

Is Shock Wave Application Effective on Various Chronic Wounds in the Geriatric Population? Preliminary Clinical Study

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Purpose: Extracorporeal shock wave therapy (ESWT) is a beneficial adjunct modality for chronic wounds. Limited research has been conducted on pressure ulcers (PUs), while the majority of studies have focused on diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). This study aimed to evaluate the short-term effects of radial ESWT in older adults with chronic wounds.

Patients and Methods: This study involved a total of 31 wounds: PUs (n=22), VLUs (n=7), and DFUs (n=2). A single radial ESWT was performed with 300 + 100 shocks per cm², pressure of 2.5 bar, energy of 0.15 mJ/mm², and frequency of 5 Hz. Assessments using digital planimetry and clinical methods, utilizing the Wound Bed Score (WBS) and the Bates-Jansen Wound Assessment Tool (BWAT) were performed before the radial ESWT application (M0) and one week after (M1).

Results: A significant wound decrease in planimetry was noted (pre-ESWT vs post-ESWT), with wound area from 9.4 cm² to 6.2 cm², length from 6.4 cm to 3.9 cm, and width from 2.8 cm to 2.1 cm (p<0.001). Additionally, a substantial clinical improvement was noted in both the WBS with a 31.25% increase and the BWAT with a 20.00% increase (p<0.001). It was also found a significant correlation between the planimetric and clinical outcomes for both tools: WBS (r=-0.446, p=0.012) and BWAT (r=0.327, p=0.073).

Conclusion: The ESWT application yields substantial immediate clinical effects that support the healing of chronic wounds in older adults. Even a single ESWT session can prove to be clinically effective and beneficial in the management of chronic wounds.

Keywords: extracorporeal shockwave therapy, wound healing, older adults, clinical assessment, pressure ulcer, venous ulcer, diabetic foot ulcer

Introduction

Chronic wounds are characterized by impaired healing and delayed tissue repair resulting in long-term anatomical and functional disturbances within the skin.¹ Chronic wounds result in severe impairment of recovery and disruption of the normal sequence of healing phases and are persistent to the use of conventional treatments.² According to the etiological classification, diabetic foot ulcers (DFUs), venous leg ulcers (VLUs) and pressure ulcers (PUs) are most common chronic wounds of the skin and soft tissue.³

Patient suffering from chronic wounds may lose independent functioning and experience a significant deterioration in quality of life.^{4,5} These problems become more significant in patients with chronic wounds and can lead to several complications resulting in disability, loss of independent functioning, the need for institutional care and, in extreme cases, even premature death.⁶ The cost to health systems of medical care and inability to work for people with chronic wounds is about \$10 billion a year, and it is likely that most of this cost is attributable to wound care for the older population over the age of 65.⁷

The vast majority of chronic wounds are associated with conditions more typically found in the elderly, such as arteriosclerosis, venous insufficiency, hypertension, or diabetes and metabolic disorders. In addition, a growing number of older adults are at risk due to surgical procedures, with potential complications in wound healing or immobilization causing pressure injury.^{8,9}

According to available data, 60–70% of all reported PUs occur in older adults over the age of 65 years, including especially geriatric ward patients with an incidence of 8–20%.¹⁰ It should be emphasized that VLUs are most common chronic wounds among elderly people with associated chronic venous insufficiency and represent 60–80% of all lower leg ulcers in the course of venous disease.¹¹ DFUs are one of the diabetic complications and its worldwide prevalence among diabetic patients ranges between 3–13%.¹² Moreover, the 5-year mortality rate for the presence of DFUs and ischemic ulcers is higher than for some cancers.¹³

The management of chronic wounds is a complex process dependent on the intricate synergy of many highly regulated factors which is focused tissue remodelling and regeneration based on promotion of re-epithelialization process.⁹ The therapeutic management and systematic approach for assessing chronic wounds is still based on the TIME principles.¹⁴

Contemporary wound care modalities and strategies being the gold standard for the treatment chronic wounds, can be effectively enhanced by a variety of biophysical methods.^{15,16} The comprehensive wound care team includes physicians, nurses, podiatrists, certified diabetes educators, registered dietitians and prosthetists or orthotists as well as specialized physiotherapists.¹⁷ Physiotherapeutic modalities have some potential to be implemented to comprehensive and inter-professional wound care management.^{18,19}

The clinical utility of a few biophysical methods including electrical stimulation or ultrasound therapy has been confirmed.²⁰ However, the effects of low-level laser therapy for improving healing process has not been proved.²¹ The remaining methods with documented experience-based efficiency can be involved, such as pulsed lavage with suction, concurrent optical and magnetic stimulation, hyperbaric oxygen therapy, ultraviolet C therapy, polarized light therapy or far-infrared therapy.^{22–25}

One of potentially valuable biophysical agent is extracorporeal shock wave therapy (ESWT). It harnesses the mechanical energy generated by acoustic waves to induce biological responses within the treated tissues.²⁶ One of the primary mechanisms of action involves generating mechanical stress that triggers cellular responses. The mechanical forces generated by ESWT are believed to activate various cellular signaling pathways, leading to increased production of growth factors, cytokines, and other molecules involved in tissue repair and regeneration as mechanotransduction phenomena.²⁷ Additionally, ESWT is thought to modulate inflammation, enhance neovascularization, and promote the recruitment of cells proliferation to the injured site. The mechanical impact of shock waves on cellular structures may trigger cellular processes that contribute to tissue healing, making ESWT a promising therapeutic approach for conditions ranging from musculoskeletal injuries to chronic wound healing.²⁸

Previous studies demonstrated that ESWT may be implemented for treating wounds, specifically of those with chronic etiology like DFUs and VLUs.^{29,30} The fact is that the usefulness of the ESWT for PU's remains poorly documented. There is only one cross-over randomized controlled trial (RCT) study by Larking et al³¹ who involved a limited group of nine patients and our previous RCT among 40 patients.³² Also, two case reports published in 2020 by Duan et al³³ and Kang et al³⁴ which reported a beneficial effect after ESWT on PUs can be found.

