



ESWT in skin & aesthetic indications

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Disclosures Prof. Knobloch, FACS

Lecturer & travel expenses

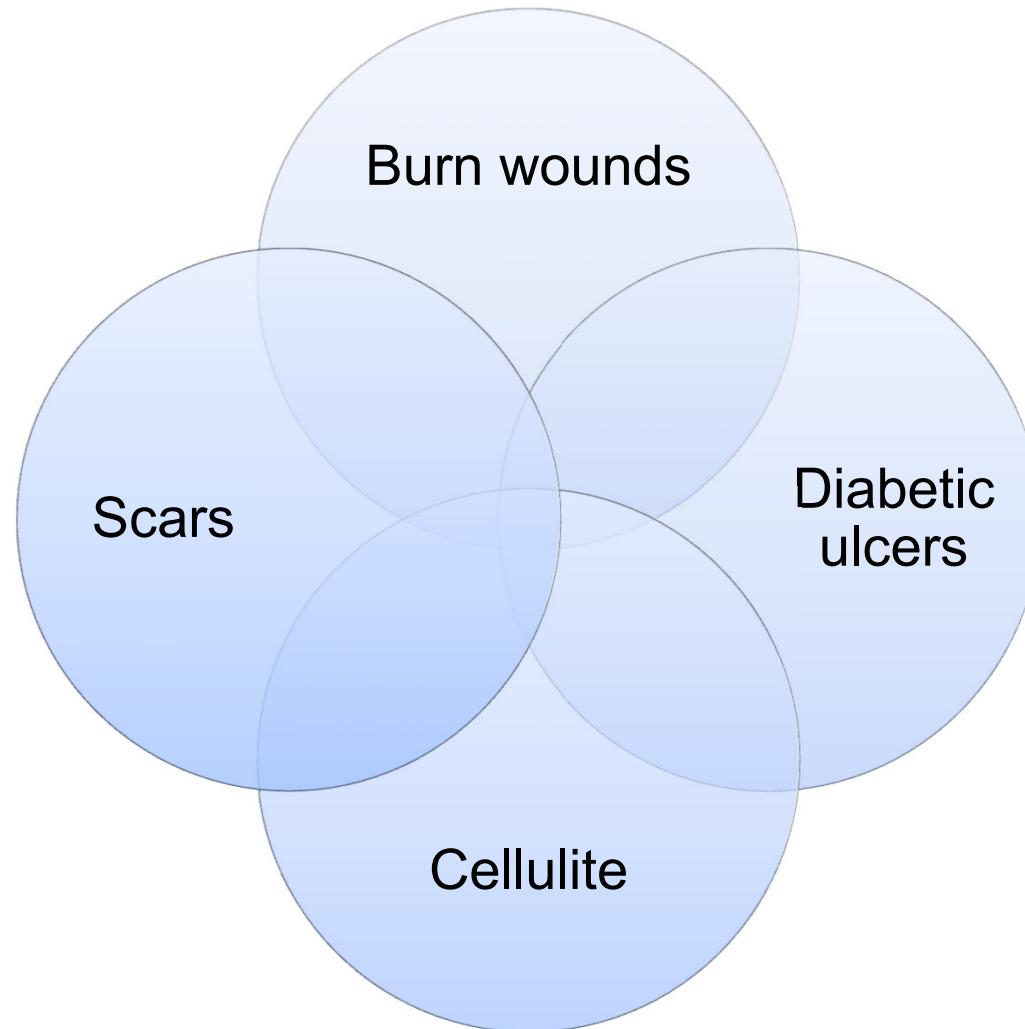


Publishers honoraries for books & chapters





ESWT in skin & aesthetics







ESWT in skin graft epithelization

3 days faster healing

Prospective Randomized Trial of Accelerated Re-epithelization of Skin Graft Donor Sites Using Extracorporeal Shock Wave Therapy

Christian Ottomann, MD, Bernd Hartmann, MD, Josh Tyler, MD, Heike Maier, MD, Richard Thiele, MD, Wolfgang Schaden, MD, Alexander Stojadinovic, MD, FACS

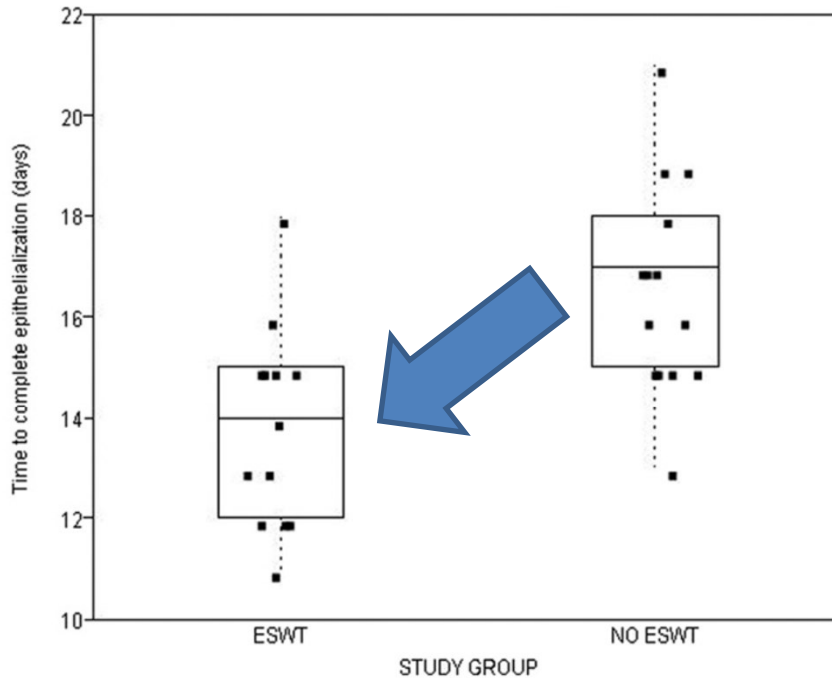


Figure 2. Time to complete split thickness skin graft donor site re-epithelialization in patients with and without single postharvest defocused shock wave treatment to the donor site. ESWT, extracorporeal shock wave therapy.



