechanism of action is often attributed to increased vascularization, growth factor expression and long term neoangiogenesis. These mechanisms of action are also associated with wound healing, and recent animal studies have supported similar safety and efficacy of **Extracorporeal Shock Wave Technology (ESWT)** in wound treatment indications. ESWT studies on skin flap survival reported a reduction of skin necrosis in flaps and a significant increase in neoangiogenic growth factors.

Shock waves are defined as **sonic pulses**. They consist of transient pressure fluctuations with three-dimensional spreading. Most recently the initial healing effects of ESWT on chronic leg ulcers in diabetic patients has been presented, but no long term follow up has been reported.

Patients and Methods:

The **diabetic population** (n=11) included 6 females and 5 males with an average age of 78 years (62-93 years).

2 ulcers were diagnosed with CVI, 4 ulcers followed trauma and 10 patients had peripheral arterial disease (PAD).

Ulcers were located on the **lower leg (n=7)** and on the **foot (n=4)**.

Ulcers existed for 289 days on average (7-1500 days). All patients had undergone unsuccessful "modern wound management" for 203 days on average (7-1100 days) before ESWT, which was continued after ESWT treatment. Osteomyelitis was excluded.

The average wound size was 1.7 cm² (0.3-3.9 cm²).

ESWT treatment was performed on days 1, 4, 8, and 11 for a total of **4 ESWT treatments**. Treatment was **painless** because of the peripheral polyneuropathy. Offloading of the mechanical forces on ulcers was achieved by half shoes.



Results:

No adverse events

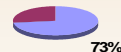
Within 36 days on average (13-59 days)

- eight wounds (72.7 %) **healed completely**

- three showed an average of 64.6 % closure during eight weeks observation

- **no recurrence** was seen during an average follow-up of 18 months (3-28)

Total wound closure within 36 days



Pat.	Sex	Age	History of Trauma	Location	Wound Size (cm ²)	Wound Depth (cm)	Wound Duration (days)	Wound Type	Wound Size (cm ²)	Wound Depth (cm)	Wound Duration (days)
1	F	78	4 x 0.500 Hz	Leg	2.0	0.5	100 days	Healed	0	0	0
2	F	78	4 x 0.500 Hz	Leg	0.2	0.2	100 days	Healed	0	0	0
3	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
4	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
5	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
6	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
7	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
8	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
9	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
10	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0
11	F	78	4 x 0.500 Hz	Leg	0.5	0.5	100 days	Healed	0	0	0



pat. 6
after 86 days of wound management



2 months after ESWT



2 years after ESWT



after 100 days of wound management



2 weeks after ESWT



1 year after ESWT

Conclusion:

ESWT has already been used successfully in the treatment of urologic and orthopedic disorders; it might prove its value in chronic **soft tissue wounds** in patients with **diabetes**. In diabetic ulcers, healing improved after ESW. Although further studies are needed to confirm these promising findings, this approach may be a feasible treatment to support established wound management in many patients.