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Shock Wave Therapy Versus Silicone Gel Sheet on Post-Burn Hypertrophic Scars

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Abstract

Background: Hypertrophic scars are severe problems after thermal injuries. Scar contractures develop and extend to the underlying connective tissue and then muscles, leading to a reduction in joint range of motion and affecting day-to-day activities.

Aim of Study: This study was conducted to determine the effect of extracorporeal shock wave therapy versus silicone gel sheet on post-burn hypertrophic scars.

Patients and Methods: Thirty patients (males and females) were suffering from scar contractures which cause functional limitations or immature hypertrophic scars in different areas of the body as a result of burn injuries, their ages ranged between 20 to 45 years, they were randomly distributed into two equal groups. Group A received Extracorporeal shock wave therapy (ESWT) and a traditional physical therapy program 2 sessions/week for 2 months. Group B received a Silicone gel sheet, worn for 20-24 hours/day (The sheets were cleansed daily and reused for 4 to 8 weeks)and a traditional physical therapy program 2 sessions/week for 2 months. The data were collected before and after the same period of treatment for both groups. Evaluation procedures were carried out using Patient and Observer Scar Assessment Scale (POSAS) and was completed before and after treatment.

Results: Comparison between post treatment and pre treatment in both groups showed a significant decreasein all items of P-SAS and O-SAS post-treatment compared with that pre-treatment in group A and B (p<0.001). There was a significant decrease in all items of P-SAS and O-SAS of group A compared with that of group B post-treatment (p<0.001).

Conclusion: Extracorporeal shock wave therapy (ESWT) is an effective, easy to apply, noninvasive treatment modality and had more significant effect on post burn hypertrophic scars than silicone gel sheet (SGS).

Key Words: *Extracorporeal shock wave therapy – Silicone gel sheet – Post burn hypertrophic scars – Patient and Observer Scar Assessment Scale.*

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Introduction

BURN injuries can be caused by friction, cold, heat, radiation, chemical or electric sources, but the majority of burn injuries are caused by heat from hot liquids, solids or fire **[1]**.

Wound healing is a complex biological process that is generally composed of four phases: hemostasis, inflammation, proliferation, and remodeling. In comparison to the previous phases, the proliferative phase is critical for successful healing. During this phase, several key processes occur, including fibroblast migration, re-epithelialization, angiogenesis, and wound contraction. General failure in the mechanism of wound healing can lead to functionally debilitating hypertrophic scar (HTS) development **[2]**.

Burn wounds are prone to hypertrophic scarring, especially if they injure the deeper dermis (second and third-degree burns). Hypertrophic scarring was found to be much more common in burn wounds that took three weeks or longer to heal **[3]**.

Hypertrophic scars (HTSs) are defined as visible and elevated scars that do not spread into surrounding tissues. Proliferation of the dermal tissue, with excessive deposition of fibroblast-derived extracellular matrix (ECM) proteins, particularly collagen, over time, as well as chronic inflammation and fibrosis, characterize these scars **[4]**.

HTSs are usually red or pink in color, hard, and pruritic, and rarely rise more than 4mm above the skin. Furthermore, these scars do not spread beyond the wound margins and tend to relapse over time. Symptoms like pain and itching are common with hypertrophic scars. They can cause serious functional issues, such as restricted movement, especially if they're close to joints **[5]**.

The therapeutic management of hypertrophic scars is a problem that has not yet been satisfactorily solved and includes, e.g., compression therapy, topical/intralesional corticosteroid application, excision, radiation, cryotherapy, laser therapy, interferon therapy, andother therapies directed at a reductionofcollagen synthesis **[6]**.

Extracorporeal shockwave treatment (ESWT) is a non-invasive physiotherapy method that was originally used to treat kidney stones using lithotripsy. With its progress, it has steadily been employed in the treatment of musculoskeletal disorders. ESWT has recently been discovered to reduce scar pain and pruritus in burn patients during rehabilitation **[7]**.