3 days faster healing
by ESWT



ESWT in 2a° burn injuries

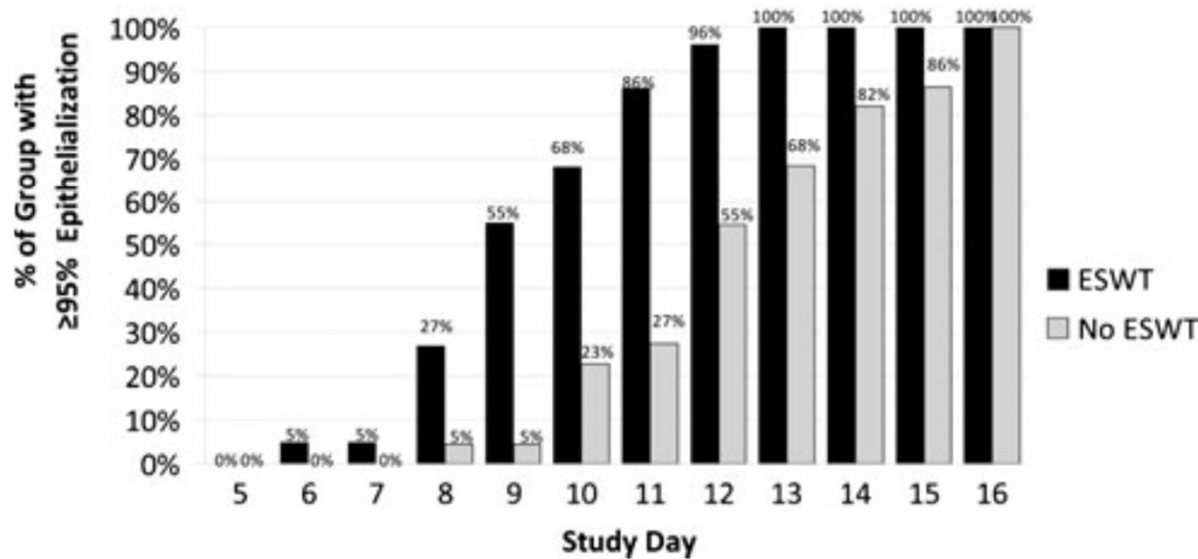
3 days faster healing

RANDOMIZED CLINICAL TRIAL

Prospective Randomized Phase II Trial of Accelerated Reepithelialization of Superficial Second-Degree Burn Wounds Using Extracorporeal Shock Wave Therapy

Christian Ottomann, MD,* Alexander Stojadinovic, MD, FACS,†‡ Philip T. Lavin, PhD,§ Francis H. Gannon, MD,¶
Michael H. Heggeness, MD,¶ Richard Thiele, MD,|| Wolfgang Schaden, MD,** and Bernd Hartmann, MD*

Proportion of patients with $\geq 95\%$ epithelialization on each study day





Reduced burn scar pruritus/itchiness after 3x focused electromagnetic ESWT

The clinical utility of extracorporeal shock wave therapy for burn pruritus: A prospective, randomized, single-blind study

*So Young Joo, Yoon Soo Cho, Cheong Hoon Seo**



Fig. 2 - The extracorporeal shock wave therapy was administered to burn patients. The administered shock wave dose was 100 impulses/cm² at 0.05 to 0.20mJ/mm² with a total of 1000-2000 impulses.





Reduced burn scar pruritus/itchiness after 3x focused electromagnetic ESWT

Table 3 – The changes in numerical rating scale (NRS), 5-D pruritus scale, Leuven Itch Scale.

	ESWT		p	Control		p
	Before therapy	After 3rd therapy		Before therapy	After 3rd therapy	
NRS	6.30±1.29	3.57±2.09	<0.001 [*]	6.87±1.32	5.35±2.31	0.002 ^a
5-D pruritus scale						
Duration	1.96±1.87	1.39±0.66	0.046 [*]	2.00±1.17	1.65±1.07	0.118 ^a
Degree	3.52±0.79	2.52±0.59	<0.001 [*]	3.48±0.73	2.96±0.93	0.017 ^a
Direction	4.17±0.83	2.78±0.90	<0.001 [*]	4.21±0.90	3.48±1.08	0.028 ^a
Disability	3.30±1.15	2.35±1.23	0.004 [*]	3.21±1.04	2.87±1.18	0.057 ^a
Leuven Itch Scale						
Frequency	78.26±18.93	67.39±23.15	0.075 [*]	79.35±12.28	72.83±19.81	0.107 ^a
Duration	33.00±34.47	20.09±25.83	0.12 [*]	45.91±34.09	43.04±37.80	0.79 ^a
Severity	63.04±12.95	35.22±20.20	<0.001 [*]	68.70±13.25	53.48±23.08	0.002 ^a
Consequences	32.51±21.50	17.19±16.24	<0.001 ^b	37.85±23.39	32.60±21.84	0.20 ^a

Values are mean±standard deviation.

^a Wilcoxon signed rank test.

^b Paired t-test.

^{*} p < 0.05 between groups.

-45% pruritus/itchiness within 14days



Literature

ESWT in soft tissue wounds

- 208pts with non-healing wounds with 75% complete wound epithelization
 - ESWT: 100-1000 shots/cm² 0.1mJ/mm², 3x
 - » Schaden W et al. J Surg Res 2007;143(1):1-12.
- Potential mechanisms for ESWT in wounds:
 - Initial neovascularisation with functional angiogenesis
 - Recruitment of mesenchymal stem cells
 - Anti-inflammatory effects
 - Antimicrobial effects
 - » Mittermayr R et al. Wound Repair Regen 2012;20:456-65



Diabetic foot ulcer - experimental

The screenshot shows a PubMed article page. The title is "Modulation of vascular endothelial growth factor and mitogen-activated protein kinase-related pathway involved in extracorporeal shockwave therapy accelerate diabetic wound healing." The authors listed are Chen RE, Chang CH, Wang CT, Yang MY, Wang CJ, and Kuo YR. The abstract describes a study on diabetic wound healing in rats, comparing ESWT treatment to control and Avastin treatment. The results show that ESWT significantly reduced wound size and increased neovascularization and tissue regeneration. The article is published in *Wound Repair Regen.* in 2019. The page also includes sections for author information, full text links, similar articles, and related information.

Format: Abstract

Wound Repair Regen. 2019 Jan;27(1):69-79. doi: 10.1111/wrr.12686. Epub 2018 Dec 7.

Modulation of vascular endothelial growth factor and mitogen-activated protein kinase-related pathway involved in extracorporeal shockwave therapy accelerate diabetic wound healing.

Chen RE¹, Chang CH¹, Wang CT¹, Yang MY², Wang CJ³, Kuo YR^{1,4,5}.

