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Extracorporeal shock waves, a new non-surgical method to treat severe burns

A. Arnó *, O. García, I. Hernán, J. Sancho, A. Acosta, J.P. Barret

Department of Plastic, Aesthetic and Reconstructive Surgery and Burn Center Vall d'Hebron University Hospital, Autonomous University of Barcelona, Passeig de la Vall d'Hebron 119-129, 08025 Barcelona, Spain

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ABSTRACT

Extracorporeal shock wave treatment (ESWT) increases perfusion in ischaemic tissues, stimulates growth factors, decreases inflammation and accelerates wound healing. It is a safe technique classically used in urology and orthopaedic surgery with success, but there is still limited literature regarding its use in the management of burns.

Purpose: The aim of this study is to analyse the effect of ESWT on deep partial/full thickness burns in patients attended at our emergency burn unit.

Materials and methods: We performed two ESWT sessions in 15 patients with <5% TBSA (total body surface area) deep partial/full thickness burns, on the third and fifth day after injury; prior to each session, we used laser Doppler imaging (LDI).

Results: Of all treated burns, 80% healed uneventfully prior to 3 weeks; as many as 15% required surgical debridement and grafting and 5% developed hypertrophic scarring. After one ESW session, burns had a significant increase in perfusion, objectivated by the LDI images.

Conclusions: Extracorporeal shock wave therapy emerges as a new non-invasive, feasible, safe and cost-effective method in deep partial/full thickness burns. It may decrease the need of surgery and therefore the morbidity of the patient. There is a strong need for more studies to establish the optimal timing and dosage of treatment.

Extracorporeal shock wave therapy (ESWT) promotes angiogenesis [1], increases perfusion in ischaemic tissues [2], decreases inflammation [3], enhances cell differentiation [4] and accelerates wound healing [5]. It was first described to treat urolithiasis [6], but its use rapidly spread to orthopaedics, where ESWT shows efficacy in treating nonunion fractures, tendinopathies and osteonecrosis [7]. More recently, further research is ongoing in the field of cutaneous wound healing.

Nowadays, non-invasive or minimal surgical treatments are preferred for the majority of plastic surgery patients, including those affected by burns. Burn surgery often leaves important functional and aesthetic sequelae, which greatly discomfort patients and reduce their quality of life. Research on nanotechnology, biomaterials and biophysics in general is bringing new and non-invasive tools to help physicians to plan their surgeries best. Laser Doppler imaging (LDI) represents one of the earliest and more feasible methods to more accurately diagnose burn depth in a non-invasive way. Developing a new non-invasive device to successfully treat burns with efficacy and safety, producing fast and good long-lasting results, without surgery and morbidity, still seems to be an unrealistic goal. However, ESWT appears to shed some light on this issue. ESWT employs a kind of acoustic energy at low intensities to improve the healing of chronic wounds; at higher doses, it serves to treat fracture nonunions. ESWT represents a mechanical stimulus to exert a biological effect. Low-energy therapeutic acoustic pressure waves may promote wound healing by optimising the cellular and molecular

* Corresponding author. Tel.: +34 934893000.
E-mail address: aiarno@vhebron.net (A. Arnó).
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microenvironments, particularly the local chemokine landscape [3]. One report discusses the efficacy of shock waves on long-term pain relief and hyperstimulation analgesia [8]. Preliminary studies suggest that unfocussed low-ESWT is a feasible and safe modality for a variety of difficult-to-treat soft tissue wounds, particularly post-traumatic and postoperative wounds, decubitus ulcers and burns [9].

An experimental study showed that ESWT suppresses the early pro-inflammatory immune response to a severe burn injury in a murine model [3]. There are many references about the healing effect of clinical application of ESWT in cutaneous ulcers, but only a few (to our knowledge, three) articles relating to burns. One is an anecdotal case report [10] and the others included seven [11] and five [12] burns in 176 and 104 miscellaneous skin lesions; all burns treated with ESWT re-epithelised. Bolstered by all these promising results of ESWT in wound healing, but not discouraged by the lack of literature regarding its application in human burns, the aim of this study is to evaluate and analyse the effect of ESWT in treating deep partial/full thickness burns in patients attending our emergency burns unit.

1. Materials and methods

We performed a clinical, observational, prospective and pilot study including 15 patients – 10 males and 5 females – attended at the emergency burns unit of the Plastic Surgery Department at Vall d'Hebron University Hospital, Barcelona, with acute deep partial/full thickness burns (second intermediate and deep ones) affecting less than 5% of their total body surface area, between January and May 2009.