ESWT can regulate burn wound healing and hypertrophic scar development through cell mechano-transduction. Through regulation of inflammatory response, promotion of angiogenesis, improvement of circulation and acceleration of cell proliferation and epithelialization. It can also soften and regulate the scar tissue, improve itching, pain and improve the appearance and function of the skin along with the scar **[8]**.

Since 1997, the FDA has authorised silicone gel sheets for use in the treatment of hypertrophic scars. They are thought to be helpful for scar reduction through wound hydration and growth factor regulation, but they are not due to the pressure effect that garments have **[9]**.

The silicone sheet is expected to affect collagen remodeling by a variety of processes, including hydration, increased local temperature, scar tissue polarization, local chemical effects, enhanced local oxygen tension, and increased local mast cell population **[10]**.

The aim of the study was to compare the efficacy of extracorporeal shock wave therapy versus silicone gel sheet on post-burn hypertrophic scars.

Patients and Methods

Subjects:

Thirty patients (males and females) were suffering from scar contractures which cause functional limitations or immature hypertrophic scars in different areas of the body as a result of burn injuries, their ages ranged between 20 to 45 years, the patients were randomly distributed into two equal groups in number.

The inclusion criteria were as follow: All patients had hypertrophic scars due to thermal burn injuries at upper limb, lower limb and trunk,all patients were free from any other pathological conditions except hypertrophic scars, the therapeutic intervention for all patients started ≥3 months post wound healing, all patients received the same medications and routine physical therapy care.

The exclusion criteria were as follow: Patients who had skin abnormalities (psoriasis and cancer), patients with mature hypertrophic scars, patients who had previously received shock wave therapy for wound closure, patients who had an open wound at or near the treatment site and pregnant female.

The participants write and read Arabic well. The work has been carried out in accordance with the ethics of committee for experiments at Faculty of Physical Therapy, Cairo University and patients signed a consent form to participate in the study. After ethical approval, patients were selected from Om El-Masryeen Hospital and the outpatient clinic at Faculty of Physical therapy, Cairo University, from November 2021 – April 2022.

Randomization:

It was carried out using odd and even numbers for random distribution of included patients into two groups of 15 patients each: Group A or Group B by a blinded and independent researcher.

Intervention:

Group A received ESWT, each treatment region covered with 2500 to 3000 impulses with an average session time of 10-15 minand a traditional physical therapy program (deep friction massage and stretching exercises) 2 sessions/week for 2 months.

Group B received Silicone gel sheet, worn for 20-24 hours/day (The sheets were cleansed daily and reused for 4 to 8 weeks)and a traditional physical therapy program (deep friction massage and stretching exercises) 2 sessions/week for 2 months.

Measuring procedures:

Method of assessment pre-treatment and 2 months post-treatment for both groups was Patient and Observer Scar Assessment Scale (POSAS), including both a Patient Scar Assessment Scale (P-SAS) and an Observer Scar Assessment Scale (O-SAS).

The evaluation was conducted before and after two months of the treatment. Arabic version of Patient and observer scar assessment scale was used. It was explained for every patient. A right mark was put at the score for each point of the six parameters of the patient scale. A right mark was

put at the score for each point of the six parameters of the observer scale. The total score was estimated for each patient.

Treatment procedures:

Extracorporeal shock wave application:

Chattanooga Intelect RPW Shock wave, radial pressure waves offer a non-invasive treatment for soft tissue pathologies. Before the beginning of the treatment, the device safety measures was checked and the device was checked to be switched off. The patient was positioned in a comfortable position. The scar site was prepared with contact gel to conduct the shock waves, 30-50 shocks/cm^2, with an energy flux density of 0.25mJ/mm^2 and a frequency of 6Hz. Each treatment region was covered with 2500 to 3000 impulses with an average session time of 10-15min **[11]**. Scars were treated for 8 weeks with ESWT, two sessions/ week. The device was unplugged after use.