Author information

Abstract

Extracorporeal shockwave therapy (ESWT) has a significant positive effect to accelerate chronic wound healing. This study investigated whether the vascular endothelial growth factor (VEGF)-related pathway has involved in ESWT enhancement of diabetic wound healing. A dorsal skin defect (area, 6 × 5 cm) in a streptozotocin-induced diabetes rodent model was used. Thirty-two male Wistar rats were divided into four groups. Group I consisted of nondiabetic control; group II, diabetic control without treatment; group III, diabetic rats received ESWT; and group IV, rats received Avastin (a VEGF monoclonal antibody) on day 0 (post-wounding immediately) to day 7 and ESWT on day 3 and day 7. The wound healing was assessed clinically. The VEGF, endothelial nitric oxide synthase (eNOS), and Ki-67 were analyzed with immunohistochemical staining. The mRNA expression of mitogen-activated protein kinase-related genes was measured by real-time quantitative real-time polymerase chain reaction. The results revealed wound size was significantly reduced in the ESWT-treated rats as compared to the diabetic control ($p < 0.01$). The positive effect of ESWT-increasing wound healing was significantly suppressed in pretreatment of the Avastin group. Histological findings revealed significant increase in neo-vessels in the ESWT group as compared to the control. In immunohistochemical stain, significant increases in VEGF, eNOS, and Ki-67 expressions were noted in the ESWT group as compared to that in controls. However, Avastin suppressed the shockwave effect and down-regulation of VEGF, eNOS, and Ki-67 expressions in the Avastin-ESWT group as compared to that in the ESWT alone group. We found that highly mRNA expression of Kras, Raf1, Mek1, Jnkk, Jnk, and Jun at early stage in the ESWT group, as compared to the diabetic control. These evidences indicated treatment with multiple sessions of ESWT significantly enhanced diabetic wound healing associated with increased neovascularization and tissue regeneration. The bio-mechanism of ESWT-enhanced wound healing is correlated with VEGF and mitogen-activated protein kinase-mediated pathway.

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PMID: 30394625 DOI: 10.1111/wrr.12686

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Recent Activity



ESWT for diabetic foot ulcers

- Meta-Analysis of 5 trials with 255 patients
 - » Hitchman LH et al. Ann Vasc Surg 2018 Nov 26.
- ESWT was superior to standard wound care
 - At complete wound healing (Odds ratio 2.66)
 - Time to healing (65 ± 8 days vs. 81 ± 4 days)
 - ESWT was better than hyperbaric oxygenation (HBO) for diabetic foot ulcers



ESWT for diabetic foot ulcers

- Randomized-controlled trial (N=23)
 - » Jeppesen SM et al. J Wound Care 2016;25(11):641-9.
 - Six ESWT treatments in 3 weeks and standard care vs. standard care alone
 - » 250shots/cm² plus 500 shots on arterial beds supplying ulcer location
 - Transcutaneous oxygen saturation was significantly increased in ESWT vs. standard therapy alone (p=0.044)
 - Ulcer area reduction was 35% in the intervention and 6% in the standard care group at week 7

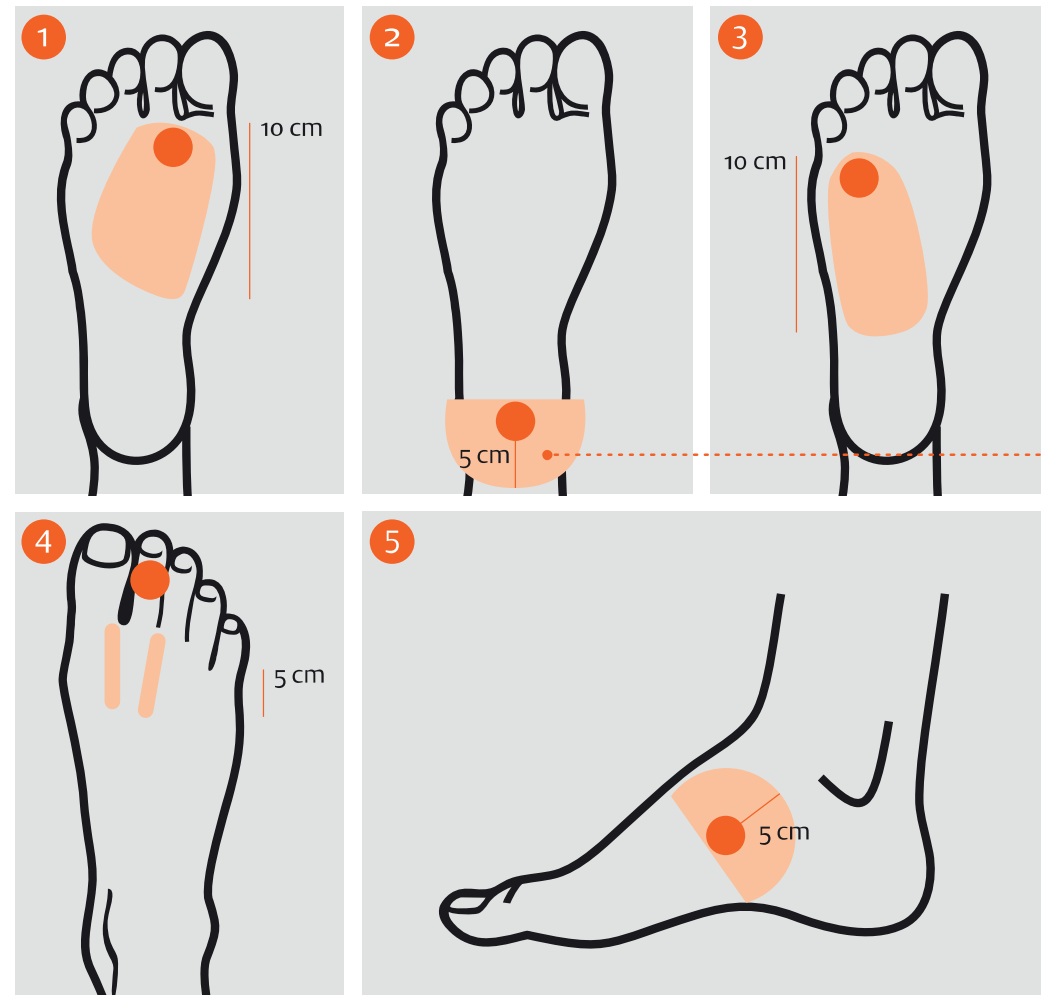


Proposed region for ESWT application on ulcers (darker point) with the recommended treatment area (orange)

Jeppesen S/Lund L. ESWT in diabetic foot

IN: Knobloch: ESWT in Aesthetics, Burns and Dermatology, 2018

*Figure 3
Illustration of the area that was treated with 500 shocks deep focus ESWT using the DUOLITH SD₁ (STORZ MEDICAL AG). ESWT was aimed at the medial plantar artery if the ulcer was located on the plantar surface medially (1), the small calcaneal branches if the ulcer was located on the heel (2), the lateral plantar artery if the ulcer was located on the plantar surface laterally (3), the interdigital arteries on each side of the metatarsal bone if the ulcer was located on a toe (4), and the proximal perimeter of the ulcer if the ulcer was located on the dorsum of the foot (5)*





FDA approval for Sanuwave for diabetic foot ulcer

The screenshot shows a PubMed article page for a study titled "Diabetic foot ulcer treatment with focused shockwave therapy: two multicentre, prospective, controlled, double-blinded, randomised phase III clinical trials." The article is published in *J Wound Care*, 2018 Dec 2;27(12):822-836. The authors listed are Snyder R¹, Galiano R², Mayer P³, Rogers LC⁴, Alvarez O⁵, and Sanuwave Trial Investigators.