Therefore, this prospective uncontrolled interventional study was performed to observe short-term clinical outcomes after one session of radial ESWT delivered to etiologically different chronic wounds. Also, the correlations between the planimetric and clinical assessments as well as comparisons of study outcomes between groups in terms of wound etiology and location were conducted.

Materials and Methods

Design and Settings

The study protocol received approval from the Bioethics Committee of Wrocław Medical University in Poland (approval no. KB–632/2016). The study was conducted in accordance with Good Clinical Practice guidelines and the 2004 revision of the Declaration of Helsinki. The study project was prospectively registered at the Clinical Trials Registry Platform (no. ACTRN12617000075381).

This prospective interventional study was carried out between January 2017 and December 2020 in two facilities: an inpatient center for long-term care and an outpatient clinic specializing in wound care, both located in Wrocław, Poland. The study is identified by the acronym SHOWN (SHOCK Waves in wounds).

Qualification Procedure

This study included patients who met all of the following criteria: (1) skin wounds with pressure, venous, or diabetic etiology; (2) wounds with a duration exceeding 3 months; (3) wounds classified as class II or III according to the Centers for Disease Control and Prevention (CDC); (4) the absence of health conditions contraindicating the application of ESWT; and (5) patient's informed consent obtained prior to the study commencement. Patients were excluded if they met any of the following criteria: (1) clinical wound infection confirmed in microbiological tests; (2) wounds classified as class I or IV according to CDC; (3) patient non-compliance with the study protocol; and (4) patients with existing contraindications to ESWT were also excluded from participation in the study.

Patients' Characteristics

At the outset, the study group comprised 33 patients; however, 14 patients were excluded from the study for not meeting the inclusion criteria. Ultimately, 19 patients with a total of 31 chronic wounds (22 PUs, 7 VLU, and 2 DFUs) were included in the study and qualified for ESWT treatment. Detailed general and clinical characteristics of the study participants are provided in Tables 1 and 2, respectively.

Table 1 Patients' Characteristics Including Demographic Items (n=19)

Variables	Statistics
Sex, n (%)	
Male	4 (21.05%)
Female	15 (78.95%)
Age (years)	
M ± SD	82 ± 11
Me (Q1 – Q3)	87 (78–89)
Min – Max	57–93
Body height (cm)	
M ± SD	167 ± 9
Me (Q1 – Q3)	167 (159–171)
Min – Max	154–184
Body mass (kg)	
M ± SD	66 ± 13
Me (Q1 – Q3)	65 (54–78)
Min – Max	45–87

(Continued)

Table 1 (Continued).

Variables	Statistics
BMI (kg/m ²)	
M ± SD	23.4 ± 3.3
Me (Q1 – Q3)	23.0 (21.3–25.7)
Min – Max	17.8–31.2

Abbreviations: n, number of participants; M, mean; SD, standard deviation; Me, median; Q1, lower quartile (25%); Q3, upper quartile; Min, minimum; Max, maximum.

Table 2 Patients' Characteristics Including Clinical Items (n=19)

Variables	Statistics, n (%)
Wound etiology	
Pressure ulcer (PU)	22 (71.0%)
Venous leg ulcer (VLU)	7 (22.6%)
Diabetic foot ulcer (DFU)	2 (6.4%)
Duration (months)	
M ± SD	9.1 ± 9.2
Me (Q1 – Q3)	6 (4–9)
Min – Max	3–36
Side	
Left	12 (38.7%)
Central	10 (32.3%)
Right	9 (29.0%)
Location	
Sacral	10 (32.2%)
Calf	8 (25.8%)
Calcaneal	5 (16.1%)
Trochanteric	4 (12.9%)
Foot	2 (6.5%)
Malleolar	2 (6.5%)
Comorbidities	
Hypertension	18 (58.1%)
Arteriosclerosis obliterans	13 (41.9%)

(Continued)

Table 2 (Continued).

Variables	Statistics, n (%)
Chronic venous insufficiency	9 (29.0%)
Diabetes mellitus	4 (12.9%)
Deep vein thrombosis	2 (6.5%)

Abbreviations: n, number of participants; M, mean; SD, standard deviation; Me, median; Q1, lower quartile (25%); Q3, upper quartile; Min, minimum; Max, maximum.

Therapeutic Intervention

The therapeutic session was conducted using a radial ESWT applicator (Cellactor[®] SC1, Storz Medical, Switzerland). The methodology for ESWT ensured safe and sterile conditions as follows: (1) a sterile ultrasound gel was used as a contact medium directly on the entire wound surface and its edges, (2) a sterile barrier in the form of polyurethane film was placed directly over the wound, previously covered by the ultrasound gel, and (3) the same ultrasound gel was applied on top of the film as a second layer to ensure full contact of the ESWT transducer with the tissues.

The delivery of the procedure should be conducted meticulously and with the use of sterile materials. During the ESWT session, the applicator head makes direct contact with the wound, facilitated by sterile ultrasound gel and a sterile polyurethane film. ESWT application should commence from the wound's edges, moving gently towards the center while meticulously treating the entire wound surface. Special attention is necessary when working near any bone structure, which should be avoided. [Figure 1](#) provides an illustration of a treatment session employing radial ESWT. The ESWT parameters were as follows: 300 baseline pulses + 100 additional pulses per square centimeter, a pulse pressure of 2.5 bars, a pulse energy of 0.15 mJ/mm², and a pulse frequency of 5 Hz. Local anesthesia was not used, and the procedure was conducted without causing pain. Any adverse events and side effects were carefully observed and reported during the ESWT procedures.

All patients continued their standard wound care procedures, including proper wound care and hygiene, individually selected and standardized dressings, using pressure relief mattresses and appropriate positioning to optimize healing conditions. These standardized and evidence-based practices adhered to the European Pressure Ulcer Advisory Panel (EPUAP) recommendations for PUs management.