Silicone gel sheet application:

The patient was placed in a comfortable position. Cerederm silicone gel sheet measuring 10x20 cm was cut, adjusted and applied to the site of the scar **[12]**. The instructions for use were to cover the scar overlapping the borders of the scar with at least 2cm beyond the scar margins. The sheet was applied three hours the first day and if there are no adverse reactions, the application was prolonged for 1 to 2 hours each day until the sheet was worn 20 to 24 hours a day **[13]**. The sheets were cleaned daily and could be reused for 4 to 8 weeks. The use of a silicone gel sheet was continued for 2 months **[14]**. Daily cleaning of the silicone sheet and the underlying skin is necessary to prevent irritation and heat rash **[15]**.

Traditional physical therapy program:

- Stretching exercises for the tightened muscles by using hold relax technique. To achieve this the limb was placed in pain free range and an isometric contraction was sustained (for 5 to 10 seconds) followed by a voluntary relaxation of the tightened muscles. The limb was then passively moved into the new range and sustained the stretch for 30 seconds for 3 repetitions at each time.
- Strengthening exercises by using dolerme technique by applying resistance to the weakened muscles for 3 sets of 10 repetitions maximum.
- Deep friction massage therapy for 10-15min.

Statistical analysis:

Unpaired *t*-test was conducted for comparison of age between groups. Chi squared test was conducted for comparison of sex distribution between groups. Mann-Whitney U test was conducted for comparison of POSAS between groups. Wilcoxon Signed Ranks Test was conducted for comparison between pre and post treatment in each group. The level of significance for all statistical tests was set at $p<0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

Results

Subject characteristics:

Table (1) showed the subject characteristics of the group A and B. There was no significant difference between groups in age and sex distribution between groups ($p>0.05$).

Table (1): Basic characteristics of participants.

	Group A	Group B	*p*-value
Age, mean ± (SD), years	32.46±7.37	32.53±7.03	0.98
Sex, n (%):			
Females	10 (67%)	9 (60%)	0.71
Males	5 (33%)	6 (40%)	

SD: Standard deviation.
p-value, level of significance.

Effect of treatment on POSAS:

Within-group comparison revealed a significant decrease in all items of P-SAS and O-SAS post-treatment compared with that pre-treatment in group A and B ($p<0.001$).

Between groups comparison pre-treatment revealed a nonsignificant difference ($p>0.05$). There was a significant decrease in all items of P-SAS of group A compared with that of group B post-treatment ($p<0.001$). The median (IQR) of total score of P-SAS of group A was 14 (18-12) while that of group B was 21 (26-20).

There was a significant decrease in all items of O-SAS of group A compared with that of group B post-treatment ($p<0.001$). The median (IQR) of total score of O-SAS of group A was 14 (16-13) while that of group B was 23 (25-21). (Tables 2,3).

The percentage of improvement in group A was 39.2% and 42% for total scores of P-SAS and O-SASrespectively. While in group B was 24.2% and 25.8% for total scores of P-SAS and O-SAS respectively.

Table (2): Pre and post treatment median values of P-SAS of group A and B.