Abstract
OBJECTIVE:: To investigate the efficacy of focused extracorporeal shockwave therapy (ESWT) as an adjunctive treatment for neuropathic diabetic foot ulcers (DFU) (1A or 2A on the University of Texas grading scheme), compared with sham treatment.
METHOD:: We performed two multicentre, randomised, sham-controlled, double-blinded, phase III clinical trials using focused ESWT compared with sham examining DFUs that did not reduce in volume by $\geq 50\%$ over 2 weeks' standard treatment immediately prior to randomisation. Patients were enrolled into the trials and randomised for either standard care and focused ESWT (pulsed acoustic cellular expression, dermaPACE System, SANUWAVE Health Inc.) active therapy, or standard care and sham therapy. Both active and sham therapy were administered four times in 2 weeks in study 1 and a maximum of eight times over 12 weeks in study 2. Standard care continued in both studies throughout the 12-week treatment phase. The proportion of DFUs that closed completely by 12, 20 and 24 weeks was measured.
RESULTS:: The two studies evaluated 336 patients; 172 patients treated with active therapy and 164 managed with a sham device. The demographic characteristics of patients in the two arms of both studies were balanced and statistical comparison of the two studies justified pooling datasets for analysis. Statistically significantly more DFU healed at 20 (35.5% versus 24.4%; $p=0.027$) and 24 weeks (37.8% versus 26.2%; $p=0.023$) in the active treatment arm compared with the sham-controlled arm. At 12 weeks the active therapy arm trended to significance (22.7% versus 18.3%).
CONCLUSION:: The outcome of these two trials suggests that ESWT is an effective therapeutic modality in combination with standard care for neuropathic DFU that do not respond to standard care alone.

KEYWORDS: PACE technology; chronic wound; diabetic foot ulcers; extracorporeal shockwave therapy; randomised controlled trial

PMID: 30557108 DOI: 10.12968/jowc.2018.27.12.822

The right sidebar of the page includes sections for "Full text links" (with a link to "Full text at MAG ONLINE LIBRARY"), "Save items" (with an "Add to Favorites" button), "Similar articles" (listing related research on shockwave therapy and tissue engineering), "Related information" (with a "MedGen" link), and "Recent Activity" (showing search results for "diabetic foot ulcer treatment with focused shockwave therapy" and "wound eswt").