1.1. *Exclusion criteria*

Exclusion criteria were all paediatric patients and pregnant women, patients with coagulopathies or cardiac pacemakers and burns located in the genitalia, thorax, face or neck regions. Patients with current participation in another clinical investigation of a medical device or a drug, the requirements of which preclude involvement in the current study, and those with active or previous (within 60 days prior to the study screening visit) systemic chemotherapy and/or radiation therapy were excluded. Patients with physical or mental disability or geographical concerns that would hamper compliance with required study visits were also excluded.

Our study protocol was approved by the Ethics Committee of the Vall d'Hebron Hospital and Vall d'Hebron Research Institute.

This non-invasive study was carried out in patients who enrolled voluntarily, in accordance with the guidance of the Research Institute of Vall d'Hebron Hospital Ethics Committee. Subjects gave written informed consent.

1.2. *Methods*

On the day of the injury, we applied semi-occlusive treatment (Mepilex® Ag, Mölnlycke Health Care, Norcross, GA, USA) on the burn. On the third and fifth day after burn, we visited the patient at the outpatient burn clinic and applied an unfocussed and low-energy ESW treatment (500 impulses at 0.15 mJ mm^{-2}). Before each of the two ESWT sessions, we performed LDI of the burn (Moor Instruments™, Devon, UK), which combines laser Doppler and scanning, to exactly diagnose the burn depth and to objectively assess any perfusion changes. During the study, the burn treatment was always kept the same (Mepilex® Ag).

We applied the ESWT treatment sessions on the third and fifth days after injury, essentially for two reasons: (1) Ideal timing to perform LDI: although there is still ongoing research on this field, there is a 95% and 97% reported accuracy in the assessment of burn depth with LDI on the third and fifth day after burn, respectively, compared with 52.5% and 71.4% for clinical evaluation [13]. Moreover, Doppler imaging is the only technique that has been shown to accurately predict wound outcome with strong evidence [13]. (2) Suitable dressing changes and patient compliance: much less important, Mepilex® Ag should be changed every 72 h, which is a reasonable treatment guideline easy to accomplish and comfortable for the patients. Apart from that, we wanted to guarantee patient study and treatment compliance by reducing the hospital visits to just the needed ones. So, when designing the treatment protocol, we kept in mind all these factors and decided to focus all the main and basic tool measurements on 3 days: day 0, 3 and 5 after burn.

Afterwards, the patients were treated in the outpatient clinic. Subjects were reviewed weekly for 1 month, and then once a month. The progress of burn wound healing was assessed using digital photography and measuring burn wound length, width and surface area. The rate of epithelialisation was carefully documented. If we observed no burn re-epithelialisation before two-and-a-half weeks afterburn despite the two ESWT sessions, we decided to operate before the third week and perform a debridement and split-thickness skin graft. However, in older or high surgical risk patients, due to its medical basal conditions, we preferred to wait till the third or even the fourth week.

ESWT was administered by different plastic surgeons of our burns unit, in sterile conditions, on an outpatient basis and without anaesthesia or antibiotics. We placed the ESWT applicator head over the non-debrided burn wound, using ultrasonic gel and plastic draping to prevent any cross-contamination of the device. The current study protocol used 100 shocks per 1 cm^2 of the wound; so the treatment lasted just 1–2 min. The entire procedure took a mean of 5 min. Because of ESWT's direct microtraumatic effects, the possibility of bleeding, petechiae, haematoma and/or seroma formation and painful sensation was documented. The visual analogue scale (VAS) for self-assessment of pain measurement was administered to the patient to quantify the painful sensation before, during and after the treatment session and to evaluate improvement of the pain threshold. This is a 0–10 scale; it consists of a horizontal or vertical 10 cm line with word anchors at the extremes, such as 'no pain' at 0 and 'pain as bad as it could be' at point 10 [14,15].

We took a digital photograph of the burn and the LDIs before and after the ESW treatment. We used a dermaPACE™ (Pulsed Acoustic Cellular Expression™, Sanuwave™, Lengwil, Switzerland) device, which is a refined form of ESWT device.

Table 1 – Patients and burns data.