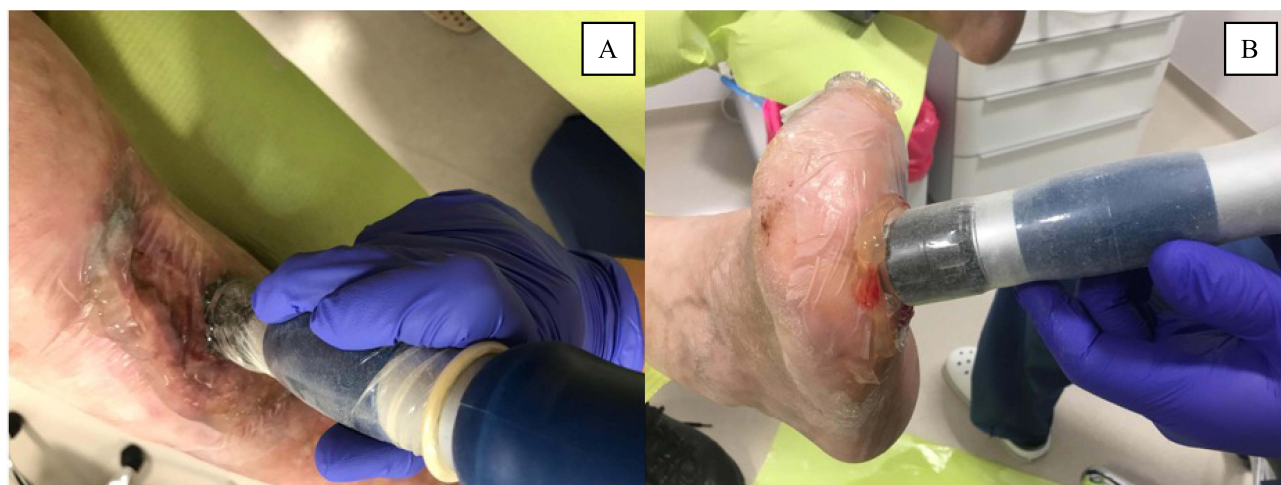


Figure 1 Example of a treatment session using radial ESWT for a VLU (A) and DFU (B).

Abbreviations: ESWT, extracorporeal shockwave therapy; VLU, venous leg ulcer; DFU, diabetes foot ulcer.

Outcomes Measurements

The primary objective of this study was to demonstrate an objective improvement in selected parameters of chronic wounds through planimetric assessment. The secondary goal was to observe enhancements in the clinical properties of chronic wounds using validated tools. The tertiary aim was to establish the relationship between wound parameters and clinical evaluation and to compare study outcomes between groups based on wound etiology and location. Both planimetric and clinical measurements were conducted immediately before the ESWT application (M0) and one week following the ESWT procedure (M1).

A digital planimetry method using the Swift Wound application on an iPhone 7 Plus (Apple Inc., Cupertino, California, United States) smartphone was employed to measure the metric parameters of chronic wounds. This application is known for its accuracy and reliability in creating comprehensive documentation of the wound healing process.³⁵ The wound measurements exhibit a very low error level (less than 0.5%), and high inter-rater reliabilities (ICC = 0.97–1.00).³⁵

The Wound Bed Score (WBS) is a standardized questionnaire used to evaluate the clinical status of soft tissue wounds. It comprises eight components represented by the acronym BEDSCORE, which assess the following wound parameters: Black eschar, Eczema or dermatitis, Depth, Scarring, Color, Edema or swelling, Resurfacing epithelium, and Exudate amount. Each component is assigned a score within the 0–2 range, resulting in a total score that falls between 0 and 16 points. A higher WBS score signifies a more favorable clinical condition of the wound. The WBS serves as a valuable tool in both research and clinical settings, aiding in the optimization of treatments and the exploration of new treatment options.³⁶

The Bates-Jansen Wound Assessment Tool (BWAT) is another standardized instrument comprising 13 components. It assesses various wound parameters, encompassing nine factors: Size, Depth, Edges, Undermining, Type of necrotic tissue, Amount of necrotic tissue, Exudate type, Exudate amount, Skin color around the wound, as well as Peripheral tissue edema, Tissue sclerosis around the wound, Granulation tissue, and Epithelialization. The first nine items are scored within a range of 1–5 points, while the last four items are scored from 0 to 5 points each. The total BWAT score falls between 9 and 65 points, with a lower score indicating a more favorable clinical wound condition. The BWAT demonstrates a level of reliability ranging from moderate to high.³⁷

Statistical Analysis

Statistical analysis was performed using STATISTICA v. 13.3 (TIBCO Software Inc., Tulsa, USA). For all quantitative parameters (age, wound area, etc.), the normal distribution was checked using the Shapiro–Wilk test. The level of significance was set at $p < 0.05$. The mean (M), standard deviation (SD), median (Me), lower (Q1), and upper (Q3) quartiles and minimum (Min) and maximum (Max) were calculated for all measurable parameters. The significance of differences in the mean values of quantitative variables in two independent groups (PU vs VLU+DFU) for parameters with a distribution significantly different from normal or with heterogeneous variances was tested using the Mann–Whitney *U*-test. For dependent variables (pre-ESWT and post-ESWT), the Wilcoxon test was applied. Parametric correlations (Pearson's *r*) were used to assess the significance and strength of relationships between quantitative variables. The results were considered significant for $p < 0.05$ and highly significant for $p < 0.001$.

Results

Patients' Characteristics

The study population consisted of 19 patients (15 females and 4 males) with a mean age of 82 ± 11 years and a mean body mass index (BMI) of 23.4 ± 3.3 kg/m². Detailed general patient characteristics are provided in Table 1. A total of 31 chronic wounds were identified (22 PUs, 7 VLUs, and 2 DFUs). The mean wound duration was 9.1 ± 9.2 months. Most of the wounds were located on the left side ($n=12$, 38.7%), with a majority situated on the sacral region ($n=10$, 32.2%). All patients had comorbidities, including hypertension ($n=18$, 58.1%), arteriosclerosis obliterans ($n=13$, 41.9%), chronic venous insufficiency ($n=9$, 29.0%), diabetes mellitus ($n=4$, 12.9%), and deep vein thrombosis ($n=2$, 6.5%). Detailed patient clinical characteristics are presented in Table 2.