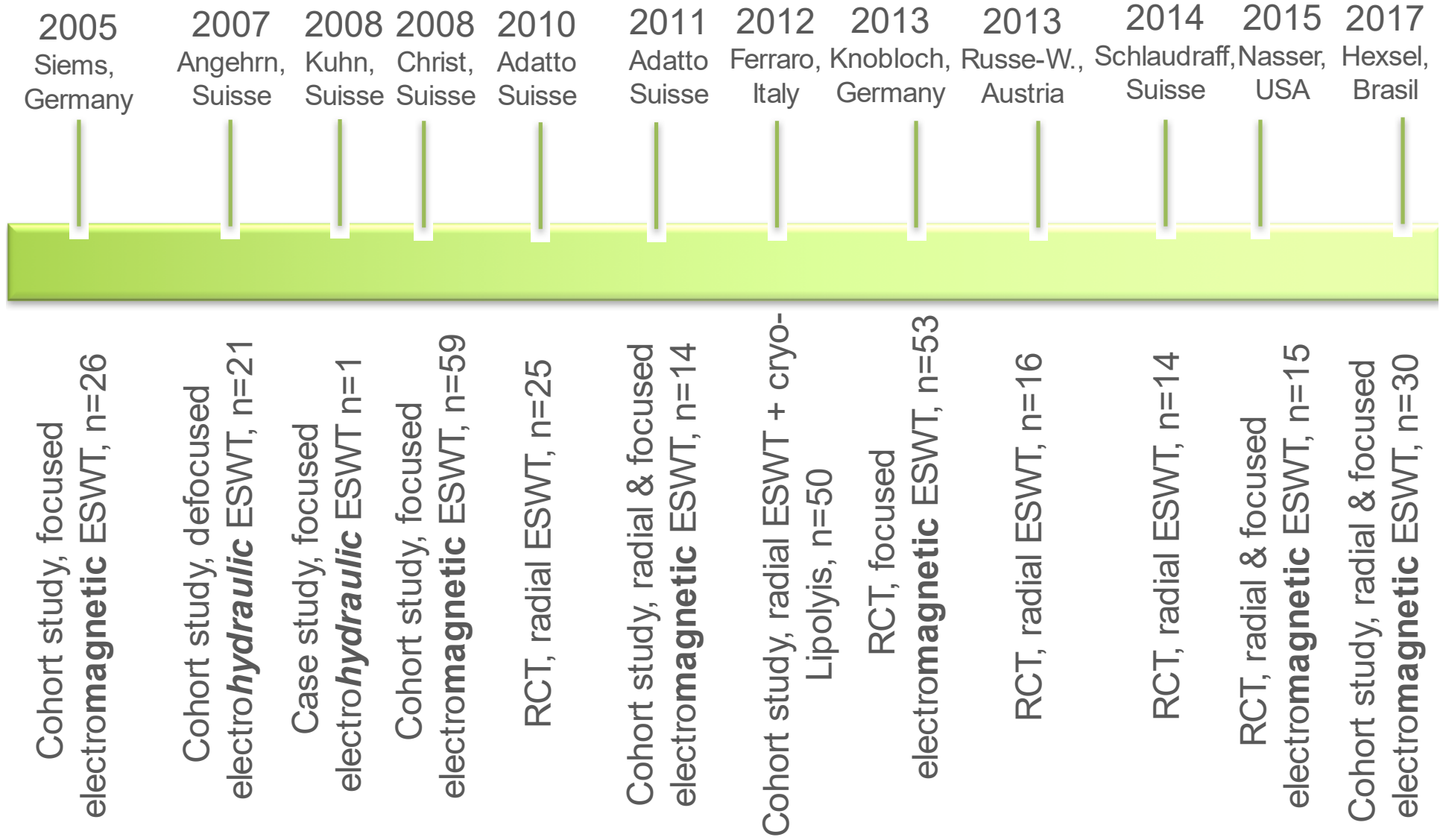
Recommended ESWT wound protocol

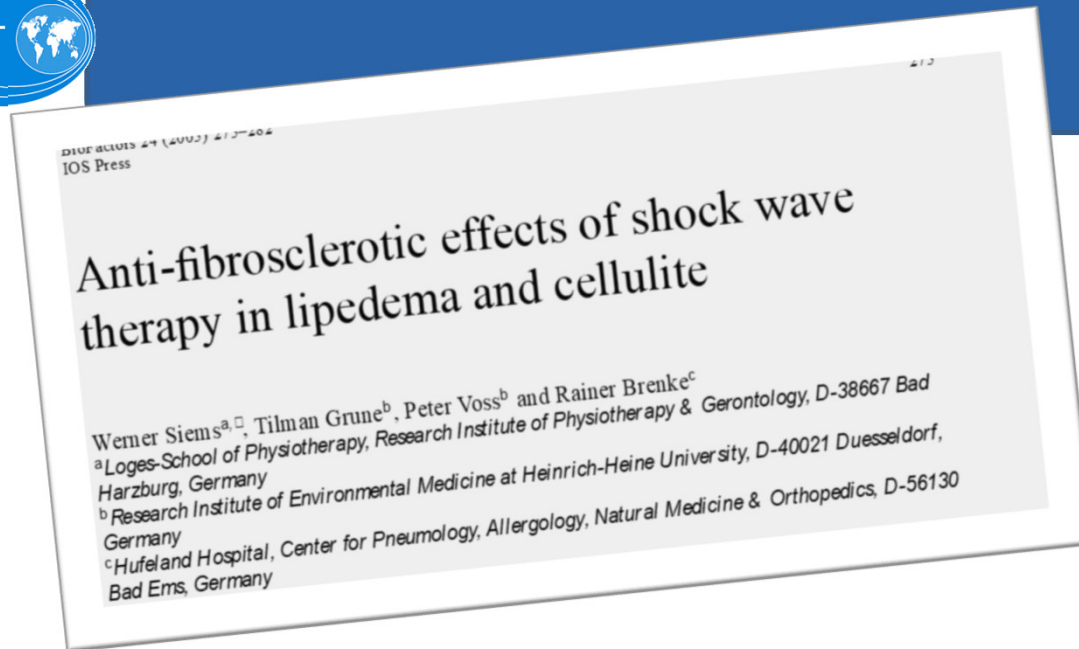
- De/-Focused ESWT

- 0.1-0.2mJ/mm²
- 2-5 Hz
- 3-6 sessions
- Wound size:
 - 350+100 impulses/cm²

wound size	wound area	number of pulses
1 x 1 cm	1 cm ²	350 + 100 = 450
2 x 2 cm	4 cm ²	350 + 400 = 750
2 x 4 cm	8 cm ²	350 + 800 = 1.150
4 x 4 cm	16 cm ²	350 + 1.600 = 1.950

Timeline of ESWT in cellulite



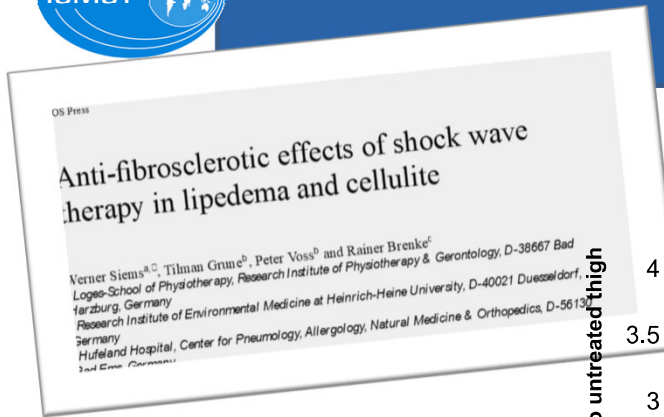


26 females with cellulite with lymphdrainage with or without ESWT

ESWT reduces oxidative stress and improves cellulite



Skin improvement with every ESWT session



6 ESWT Sessions

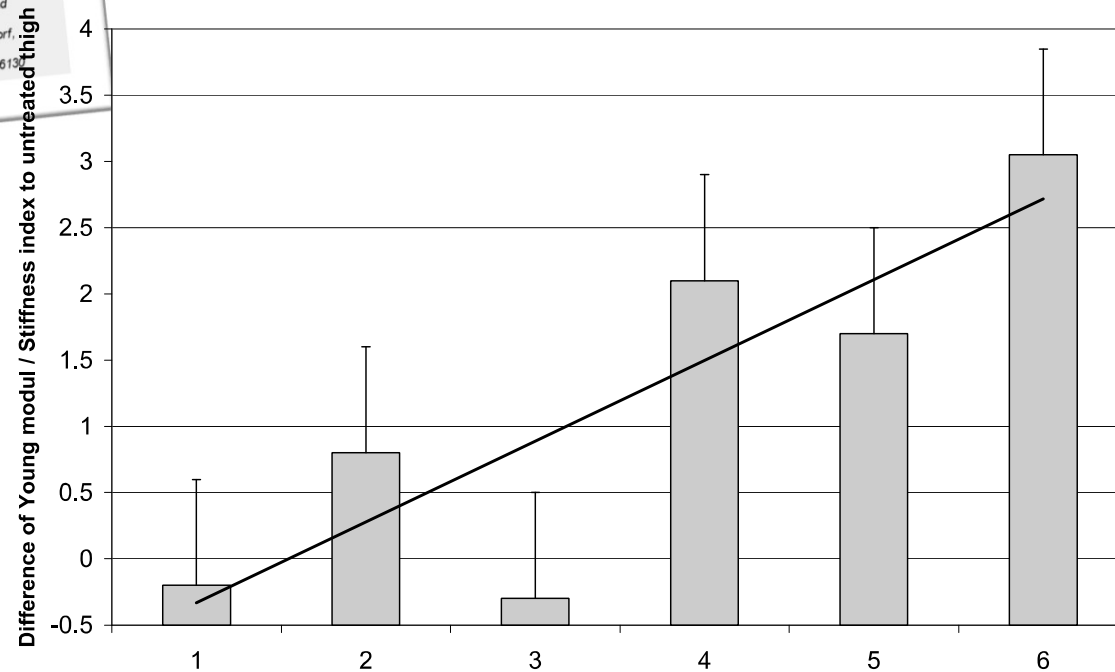


Fig. 3. Improvement of biomechanic skin properties during a 2 weeks-period with 6 sessions of shock wave application each for 8 minutes (1.000 impulses) in 5 patients with cellulite. In this part of the study the patients were treated only with SWT, but without parallel CPDT. Therefore, the increases of smoothing and elasticity (Young modul or stiffness index) which are given as difference between Young modul/stiffness index of the treated and untreated extremity are completely due to SWT. Values as Young modul/stiffness index without dimension; trend was calculated as linear trend.