P-SAS	Group A Median (IQR)	Group B Median(IQR)	U-value	*p*-value
Pain:				
Pre	4 (5-3)	4 (5-3)	112.5	1
Post	1 (2-0)	3 (3-2)	12	0.001
Z-value	-3.57	–3.37		
	p=0.001	*p*=0.001		
Itch:				
Pre	5 (6-5)	5 (6-5)	112.5	1
Post	2 (3-2)	3 (4-3)	38	0.001
Z-value	–3.62	–3.49		
	p= 0.001	*p*=0.001		
Color:				
Pre	7 (8-6)	7 (7-6)	83	0.18
Post	3 (4-3)	5 (5-4)	21	0.001
Z-value	–3.54	–3.49		
	p=0.001	*p*=0.001		
Stiffness:				
Pre	8 (8-7)	7 (8-7)	75.5	0.1
Post	3 (3-2)	4 (5-4)	33	0.001
Z-value	–3.48	–3.57		
	p=0.001	*p*=0.001		
Thickness:				
Pre	7 (8-6)	7 (8-7)	99	0.55
Post	2 (3-2)	4 (5-3)	21	0.001
Z-value	–3.62	–3.50		
	p=0.001	*p*=0.001		
Irregularity:				
Pre	7 (8-7)	7 (8-6)	95	0.43
Post	3 (4-3)	4 (5-4)	33	0.001
Z-value	–3.53	–3.50		
	p=0.001	*p*=0.001		
Overall opinion:				
Pre	8 (8-7)	7 (8-7)	94.5	0.39
Post	3 (4-3)	4 (5-4)	29	0.001
Z-value	–3.52	–3.77		
	p=0.001	*p*=0.001		
Total score:				
Pre	38 (42-34)	36 (41-35)	95.5	0.47
Post	14 (18-12)	21 (26-20)	5.5	0.001
Z-value	–3.44	–3.42		
	p=0.001	*p*=0.001		

U- value: Mann-Whitney test value.
Z- value: Wilcoxon signed ranks test value.
p-value: Level of significance.

Table (3): Pre and post treatment median values of O-SAS of group A and B.

O-SAS	Group A Median (IQR)	Group B Median (IQR)	U-value	*p*-value
Vascularity:				
Pre	5 (6-5)	5 (6-5)	106.5	0.78
Post	2 (3-2)	3 (4-3)	32	0.001
Z-value	–3.52	-3.62		
	p=0.001	*p*=0.001		
Pigmentation:				
Pre	6 (7-5)	6 (7-6)	108	0.84
Post	2 (3-2)	4 (5-4)	3.5	0.001
Z-value	–3.49	–3.46		
	p=0.001	*p*=0.001		
Thickness:				
Pre	7 (8-6)	7 (7-6)	107.5	0.82
Post	2 (2-2)	3 (4-3)	8	0.001
Z-value	–3.5	–3.5		
	p=0.001	*p*=0.001		
Relief:				
Pre	7 (7-6)	7 (7-6)	103	0.67
Post	3 (3-2)	4 (5-3)	22.5	0.001
Z-value	–3.57	–3.48		
	p=0.001	*p*=0.001		
Pliability:				
Pre	7 (8-7)	7 (7-6)	75	0.1
Post	2 (3-2)	3 (4-3)	24	0.001
Z-value	–3.5	–3.45		
	p=0.001	*p*=0.001		
Surface area:				
Pre	8 (8-7)	7 (8-7)	102.5	0.65
Post	3 (3-2)	5 (5-4)	0.	0.001
Z-value	–3.54	–3.48		
	p=0.001	*p*=0.001		
Overall opinion:				
Pre	7 (8-7)	7 (8-7)	102	0.63
Post	3 (3-2)	4 (5-3)	20	0.001
Z-value	–3.54	–3.48		
	p=0.001	*p*=0.001		
Total score:				
Pre	39 (43-36)	40 (42-35)	98.5	0.55
Post	14 (16-13)	23 (25-21)	0	0.001
Z-value	–3.43	–3.41		
	p=0.001	*p*=0.001		

U- value: Mann-Whitney test value.
Z- value: Wilcoxon signed ranks test value.
p-value : Level of significance.

Discussion

The current study was performed to study the effect of ESWT versus Silicone gel sheet on post burn HTS. This study's results pointed out that the ESWT group performed statistically significantly better than the SGS group to improve post burn scars. The POSAS, Patient and Observer scores, showed a statistically significant difference between the groups over time in favor of the ESWT group.

Our results come in agreement with Joo et al. **[16]**, Cui et al. **[7]**, Saggini et al. **[17]**, Lee et al. **[18]**, Cho et al. **[19]**, Aguilera-Sáez et al. **[20]**, Taheri et al. **[21]** and Fioramonti et al. **[22]**.