Wounds' Size

After completing the study, it was observed that a single ESWT session led to a significant and immediate improvement in wound healing parameters. There was a significant reduction in wound metric parameters: a reduction in the mean wound area from $9.4 \pm 9.1 \text{ cm}^2$ to $6.2 \pm 7.1 \text{ cm}^2$ (a difference of $3.2 \pm 2.6 \text{ cm}^2$, $p < 0.001$), a reduction in the mean wound length from $6.4 \pm 2.7 \text{ cm}$ to $3.9 \pm 2.8 \text{ cm}$ (a difference of $0.7 \pm 0.6 \text{ cm}$, $p < 0.001$), and a reduction in the mean wound width from $2.8 \pm 1.7 \text{ cm}$ to $2.1 \pm 1.5 \text{ cm}$ (a difference of $0.7 \pm 0.4 \text{ cm}$, $p < 0.001$). Similar improvements were observed for PUs in all tested planimetric parameters ($p < 0.001$). Detailed results are presented in Table 3. Examples of radial ESWT application effects using planimetric assessment are summarized in Figure 2.

Wounds' Condition

There was a significant beneficial effect on the clinical condition of the wound when considering the pre- and post-ESWT comparison. The WBS score improved significantly from 4.6 ± 2.8 to 10.4 ± 3.6 points, indicating a better clinical condition of the wound, with an improvement of 31.25% ($p < 0.001$). The BWAT score also showed a significant enhancement, improving from 43.8 ± 7.9 to 30.7 ± 7.5 points, representing a better clinical condition by 20.00% ($p < 0.001$). Similar improvements were observed for PUs in terms of clinical evaluation, with significant improvements in both the WBS ($p < 0.001$) and BWAT ($p < 0.001$) scores. Detailed results are presented in Table 4.

Selected Correlations

The strongest positive correlation was observed between the wound width parameter and the BWAT assessment ($r = 0.472$, $p < 0.001$). Both wound assessment models—the WBS and BWAT—demonstrate relatively weak correlations for small wounds up to 5 cm^2 but provide better estimations for larger wounds above 5 cm^2 . Detailed results are presented in Table 5.

A statistically significant correlation was observed between the changes in the wound surface area and the clinical assessment for both WBS and BWAT scores. There was a strong negative correlation between the wound area and WBS

Table 3 Planimetric Results Prior-ESWT and Post-ESWT for All Wounds (n=31) and PUs Alone (n=22)

PU (n = 22) VLU (n = 7) DFU (n = 2)	M0	M1	P-value	M0-M1
Area (cm ²)	9.4 ± 9.1 5.0 (3.7–12.5)	6.2 ± 7.1 3.3 (1.8–6.4)	<0.001	3.2 ± 2.6 2.3 (1.5–3.9)
Length (cm)	6.4 ± 2.7 3.5 (2.7–6.1)	3.9 ± 2.8 2.8 (2.0–6.0)	<0.001	0.7 ± 0.6 0.6 (0.3–0.9)
Width (cm)	2.8 ± 1.7 2.1 (1.7–3.0)	2.1 ± 1.5 1.6 (1.2–2.3)	<0.001	0.7 ± 0.4 0.6 (0.4–0.9)
PU (n = 22)	M0	M1	P-value	M0-M1
Area (cm ²)	11.1 ± 10.3 5.1 (3.8–22.2)	7.6 ± 8.0 3.6 (2.1–16.8)	<0.001	3.6 ± 2.9 2.3 (1.8–5.4)
Length (cm)	4.9 ± 3.0 3.5 (2.7–6.7)	4.3 ± 3.1 2.9 (2.0–6.0)	<0.001	0.7 ± 0.7 0.6 (0.2–0.9)
Width (cm)	3.1 ± 1.9 2.2 (1.8–4.5)	2.4 ± 1.6 1.7 (1.4–2.8)	<0.001	0.7 ± 0.4 0.7 (0.4–1.0)

Note: M \pm SD, Me (Q1–Q3), P-value – Wilcoxon Matched Pairs Test.

Abbreviations: PU, pressure ulcer; VLU, venous leg ulcer; DFU, diabetes foot ulcer; M0, pre-ESWT measurement; M1, post-ESWT measurement; M0–M1, difference between pre- vs post-ESWT.