CelluShock RCT Knobloch K

Intervention group

- 6 sessions of focused extracorporeal shockwave therapy $0,35\text{mJ/mm}^2$ 2000 shocks and daily gluteal strength training (Storz Duolith SD1)

Control group

- 6 sessions of SHAM focused extracorporeal shockwave therapy $0,01\text{mJ/mm}^2$ 2000 shocks and daily gluteal strength training





RCT Cellushock Knobloch et al.

Before and after 6x focused ESWT



Intervention group A
baseline

CSS 15



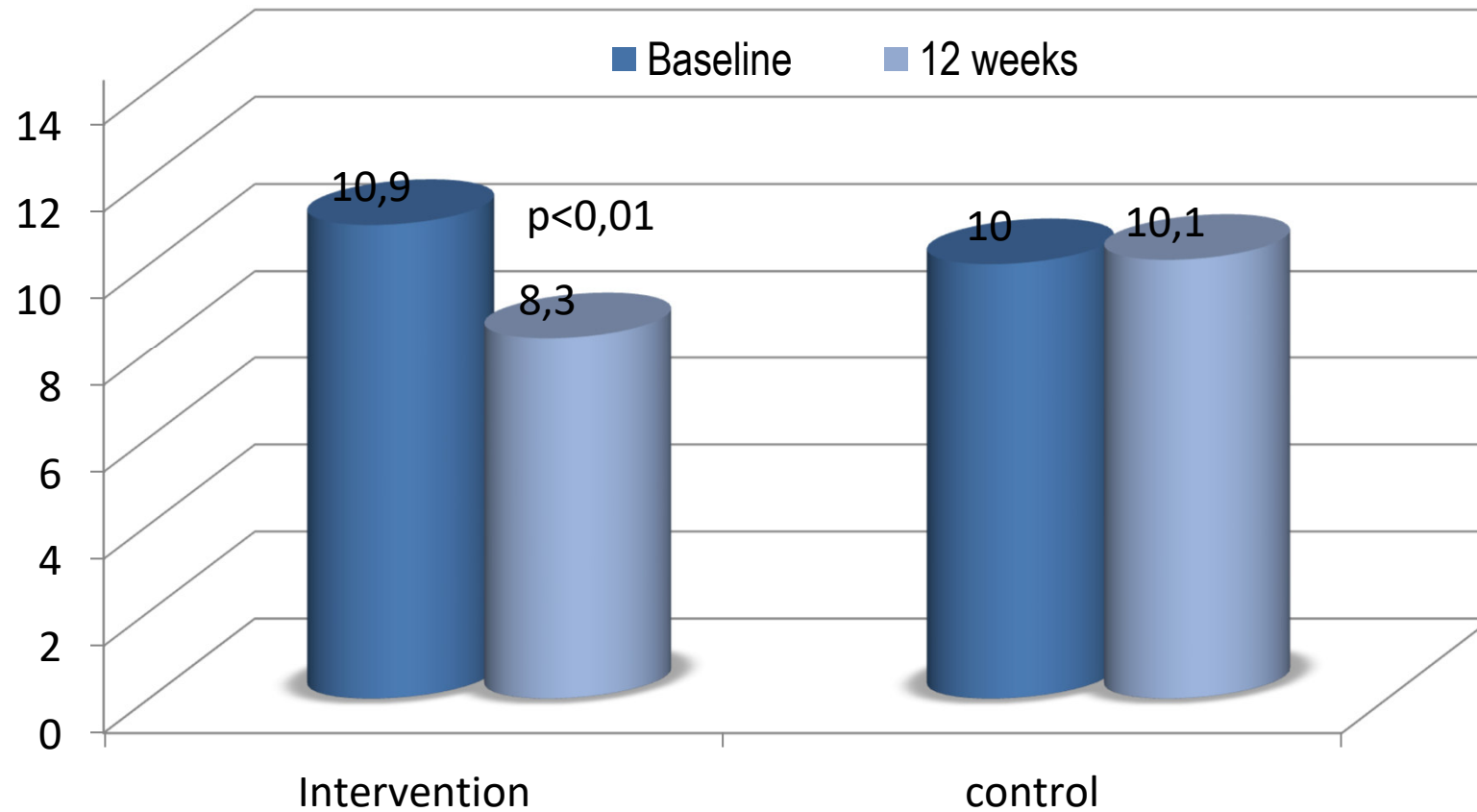
Intervention group A
3 months post intervention

CSS 7



RCT Cellushock Knobloch et al.

Before and after 6x focused ESWT





Metaanalysis ESWT in cellulite

Knobloch & Krämer 2015

International Journal of Surgery 24 (2015) 210–217



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International Journal of Surgery

journal homepage: www.journal-surgery.net



Review

Extracorporeal shock wave therapy (ESWT) for the treatment of cellulite – A current metaanalysis



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H I G H L I G H T S

- Both, focused & radial ESWT devices are effective in treating cellulite.
- Typically, one or two weekly sessions and 6–8 sessions overall were studied.
- Outcome parameters mainly focused on photographs, circumference measurements and ultrasound.
- Reporting quality showed substantial heterogeneity from 22 to 82 points with a mean of 57 points.

Table 1

All included clinical studies on the effects of extracorporeal shock wave therapy (ESWT) on cellulite with details on study design, number of participants, type, device and treatment parameters, number of treatments, follow-up and main results of the trials.