Age (years)	N/Sex	Burn location	TBSA (%)	Burn etiology	Burn depth[a]
28	1/M	L hand (first web)	0.25	Flame	DP/FT
29	2/M	R hand	1.5	Flame	DP
41	3/M	B hand	4.5	Flame	DP
47	4/F	L Knee	1	Flame	DP/FT
36	5/F	R hand (first web)	0.4	Scald	DP/FT
48	6/M	L foot	0.5	Scald	DP/FT
31	7/M	B hand and wrist	0.5	Scald	DP
33	8/F	R hand(2nd finger)	0.3	Scald	DP/FT
26	9/M	R leg	2.5	Flame	DP/FT (Lost)
34	10/M	L hand + forearm	2.5	Scald	DP
53	11/F	R + L foot	1	Scald	DP/FT
18	12/M	R hand	0.5	Scald	DP/FT
38	13/M	L hand	0.5	Flame	DP/FT
31	14/M	L forearm	4	Flame	DP/FT
42	15/F	R hand + forearm	1	Flame	DP

M: male; F: female; L: left; R: right; B: bilateral; DP: deep partial; FT: full thickness.
[a] According to Laser Doppler Imaging.

2. Results

Of the patients initially enrolled in the study, one was lost due to extramedical reasons. The rest of them, except two, healed uneventfully without surgery, on an average after 15 days (see Table 1). These two cases were young adults with deep burns on their hands, including zones of third degree.

Doppler imaging was used to determine the acute perfusion levels of each burn lesion. It is important to note that all burns were initially deep enough to require surgical treatment, as the first LDI diagnosed. After one ESW session on the third day after injury, burns had a significant increase in acute perfusion, objectified by the laser performed on the fifth day (see Illustrations 1–4). On the outpatient clinics' routine visits, we observed a progressive decrease of deeper wound zones in favour of an increase size of superficial areas. Most wounds achieved spontaneous healing prior to 3 weeks after burn (see Table 2). Two cases of full-thickness burns located on the dorsum of the hands were not re-epithelialised by day 18; due to the scarce improvement seen on the second LDI compared with similar burns of other patients, and the functional and aesthetic relevance of the anatomical location of the lesions, in those two cases we preferred to perform surgical debridement and grafting with a sheet split-thickness skin graft on the 21st day after injury. One of the two grafted burns located at the left first web developed mild hypertrophic scarring.

Patients tolerated ESWT well without any adverse side effects; we found no bleeding, petechiae, haematoma nor seroma. The most sensation the patient noticed was the sound of the ESWT machine as it generates the shockwaves and bright flashes of light that correspond to those waves. Just three in 15 patients referred some pain during the treatment, but all VAS scores remained below 3.

Throughout the course of this pilot study, none of the wounds was infected nor did the wounds deteriorated with ESWT. Moreover, they did not contract more than expected.

After burn healing, all patients were told to use hydrating cream and silicone sheeting or pressure therapy. Since the beginning of treatment, the resulting burn scar was not

Illustration 1 – Case 1: Deep partial/full thickness burn on the dorsum of the hand (day 0 postburn).

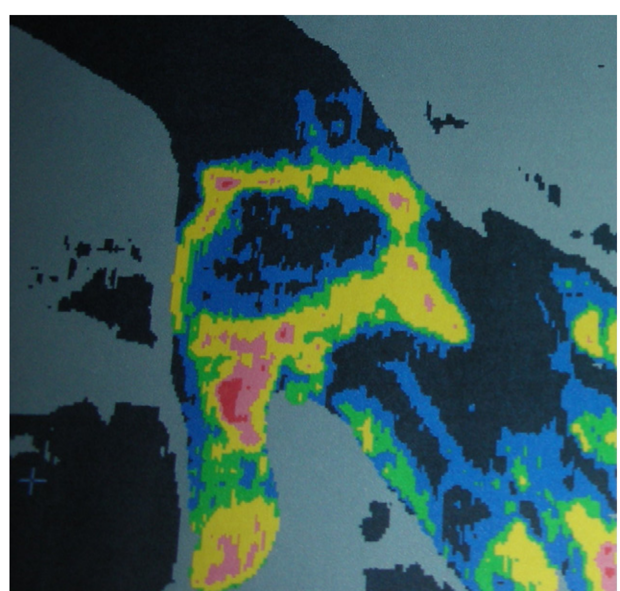

Illustration 2 – Case 1: Third day postburn (LDI + ESWT).