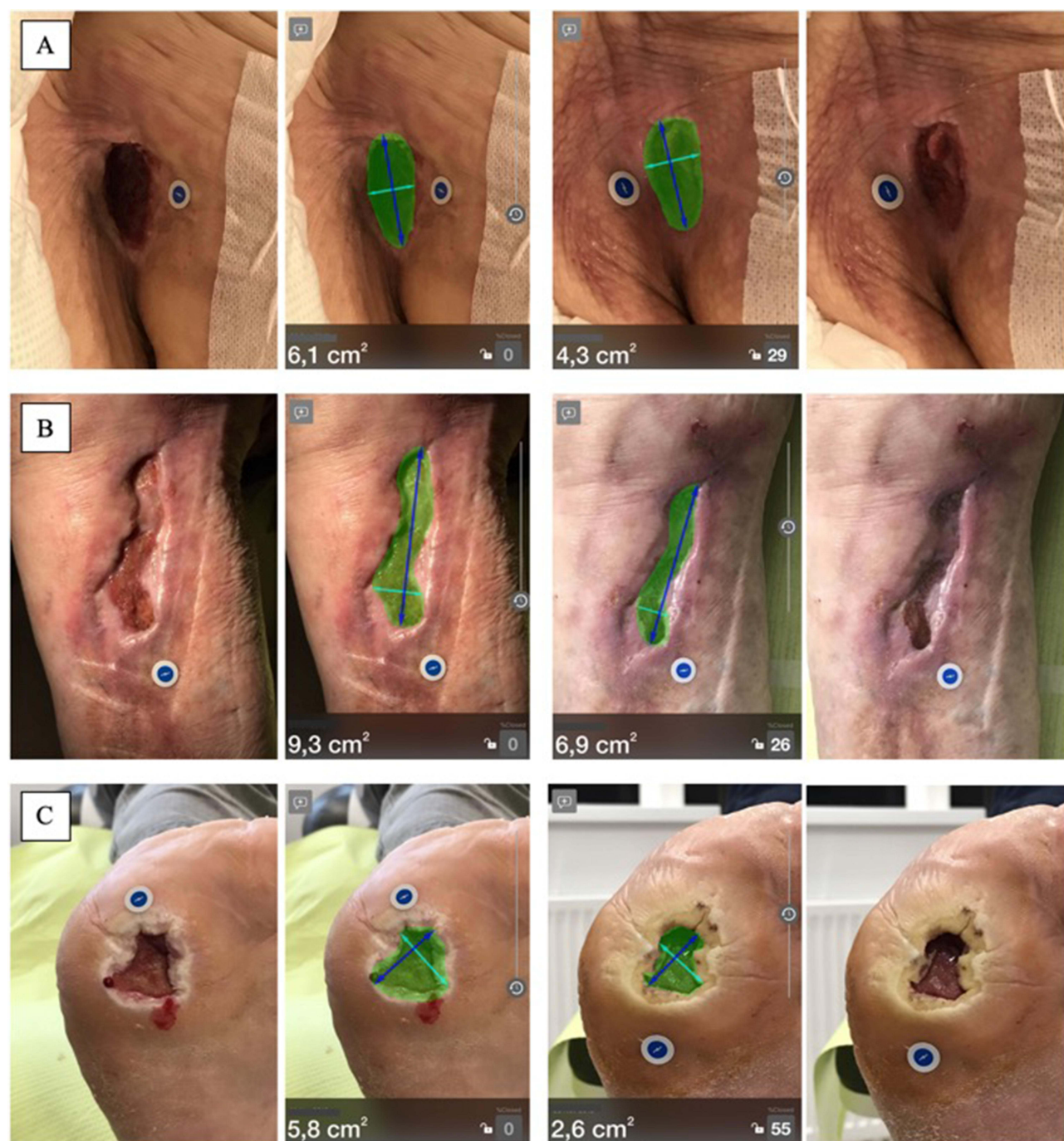


Figure 2 Example of planimetric effects of radial ESWT for a patient with a PU (A), VLU (B), and DFU (C).

Abbreviations: ESWT, extracorporeal shockwave therapy; PU, pressure ulcer; VLU, venous leg ulcer; DFU, diabetes foot ulcer.

score ($r=-0.367$, $p=0.003$), as well as a strong positive correlation between the wound surface area and BWAT score ($r=0.368$, $p=0.003$). Similar results were obtained for correlations after ESWT treatment for both the WBS ($r=-0.446$, $p=0.012$) and BWAT ($r=0.327$, $p=0.073$). Detailed results are provided in Figure 3.

A statistically significant and strong negative correlation was observed for both the WBS and BWAT in terms of clinical wound evaluation ($r=-0.892$, $p<0.001$). This correlation was also confirmed for the WBS and BWAT during the pre-ESWT ($r=-0.807$, $p<0.001$) and post-ESWT ($r=-0.825$, $p<0.001$) assessments. Detailed results are shown in Figure 4.

Table 4 Clinical Results Using the WBS and BWAT Results Prior-ESWT and Post-ESWT for All Wounds (n = 31) and PUs Alone (n=22)

PU (n = 22) VLU (n = 7) DFU (n = 2)	M0	M1	P-value	M0-M1
WBS (points)	4.6 ± 2.8 5 (2–7)	10.4 ± 3.6 11 (8–13)	<0.001	5.7 ± 2.8 5 (3–8)
BWAT (points)	43.8 ± 7.9 42 (37–50)	30.7 ± 7.5 30 (24–36)	<0.001	13.1 ± 6.0 12 (8–16)
PU (n = 22)	M0	M1	P-value	M0-M1
WBS (points)	3.8 ± 2.8 3 (2–6)	9.6 ± 3.9 10 (7–13)	<0.001	5.8 ± 3.0 5 (3–9)
BWAT (points)	45.4 ± 8.6 47 (37–52)	30.9 ± 8.3 29 (24–37)	<0.001	14.5 ± 6.4 14 (9–19)

Note: M ± SD, Me (Q1–Q3), P-value – Wilcoxon Matched Pairs Test.

Abbreviations: PU, pressure ulcer; VLU, venous leg ulcer; DFU, diabetes foot ulcer; M0, pre-ESWT measurement; M1, post-ESWT measurement; M0-M1, difference between pre- and post-ESWT; WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

Table 5 Correlations Between Clinical Wound Assessment Using the WBS and BWAT and Their Metric Parameters Following the Planimetric Assessment

Parameters	WBS	BWAT	WBS		BWAT	
	All	All	M0	M1	M0	M1
Area (cm ²)	−0.367	0.368	−0.230	−0.446	0.328	0.327
Length (cm)	−0.307	0.378	−0.194	−0.395	0.389	0.409
Width (cm)	−0.394	0.472	−0.226	−0.447	0.507	0.387

Note: Pearson's r correlation coefficient.

Abbreviations: M0, pre-ESWT measurement; M1, post-ESWT measurement; WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

Selected Comparisons

It was observed that the therapeutic effect of ESWT (the difference between M0 and M1) for wounds with different etiologies (PU vs VLU+DFU) was statistically significant only for the BWAT score (14 vs 9 points, $p<0.031$). The differences in the WBS were found to be statistically insignificant ($p=0.913$). Detailed results are presented in [Figure 5](#). Furthermore, there was no statistically significant difference in the changes in the therapeutic effect of ESWT (the difference between M0 and M1) with respect to the anatomical location of the wound in terms of clinical evaluation using both the WBS ($p=0.187$) and BWAT ($p=0.215$). Detailed results are provided in [Figure 6](#).