Author	Year	Study design	Level of evidence	Number of patients	Type of ESWT	Device type	Energy flux densities	Pressure	Number of sessions	Follow-up	Outcome measures
Siems et al.	2005	Cohort study	3	26 (intra-individual control, one treated leg)	Focused ESWT	DermaSelect, Storz Medical	0.16 mJ/mm ² , 1000 impulses	—	3–6 sessions	2 weeks	<ul style="list-style-type: none"> Mitigation of oxidative stress
Angehrn	2007	Cohort study	3	21	Low-energy defocused ESWT	ActiVitor-Derma	0.018 mJ/mm ² , 40.000 shots	—	12 (twice a week)	8 weeks	<ul style="list-style-type: none"> Improvement of high resolution ultrasound with collagen remodelling
Kuhn	2008	Case study	4	1 (intra-individual control, one treated leg)	Focused ESWT	ActiVitor-Derma electrohydraulic device, SwiTechMedical	0.115 mJ/mm ² , 4 Hz, 800 impulses on 2 × 2 cm ² sample	—	4	unclear	<ul style="list-style-type: none"> Epidermal improvement, neocollagenogenesis
Christ	2008	Cohort study	3	59	Planar ESWT	Storz CellActor SC1	0.25 mJ/mm ² , 3200 impulses per session	—	6 (n = 15) or 8 (n = 44) sessions (twice a week)	3 & 6 months	<ul style="list-style-type: none"> Skin elasticity improvement 105% at 6 months f/u
Adatto	2010	RCT, 1:1 allocation	1b	25 (intra-individual control, one treated leg)	Radial ESWT	Storz D-Actor 200	—	2.6–3.6 bar, 15 Hz, 3000 impulses on 10 × 15 cm rectangle	6 twice a week	12 weeks	<ul style="list-style-type: none"> Improvement on skin roughness, number of depressions and elevations
Adatto	2011	Cohort study	3	14	Radial and focused ESWT	Storz CellActor SC1	0.45–1.24 mJ/mm ² , 1500 impulses	3–4 bar, 3000 impulses	8 (twice a week)	12 weeks	<ul style="list-style-type: none"> Reduction of subcutaneous fat layer
Ferraro	2012	Cohort study	3	50	Radial ESWT + cryo-lipolysis	Proshockice (Promoltalia)	—	50–500 bar, 1–6 Hz combined with a freezing probe for cryolipolysis	4 sessions every 15 days	12 months	<ul style="list-style-type: none"> Mean fat thickness reduction by 3 cm Circumference reduction by 4.5 cm
Knobloch	2013	RCT, 1:1 allocation, 1b gluteal strength training ± focused ESWT	1b	53	Focused ESWT	Storz Duolith	0.35 mJ/mm ² , 2000 impulses	—	6 (once a week)	12 weeks	<ul style="list-style-type: none"> Improvement of Cellulite Severity scale CSS from 10.9 to 8.3 by 24% (double-blinded standardized photographic evaluation)
Russe-Wilflingseder	2013	RCT, 2:1 allocation	1b	16 (11 verum, 5 placebo)	Radial ESWT	Storz D-Actor 200	—	2–3 bar, 3.500 impulses	8 (once a week)	12 weeks	<ul style="list-style-type: none"> Subjective patient improvement Photoscore improvement
Schlaudraff	2014	RCT, 1:1 allocation	1b	14 (intra-individual control, one treated leg)	Radial ESWT	EMS Swiss DolorClast	—	3.5–4 bar, 15.000 impulses, 15 Hz	8 (twice a week)	4 weeks	<ul style="list-style-type: none"> Improvement of cellulite grade by 0.93 grades
Nassar	2015	RCT, 1:1 allocation	1b	15 (crossleg study, 1 leg being treated, one served as intraindividual control)	Focused and radial ESWT	Storz SC1	0.56–1.24 mJ/mm ² , 1500 impulses, per leg	2.6–5 bar, 16 Hz, 3.000 impulses	8 (twice a week)	12 weeks	<ul style="list-style-type: none"> Crossleg study Reduction of subcutaneous fat layer from 1.4 ± 0.4 cm to 1.0 ± 0.3 cm at 3 months follow-up 1.7 cm circumference reduction

Metaanalysis ESWT in Cellulite

Knobloch & Krämer 2015

- Both, focused as well as radial ESWT devices have been found effective in treating cellulite so far
- Typically, one or two sessions per week and 6–8 sessions overall were studied in the published clinical trials
- Follow-up typically ranged between three and six months
- Overall, outcome parameters mainly focused on digital standardized photographs, circumference measurements and specific ultrasound examinations
- Only one RCT to date used a non-validated patients' questionnaire to assess the patients' evaluation of the treatment



Timing of ESWT

Improved function

Less scarring
Faster healing

Therapeutic
ESWT

Preventive
ESWT

AFTER

BEFORE

Less pain

Preconditioning



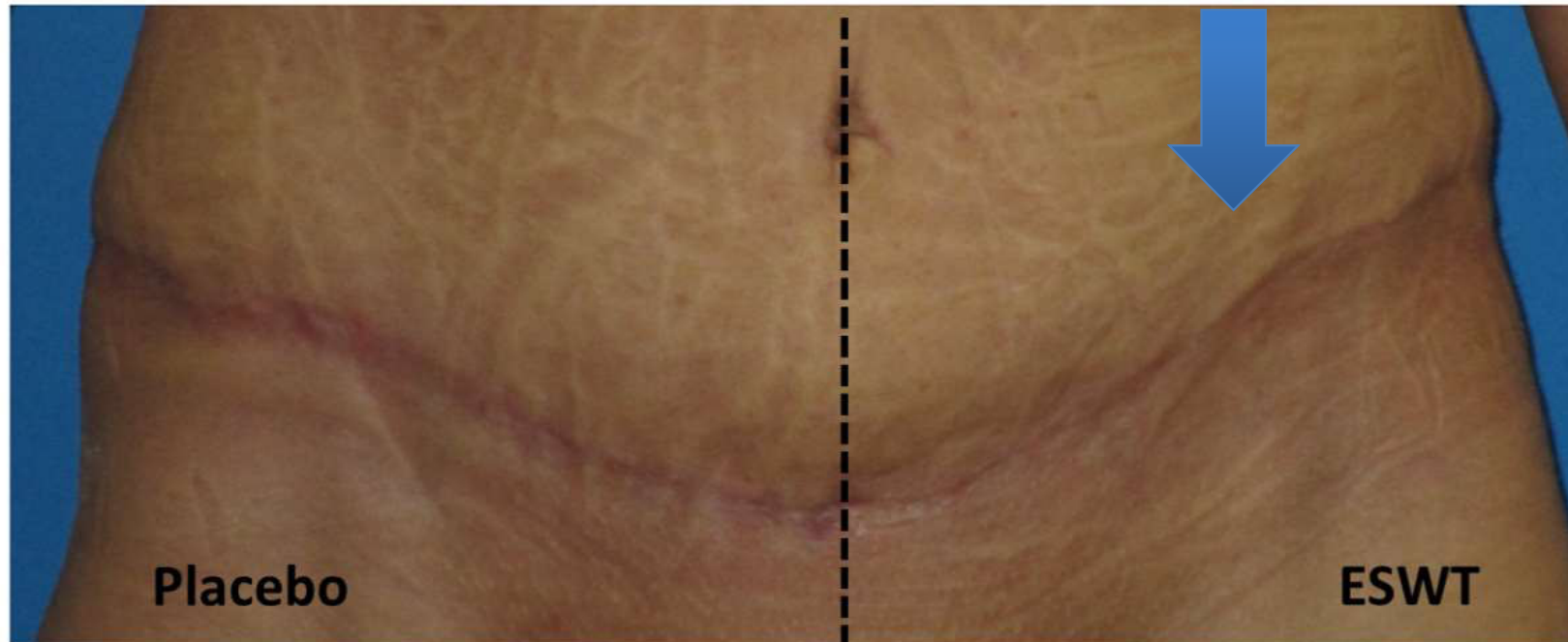
ESWT - Improved scarring after body lift