Joo et al. **[16]** tested the effectiveness of ESWT on 48 patients who had a deep partial-thickness (second-degree) burn or a full thickness (third-degree) burn on just their right hand. ESWT was administered to the research group at 100 impulses /cm^2, an energy flux density (EFD) of 0.05 to 0.30mJ/mm^2, and a frequency of 4Hz. 1000 to 2000 impulses were delivered every session, once a week for four weeks. The therapeutic effects were assessed before and after four weeks of therapy. The ESWT application on hypertrophic scarring following burn damage to the hands improved hand function, decreased discomfort, and suppressed hypertrophic scar development significantly.

Cui et al. **[7]** demonstrated that ESWT inhibits epithelial-mesenchymal transition (EMT) in fibroblasts derived from scar tissue (HTSFs) by inhibiting the expression of TGF-1, a potent EMT inducer, as well as alpha-smooth muscle actin (α-SMA), collagen-I, fibronectin, and N-cadherin, and upregulating E-cadherin. Furthermore, ESWT limits HTSF migratory ability. These molecular alterations contribute to ESWT's anti-fibrotic actions on HTSFs, and it has the potential to be used as a therapeutic target in the management of post-burn scars.

According to Saggini et al. **[17]**, ESWT is an emerging therapeutic option for painful, retraction hand scars; administration of ESWT appears to result in considerable changes in scar clinical appearance, hand mobility, and subjective discomfort. ESWT increased dermal fibroblasts, small vessel density (dermal angiogenesis), the type-I-to-type-III collagen ratio, and the deposition of new collagen, which was characterised by thinner collagen fascicles and parallel orientation to the dermo-epidermal junction.

Lee et al. **[18]** aimed to investigate the impact of ESWT on the treatment of hypertrophic scars. The scars that underwent split-thickness skin grafting (STSG) with the identical artificial dermis were compared. During the trial period, they discovered that ESWT had a positive impact on scar thickness, erythema, and sebum levels. ESWT can be one of the treatments used to improve scar characteristics.

ESWT, according to Cho et al. **[19]**, reduces scar pain significantly. The ESWT-induced vascularization, which increased blood flow to facilitate tissue regeneration, inhibited nociceptors in the peripheral skin scar to block central sensitization to pain, and decreased substance P synthesis in the dorsal root ganglion to inhibit neuronal hyperexcitability, could explain why the ESWT group showed significantly greater pain reduction than the control group.

The efficacy of ESWT on post-burn scars was investigated by Aguilera-Sáez et al. **[20]**. The patients were split into two groups, each with twenty patients. The conventional therapy for post-burn scars was given to the control group. The ESWT group got conventional therapy as well as ESWT 512 impulses of 0.15mJ/mm^2 twice a week for four weeks to treat post-burn scars. They measured scar appearance with the Vancouver Scar Scale (VSS), as well as pruritus and pain with the Visual Analog Scale (VAS) before and after treatment, at 6 weeks and 6 months. For all three parameters, the two groups are comparable. The median values of all three measures (VSS, VAS pain, and VAS pruritus) improved as time progressed, to a higher degree for the ESWT group.

Taheri et al. **[21]** reported that ESWT was effective on improving the pain, itching, and the appearance of burn scar.

Extracorporeal shock wave therapy (ESWT), which primarily targets the fibroblasts in scar tissue, was explored by Fioramonti et al. **[22]** as an effective scar treatment technique in burn patients. Before and after treatment, digital photos were taken and visual analogue scales were completed. Scars seemed more pliable and colour mismatch was less noticeable after the first session. All treated scars had a more acceptable look at the end of the research period.

Silicone gel sheet (SGS) was used as a control for both groups because SGS is considered as the gold standard and non-invasive approach for hypertrophic scar prevention and treatment. To get better outcomes, SGS can be used in combination with other invasive and non-invasive therapy approaches **[23]**.