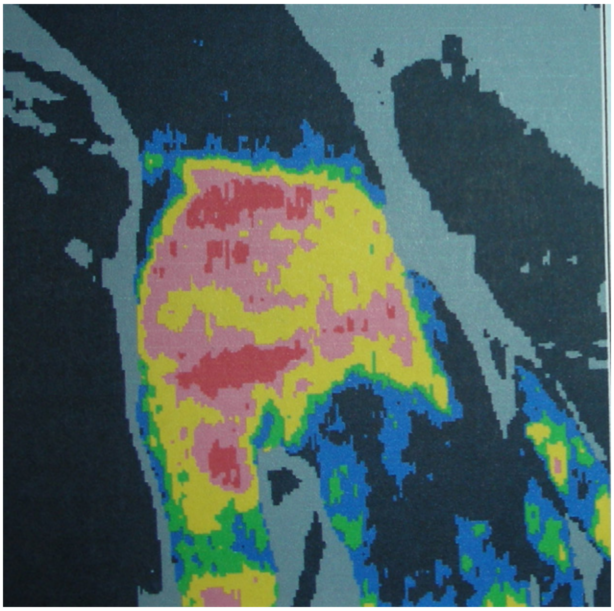

Illustration 3 – Case 1: Fifth day afterburn (LDI post-ESWT).

Illustration 4 – Case 1: Three weeks afterburn.

pruritic nor painful in 75% of the cases; hypertrophic scarring developed in 5% of the patients.

3. Discussion

ESWT emerges as a new non-invasive treatment method for deep partial-thickness burns. To our knowledge, this is the only study with the highest number of burned patients currently described using ESWT. One clinical case report and two clinical studies of 176 and 104 patients with skin lesions including seven and five burns found complete and fast re-epithelialisation after two and three sessions of ESWT, respectively. In the first study [10], the burned area was treated on days 3 and 7 after-trauma with 1500 impulses at 0.11 mJ mm^{-2}; by 15 days after injury nearly the whole wound was re-epithelialised; a 6 months follow-up revealed an uneventful healed wound without scarring. The other study describes the use of low-energy flow-density ESWT in 104 miscellaneous skin lesions, including five burns, with 100–1000 impulses in a weekly or biweekly interval; all burns healed [12].

The third study is a phase II trail of ESWT for acute and chronic soft tissue wounds in 176 patients, seven of them affected by burns. They applied an average of three ESWT weekly or every other week (DermaGold^{TM}, TRT, Tissue Regeneration Technologies, Woodstock, Georgia, 0.1 mJ mm^{-2}, 100–1000 pulses per cm^2). The authors appreciated a better healing effect in smaller and less chronic lesions. Burned patients re-epithelised before 19 days [11]. In contrast to these findings, in our study we did not find correlation between burn size and ESWT healing effect. We applied the ESWT treatment sessions on the third and fifth days afterburn, because at the same time we obtained LDIs of the burn; to our knowledge, these offer the best way to use this useful burn depth diagnostic tool [13]. On the second LDI, we objectively assessed an improvement of blood supply to the burn, and we observed spontaneous re-epithelialisation mostly prior to 3 weeks. It is important to point out that there are no decisive published results that

Table 2 – Patients and wounds outcome data.

No.	1st LDI	2nd LDI	Spont.healing/time	Wound contracture
1	Blue	Blue-Green	No	Yes (on skin graft): ++
2	Blue	Yellow	Yes/18 d	No
3	Yellow	Red	Yes/14 d	No
4	Blue	Yellow	Yes/17 d	No
5	Blue	Red-Yellow	Yes/13 d	No
6	Blue-green	Green-Yellow	Yes/18 d	No
7	Yellow	Red	Yes/12 d	No
8	Yellow	Red	Yes/12 d	No
9	Green-Blue	? (Lost)	?(Lost)	?(Lost)
10	Yellow	Red	Yes/11 d	No
11	Blue	Green	Yes/29 d	No
12	Yellow-Green	Red	Yes/10 d	No
13	Green	Green	No	No
14	Green	Yellow	Yes/16 d	No
15	Yellow	Red	Yes/17 d	No

Spont.: spontaneous; d: days to reach spontaneous healing.

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can suggest the optimal time, frequency and dose of ESW treatment [16]. There is one experimental study in rats about flap survival enhanced by ESWT, but more so when just applied once postoperatively, and not when repeating a second dose on the day after [17]. In treating diabetic skin ulcers, there are papers reporting a beneficial effect of EWST in wound healing applied on several sessions (on an average over 4 days) [18]. There are not enough studies in burns to know the best time to apply ESWT. Apart from the optimal dosage and intervals of treatment, there is also no consensus on the optimal amount of energy required. For instance, in one study performed in rats, only low-energy ESWT (no more than 200 impulses) was effective to repair tendon tissue; on the contrary, in humans higher energies are required to obtain the same effect [7].

Moreover, another issue to be considered is the need of focussed or unfocussed shockwave [6]. The International Society for Medical Shockwave Treatment (ISMST) recommends using a high-energy focussed shockwave device to treat bone ailments; however, to treat superficial soft tissue conditions, devices with or without focussing technology may be used [19].