Discussion

This study highlights the potential for favorable effects following just one session of radial ESWT, indicating a rapid onset of benefits. Immediate reductions in key planimetric parameters, such as wound area, length, and width, were observed. Additionally, there was a notable enhancement in the clinical status of the wounds, as assessed by validated scales like WBS and BWAT. Furthermore, the study establishes a correlation between wound surface area and clinical assessment using WBS and BWAT. A strong negative correlation was noted between wound surface area and WBS score,

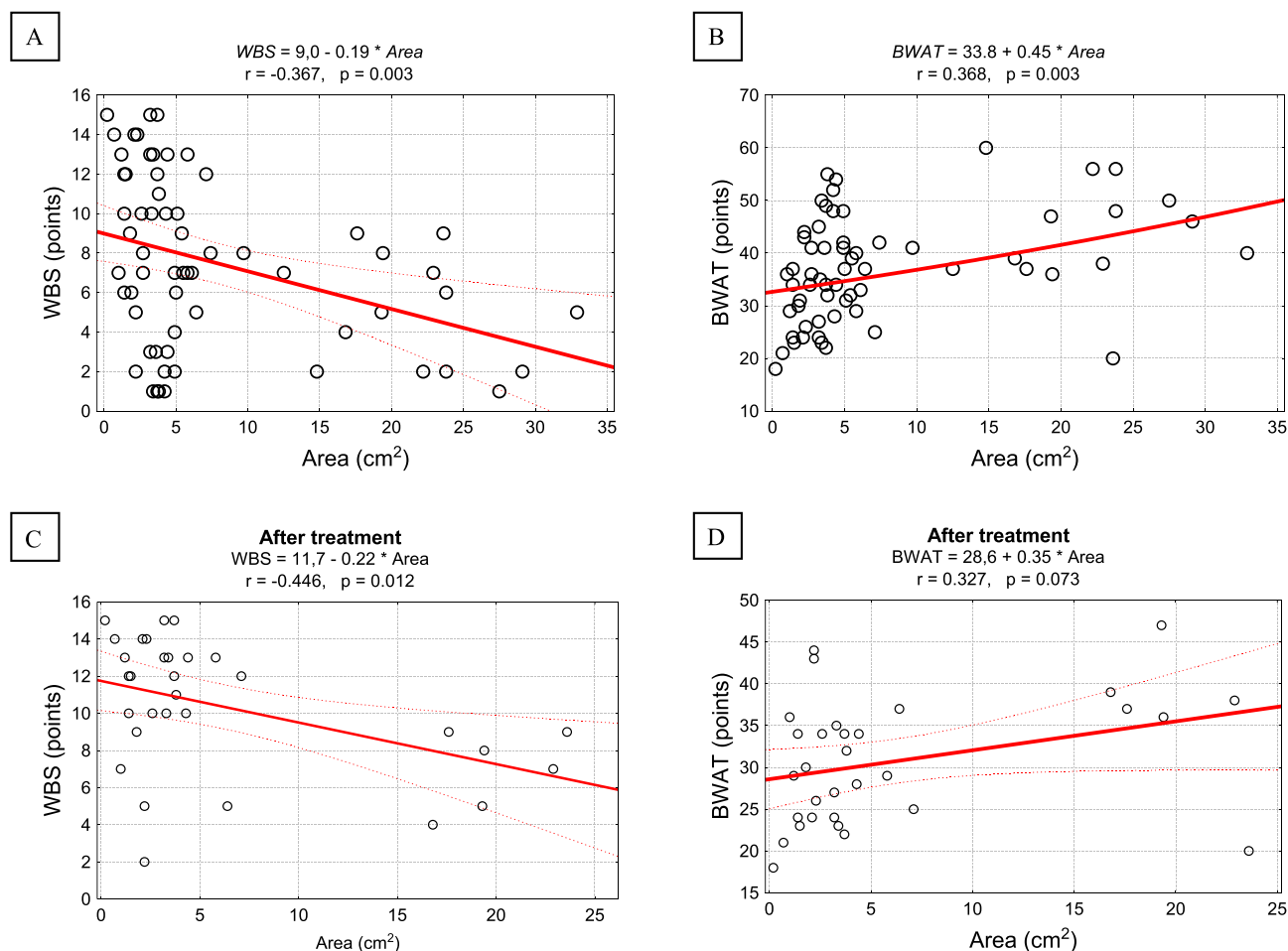


Figure 3 Correlation diagrams for clinical wound assessment using the WBS and BWAT with the wound area before and after ESWT (**A** and **B**) and separately after ESWT only (**C** and **D**).

Notes: Pearson r correlation coefficients and linear regression equations.

Abbreviations: WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

while a robust positive correlation was identified between wound surface area and BWAT score. This implies that a decrease in wound surface area is associated with an improvement in the clinical condition of the wound, reflected by a higher WBS score and a lower BWAT score.

So far, there have been limited reports on the use of ESWT in wound management. The majority of studies with well-documented RCT designs have focused on DFUs,^{38–44} with only one study addressing VLU⁴⁵ and PUs.³¹ Furthermore, in the aforementioned trials, both focused and defocused (planar) ESWT were applied as treatment interventions. Drawing comparisons with prevailing literature highlights the scarcity of rigorous RCTs focused on ESWT in PUs.³¹ Our earlier parallel RCT demonstrated the superiority of radial ESWT, presenting not just improvements but significant strides in planimetric measures and clinimetric outcomes. In contrast to the conventional, our study stands as a torchbearer, injecting a much-needed jolt of evidence into the relatively unexplored realm of radial ESWT in wound care.³²

Considering anecdotal evidence from case reports, particularly those emanating from Chinese researchers,^{33,34} lends weight to our unconventional approach. While these narratives remain anecdotal, they echo our findings of rapid wound closure and effective management. Our study, in the face of skepticism, emerges as a bold protagonist, providing tangible, real-world evidence of the impact of radial ESWT on chronic wounds.

