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# ESW-Therapy in diabetic foot ulcers

Extracorporeal ShockWave Therapy (ESWT) has been used since 1990 in various orthopaedic and emergency surgical treatments. Schaden et al. reported successful application of shockwave therapy for wound treatment, starting from 2005 and publishing their results in 2007.<sup>1,2</sup> In the same year, a comparison study between ESWT and HyperBaric Oxygen (HBO) therapy was disclosed, which showed unequivocal advantages of ESWT.<sup>3</sup> The goal of this research study is to investigate the impact of ESWT on the healing process of diabetic foot ulcers.

## Methods

Between July 2007 and April 2008, 18 patients (six females and twelve males) affected by 21 ulcers in IA or IIA stage (according to the Armstrong scale) were treated by ESWT. Patients were 60 years old in average (39 to 83 years of age). The wounds had been observed for more than six weeks. In nine cases the wounds were located in non-loaded areas, such as the edge of the foot, or appeared after previous toe amputation. In twelve cases

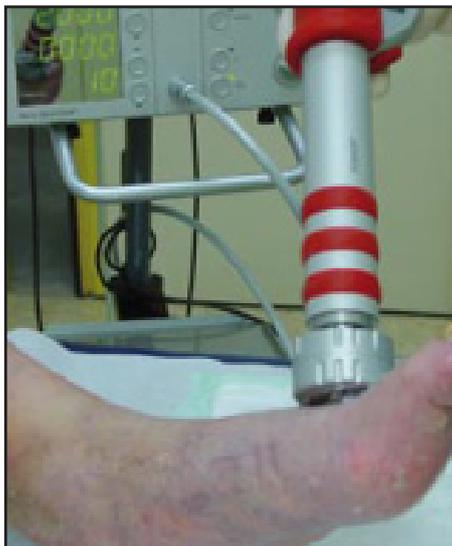


Fig. 1. Use of ESWT: after sterilisation and debridement, the wound is covered with sterile drape, gel is applied and the hand-piece is put into place.

the wounds were located on the sole, the toes or the heel; in these cases the average diameter of the wounds was 351 mm<sup>2</sup> (116 to 599 mm<sup>2</sup>). The patients affected by wounds in load-carrying areas were provided with relief shoes, whereas a full-contact-cast therapy was not considered. Local wound treatment consisted of regular debridement by scalpel, followed by disinfection with sterile saline solution and application of wet treatment adequate to the stage of the wounds. Depending on the amount of secretion, the depth of the ulcer and the healing stage, the following bandage materials were used: Mepitel® (Mölnlycke) on four wounds, Mepilex® (Mölnlycke) on twelve



Fig. 2a: 63 year old patient with a 367 mm<sup>2</sup> 1A-stage (Armstrong scale) ulcer before ESWT.



Fig. 2b: State of the ulcer after two ESWT sessions, at the end of week 2 of the treatment. The surface of the wound was reduced to 49%.



Fig. 2c: Completely healed wound after seven weeks.

wounds, Auquacel® (Convatec) on two wounds, and Suprasorb X® (Lohman-Rauscher) on three wounds.

In addition to standard wound therapy, ESWT was applied (EMS Swiss Dolor-Clast®) at intervals depending on the size and the depth of the ulcers, once or twice a week for three to six weeks; 1,000 impulses per cm<sup>2</sup> at 0.1 mJ/mm<sup>2</sup> were delivered in each session. Ulcers were then covered with sterile drape (Opsite, Smith & Nephew) in order to avoid direct contact of gel and handpieces with the ulcers. After further disinfection with sterile saline solution, bandage was applied. The state of the ulcers was photographically documented at regular intervals and

the size of the ulcers was digitally calculated using WHAT®. Wounds were evaluated after the first, second and third week. Observation was interrupted either after wound healing or when no progress whatsoever was detected in wound healing after three weeks, or after surgical wound closure with gap tissue covering after adequate granulation tissue formation for deeper ulcers.