Shock waves are acoustic waves, which accompany our daily life without being noticed. The exact mechanism of action of ESWT is still unknown [20]. It seems that ESWT represents a mechanical stimulus to exert a biological effect. Other hypothesis include endothelial nitric oxide synthase (eNOS) [1] and/or heat shock protein (HSP) increase [21].

More recently, the modulation of oxygen radicals, attenuation of leucocyte infiltration, decrease in tissue apoptosis, recruitment of skin fibrobasts [17] and an increase in transforming growth-factor β1 (TGF-β1) and insulin growth factor-I (IGF-I) [7] have been postulated vias, known to enhance flap tissue survival or promote tendon regeneration. Meirer et al. [22] conclude that the success of the shock wave treatment may partly be due to the modulation of growth factor expression.

It has experimentally been proved that ESWT increases vascular endothelial growth factor (VGEF), eNOS and proliferating cell nuclear antigen (PCNA), enhances perfusion to ischaemic tissues (myocardial and skin flaps) and stimulates angiogenesis [1]. It also diminishes inflammation [3]; ESWT suppresses the inflammatory response and increases tissue perfusion, which is responsible for rescuing ischaemic flap zones. A recent study states that ESWT suppresses the early pro-inflammatory immune response to a severe cutaneous burn injury in mice [3]. They showed that applying unfocussed, low-energy (200 impulses, 0.1 mJ mm^{-2}, 5 pulses per second) ESWT to burn wounds 1 h post-injury significantly blunts polymorphonuclear neutrophil and macrophage infiltration into the wound, and attenuates acute pro-inflammatory cytokine expression and extracellular matrix proteolytic activity at the wound margin. Although the onset of inflammation is a requisite part of healing, excessive production of mediators of inflammation following burn, specially proteases and oxidants, can cause additional capillary endothelial and skin damage. Clinical studies in humans showed that ESW increases microcirculation in lower-leg chronic ischaemia [23], improves myocardial perfusion in patients with severe coronary artery disease [24,25], decreases pain and calcinosis and enhances re-epithelialisation in CREST syndrome and chronic leg ulcers [9,11,25]; it may revert bone vascular disorders such as osteonecrosis [1,26] and may have a bactericidal effect against *Staphylococcus aureus* [27]. ESWT seems to be superior to gene therapy (with TGF-β or VEGF adenovirus) in reverting tissue necrosis [28]. Schaden et al. [11] defends that ESWT is an innovative method of treatment in skin lesions, as important as the appearance of VAC therapy was in treating soft tissue wounds 10 years ago. Shock wave therapy is currently being evaluated by the Food and Drug Administration (FDA) in phase III trials for acute combat wounds and diabetic foot ulcers [11,3].

In our study, we observed a probable beneficial effect of ESWT in treating deep partial/full thickness burns: re-epithelialisation was achieved without surgery in most of the cases. Patients referred no special pain during the session treatments, no side effects were observed and we applied the therapy on an outpatient basis. The lack of controls in this study does not allow us to state a significant correlation between ESWT, increase in perfusion by LDI and fast re-epithelialisation burn rate; however, due to the fact that it is a pilot and observational study, it just describes our data and results, which seem to be promising. This should serve to encourage us to perform new clinical trials to add more scientific evidence in a barely explored field in human burns. The small number of patients is also a limitation of this study; however, to our knowledge, the results are quite homogeneous and there are still no studies with a larger number of enrolled burn patients. Despite all these facts, our results might be seem too optimistic or we might just have randomly been lucky to recruit the best-responding patients to this therapy; but they actually agree with the increasing evidence that ESWT enhances reperfusion of ischaemic tissues.

The ISMST considers ESWT a ‘common empirically tested clinical use’ in burns. There is a strong need of more experimental research and clinical studies to achieve an approved standard indication of ESWT in burns.

Extracorporeal shock wave therapy emerges as a new non-invasive, feasible, safe and cost-effective method in deep partial-/full-thickness burns. It may decrease the need of surgery and therefore the morbidity of the patient. This is a pilot study that clinically describes the experimentally beneficial effects of ESW obtained previously in diminishing acute inflammation and enhancing wound reperfusion and healing in burns. It needs more studies with a greater number of burned patients, in a multicentric manner, and phase II trials, stating the optimal timing and dosage of treatment, to standardise a protocol of use of ESWT in the management of thermal injuries. ESWT seems to be a new non-surgical method to successfully treat some severe burns.

Conflict of interest statement

None of the authors has any financial interest whatsoever in any of the techniques or instruments mentioned in this article.

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