Aligning our results with prior clinical studies and case series brings forth a defiance echoing the positive trends observed by pioneers like Porso et al⁴⁶ and Saggini et al.⁴⁷ These studies, while suggesting the need for more research,

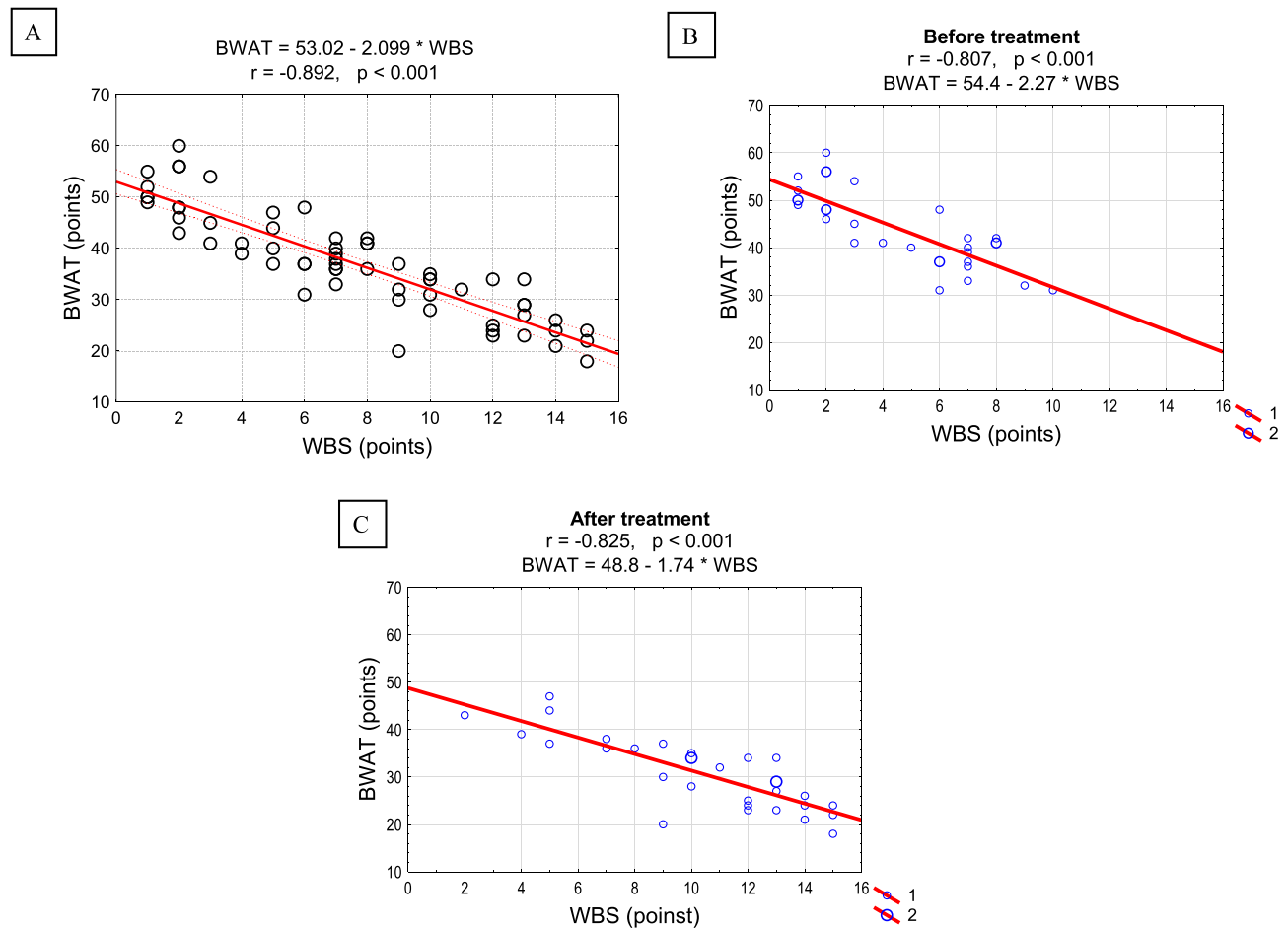


Figure 4 Correlation diagram for clinical wound assessment using the WBS and BWAT overall (A) and separately before and after ESWT (B and C).

Notes: Pearson r correlation coefficients and linear regression equations.

Abbreviations: WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

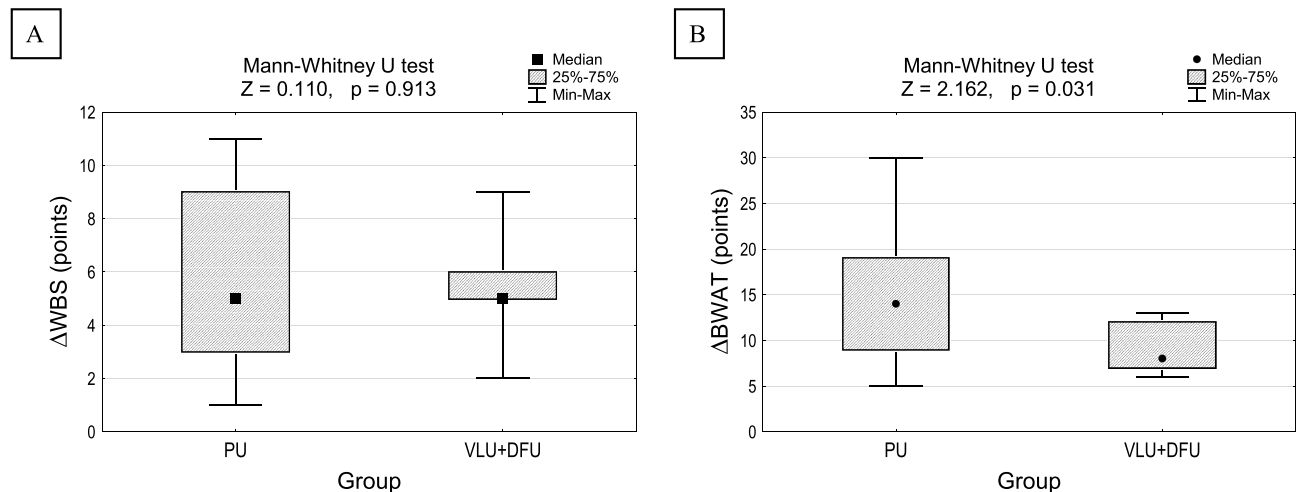


Figure 5 Summary of therapeutic effect for clinical wound assessment using the WBS (A) and BWAT (B) in terms of the groups of wounds of different etiology.