Thanks to Dr. Wolfgang Schaden, AUVA Vienna



Russe E et al. in press

Improved scarring after
a single preventive F-SW



45yrs female 6 weeks postoperatively

(BMI: 24.4 kg/m²)



THE DIFFERENCES BETWEEN NORMAL WOUND HEALING | Figure 1

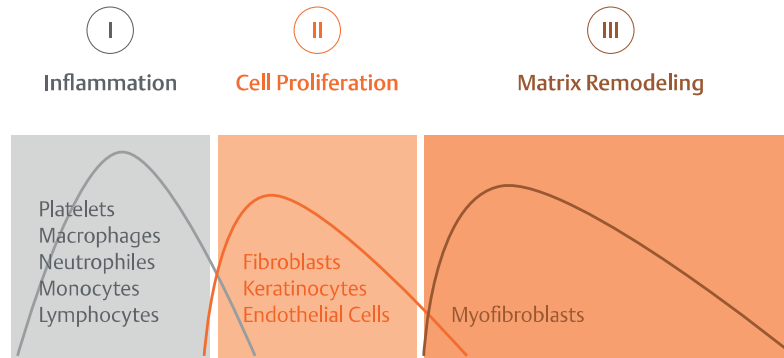
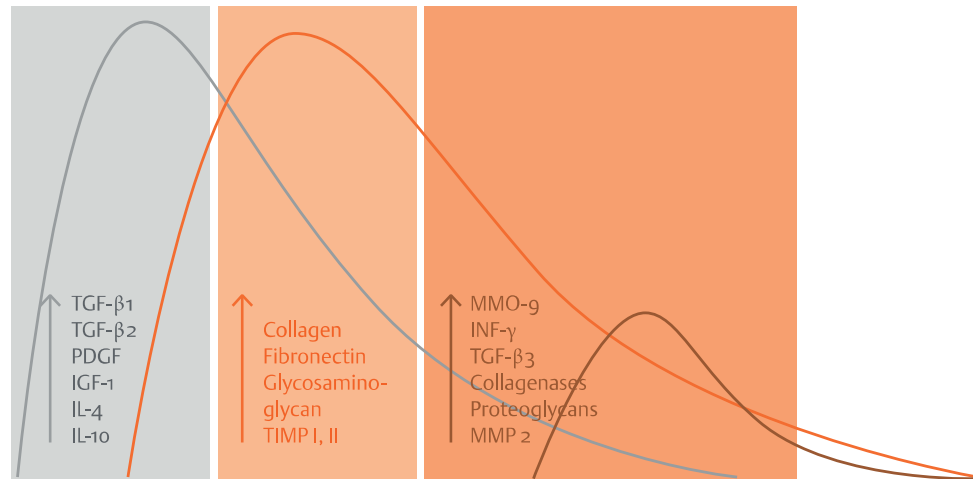


Figure 1
The differences between normal wound healing and excessive scar formation (Gauglitz et al., 2011, Hypertrophic Scarring and Keloids: Pathomechanisms and Current and Emerging Treatment Strategies)

A | Normal Wound Healing

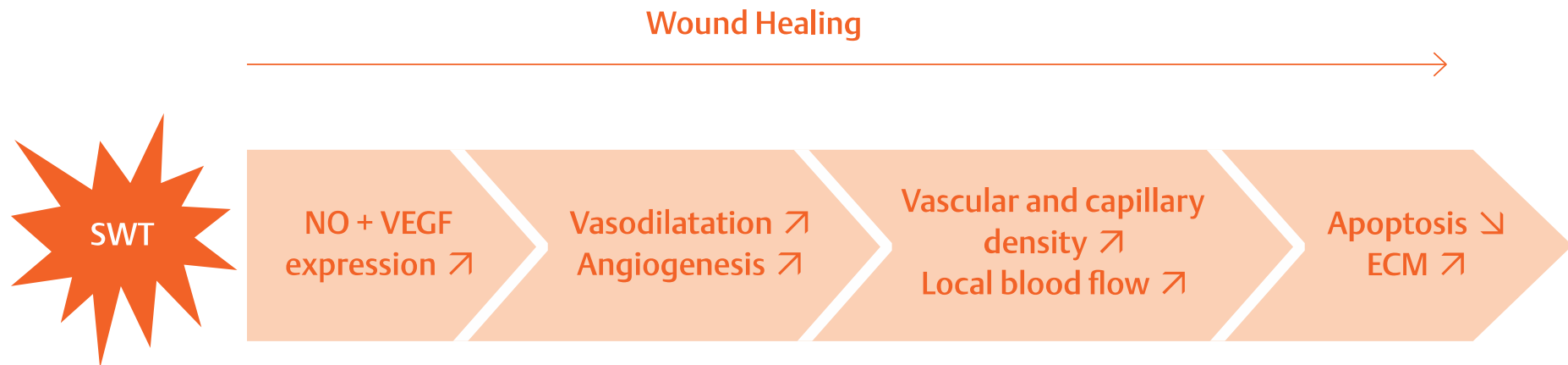


B | Excessive Scarring

Time



CASCADE OF WOUND HEALING PROCESSES AFTER SWT | Figure 3



SUGGESTED SWT SETTINGS FOR FOCUSED ELECTROMAGNETIC DEVICES WHEN TREATING WOUNDS OR SCARS | Table 1

	Energy Flux Density	Number of pulses	Pulse Frequency	Treatment interval	Number of treatments
SWT for Wound Healing	0,03–0,20 mJ/mm ²	500–1,000	4–6 Hz	1 x per week	1–3
SWT for scar treatment	0,15–0,33 mJ/mm ²	800–1,500	4–6 Hz	1 x per week	8–12





ESWT in skin & aesthetics

ESWT can

- Accelerate skin epithelization
 - in burns
 - In diabetic ulcers
- Improve scaring
- Improve cellulite