**Results**

The extracorporeal shockwave treatment caused no pain to patients. Throughout the observation period, for a maximum of nine weeks, no local or generalised infections appeared. After nine week at most, on average after week 6 (after week 3 to 9), 16 of 21 wound healed. In three cases, sufficient granulation tissue was formed after eight weeks in average, which allowed for wound covering by gap tissue transplant. In two cases no significant improvement in wound healing was detected. On average, the size of the ulcers was reduced to 67% (20-100%) after week 1, to 53% (15-90%) after week 2, and to 35% (9-78%) after week 3 when compared to initial values (see table).

**Discussion**

In 2007, Schaden et al. reported a 74% healing rate out of 104 total wounds treated with ESWT. In 15 patients with chronic arterial ulceration the rate was 67%<sup>1</sup>. In their prospective randomised study, Wang et al. reported a 31% healing rate with a 58% improvement rate for ulcers subject to ESWT within six weeks<sup>3</sup>. Such rates are higher than the observed rates for the wounds in the control group subject to HBO therapy, which showed complete healing in 22% of the cases and improvement in 50% of the cases. The results of the present research study show further improvements when compared to either of the mentioned studies. Out of 21 diabetic ulcers

that were treated with ESWT, 10 were healed (48%) after six weeks, while other six (29%) showed reduction down to 39% of their initial size. No effect on the healing process was detected by Schaden et al. in 7% of the cases, by Wang et al. in 11%, by the present author in 10% of the cases. Not only did Wang et al. find better clinical results using ESWT, but also higher local blood perfusion, improved cell proliferation, and changes in immunohistochemical assays. Such effects and mechanisms had already been postulated by Schaden after his first successful ulcer treatment. Therefore, ESWT was more effective than HBO under direct comparison when applied to diabetic ulcer treatment. A further advantage of ESWT is that treatment is possible with a lower effort. Treatment sessions last seven minutes on average. Neither hospitalisation nor any sort of anaesthetisation is required. At the moment we are not able to provide statistical experimental proofs of quicker wound healing under ESWT application when compared to standard therapy, as no randomised study has been disclosed yet. However, in the present study only ulcers were investigated that had already been treated for over six weeks using standard therapy. Subjective opinions from the patients expressed only favourable assessment after ESWT application, in view of quicker wound healing progress and therapy tolerability.

	Age	Armstrong-Scale	Woundsize				Results healed (Weeks)
			Before ESWT (mm <sup>2</sup> = 100%)	Week 1 (%)	Week 2 (%)	Week 3 (%)	
01	71	2A	560	100	90	78	-
02	63	2A	367	54	51	39	7
03	56	1A	206	20	15	9	4
04	83	2A	251	90	75	22	5
05/1	56	2A	274	57	47	32	6
05/2		1A	298	81	69	24	6
06	39	2A	116	59	37	18	5
07	52	1A	262	79	63	39	SH
08	52	2A	599	71	62	35	8
09	59	1A	279	66	52	41	9
10	62	1A	199	90	85	56	5
11	60	1A	298	69	51	39	SH
12/1	79	1A	430	83	69	48	7
12/2		1A	223	30	13	31	4
13	71	1A	345	59	47	33	SH
14	58	1A	141	78	47	21	5
15/1	41	1A	329	51	27	19	6
15/2		1A	241	61	49	25	8
16	72	1A	395	71	62	48	-
17	63	2A	311	59	36	20	6
18	44	1A	195	79	57	28	7
<b>Total 60 (39-83)</b>			351 (116-599)	67 (20-100) (15-90)	53 (9-78)	35	

Table: patient age, wound assessment according to the Armstrong scale, size of wound (mm<sup>2</sup>) before ESWT, wound size in % on the initial size after weeks 1, 2 and 3, final result (SH = gap tissue transplant).

**Conclusion**

The application of extracorporeal shockwave therapy (ESWT) is a low-effort and effective complement to standard therapy in diabetic foot ulcers without signs or infection or ischemia. Patients are extremely satisfied by the good tolerability and absence of significant side effects.

*Bibliography:*

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- <sup>3</sup> Wang CJ, Kuo YR, Wu RW, Liu RT, Wang FS, Yang KD: *Extracorporeal Shockwave Treatment for Chronic Diabetic Foot Ulcers. J Surg Res 2008; 144: 50-56.*