SGS' efficacy, according to Bleasdale et al. **[24]**, is due to its ability to enhance occlusion and hydration of the skin, which assists in maintaining optimal water levels. As a result, fibroblast proliferation and collagen production are reduced in scars treated with SGS. The rate of pathological scarring development is also reduced when tension is passed from the sides of the wound bed to SGS. SGS has also been proven to decrease the body's usual reaction to hyperemia, which improves blood circulation and reduces blood flow to the region of the hypertrophic scar, improving scar appearance. As the temperature rises, collagenase activity rises, and SGS breaks down collagen fibers, reducing hypertrophic scars.

The impact of silicone gel therapy on Chinese subjects with severe hypertrophic scar was studied by Li-Tsang et al. **[25]**. The silicone gel sheeting group (SGS group) and the control group were assigned at random to 45 patients. Patients in the SGS group were told to use silicone gel sheeting (Cica-Care) for 24 hours a day for six months. The scar appearance was assessed using the Vancouver Scar Scale, while pain and itching were assessed using the Visual Analog Scale (VAS). Silicone gel sheeting (SGS) was shown to be an excellent therapy for hypertrophic scars caused by scald, burns, and skin damage. There was significant difference in scar thickness between the experimental and

control group. The scars in the experimental group became thinner (less hypertrophic), more pliable and less vascular after intervention.

Li-Tsang et al. **[26]** suggested that silicone gel sheet (SGS) would be more successful in alleviating itchingwhen compared with pressure garment (PG). The silicone gel sheet's hydration and lubricating properties may explain its beneficial effect on pain and pruritus relief. Furthermore, continuous use of a pressure garment during the summer months may alter skin perspiration and, as a result, cause pruritus.

Conclusion:

Extracorporeal shock wave therapy (ESWT) and silicone gel sheet (SGS) had a positive effect on post burn hypertrophic scars but ESWT was more significant in reducing pain, itching, pigmentation, pliability and thickness ofpost burn hypertrophic scars.

ESWT is an effective, easy to apply, noninvasive treatment modality and had more significant effect on post burn hypertrophic scars than SGS.

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العلاج بالموجات التصادمية مقابل صفائح هلام السيليكون على ندبات ما بعد الحروق

الهدف من الدراسة : أجريت هذه الدراسة لمعرفة تأثير العلاج بالموجات التصادمية مقابل صفائح هلام السيليكون على ندبات ما بعد الحروق.

شارك فى هذه الدراسة ثلاثون مريضاً ممن يعانون من ندبات ما بعد الحروق، قسموا عشوائياً إلى مجموعتين متساويتين فى العدد.

– المجموعة الأولى : تلقت العلاج بالموجات التصادمية جلستين فى الأسبوع بالإضافة إلى العلاج الطبيعى الروتينى وذلك لمدة شهرين.

– المجموعة الثانية : تلقت العلاج بصفائح هلام السيليكون لمدة ٢٠–٢٤ ساعة باليوم بالإضافة إلى العلاج الطبيعى الروتينى جلستين فى الأسبوع وذلك لمدة شهرين.

تضمنت طرق التقييم قبل وبعد الدراسة مقياس تقييم الندبات بواسطة المريض والملاحظ.

وقد أظهرت النتائج ما يلى : أن هناك إنخفاض ذو دلالة إحصائية فى كل عناصر مقياس تقييم الندبات بواسطة المريض والملاحظ بعد العلاج مقارنة بقبل العلاج في كلتا المجموعتين. وقد أوضحت المقارنة بين المجموعتين بعد العلاج أن هناك إنخفاض ذو دلالة إحصائية فى كل عناصر مقياس تقييم الندبات بواسطة المريض والملاحظ فى المجموعة الأولى مقارنة بالمجموعة الثانية.

وبمناقشة هذه النتائج وتحليلها، تبين أن العلاج بالموجات التصادمية فعال وله تأثير أفضل وذو دلالة إحصائية فى علاج ندبات ما بعد الحروق من العلاج بصفائح هلام السيليكون.