Notes: P-value: Mann-Whitney U-test; Wound etiology: PUs (n=22) and VLUs with DFUs (n=9). WBS PU: Me = 5; Q1 = 3; Q3 = 9 BWAT PU: Me = 14; Q1 = 9; Q3 = 19. WBS VLU+DFU: Me = 5; Q1 = 5; Q3 = 6 BWAT VLU+DFU: Me = 8; Q1 = 7; Q3 = 12.

Abbreviations: PU, pressure ulcer; VLU, venous leg ulcer; DFU, diabetes foot ulcer; WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

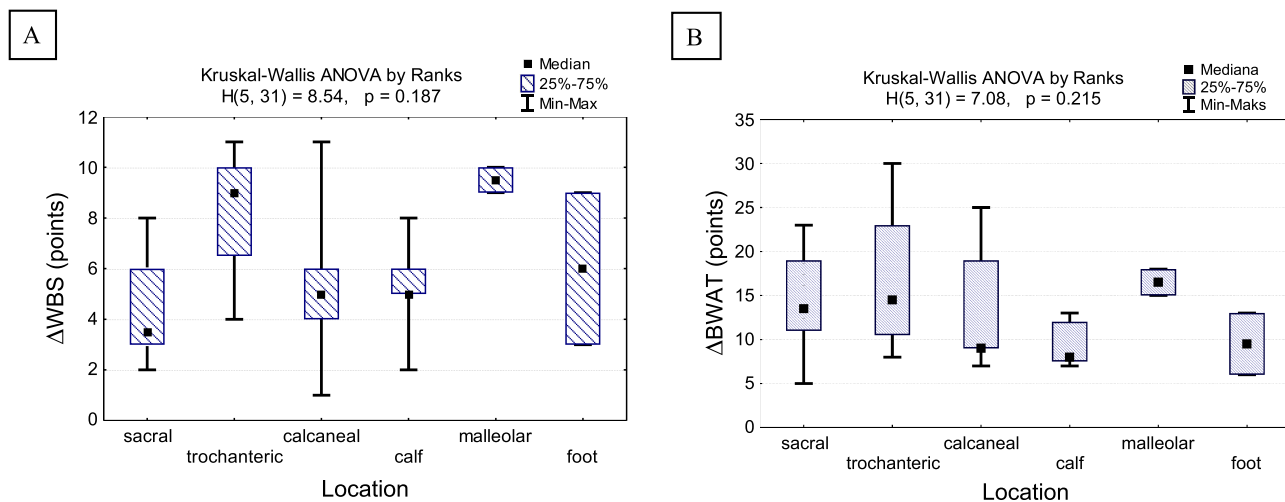


Figure 6 Summary of therapeutic effect for clinical wound assessment using the WBS (A) and BWAT (B) in terms of the groups of wounds with different anatomical locations.

Notes: Kruskal-Wallis ANOVA test; Wound location: sacral (n=10), calf (n=8), calcaneal (n=5), trochanteric (n=4), foot (n=2), and malleolar (n=2). WBS sacral: Me = 3.5; Q1 = 3; Q3 = 6 BWAT sacral: Me = 13.5; Q1 = 11; Q3 = 19 WBS trochanteric: Me = 9; Q1 = 6.5; Q3 = 10 BWAT trochanteric: Me = 14.5; Q1 = 10.5; Q3 = 23 WBS calcaneal: Me = 5; Q1 = 4; Q3 = 6 BWAT calcaneal: Me = 9; Q1 = 9; Q3 = 19 WBS calf: Me = 5; Q1 = 5; Q3 = 6 BWAT calf: Me = 8; Q1 = 7.5; Q3 = 11 WBS malleolar: Me = 9.5; Q1 = 9; Q3 = 10 BWAT malleolar: Me = 16.5; Q1 = 15; Q3 = 18 WBS foot: Me = 6; Q1 = 3; Q3 = 9 BWAT foot: Me = 9.5; Q1 = 6; Q3 = 13.

Abbreviations: PU, pressure ulcer; VLU, venous leg ulcer; DFU, diabetes foot ulcer; WBS, Wound Bed Score; BWAT, Bates-Jensen Wound Assessment Tool.

could not anticipate the disruptiveness of our study, diving into chronic wounds of varied etiologies and unraveling the potential of radial ESWT in diverse clinical scenarios. The authors suggested that additional research is necessary before considering the clinical implementation of ESWT for chronic wounds.

Comparisons with the grand narrative of expansive trials, such as Schaden et al⁴⁸ which encompassed a myriad of chronic wounds treated with defocused ESWT, direct the spotlight back to radial ESWT, particularly in the context of pressure ulcers. In this clash of narratives, our study emerges as the radical underdog, insisting that the unique characteristics of radial ESWT deserve a distinct place in the annals of wound healing. The authors concluded that additional clinical trials are essential to assess the biophysical characteristics of ESWT and to establish a standardized ESWT protocol for chronic ulcers.

In substantiating our audacious claims, our study presents concrete evidence. A single session of radial ESWT yielded significant reductions in wound area, length, and width, transcending the confines of conventional wound care. The clinical condition of the wounds, assessed through Wound Bed Score (WBS) and Bates-Jensen Wound Assessment Tool (BWAT), witnessed remarkable enhancements. WBS scores soared from 4.6 ± 2.8 to 10.4 ± 3.6 points, showcasing a staggering 31.25% improvement. The BWAT score, a testament to the comprehensive clinical evaluation, exhibited a parallel rise from 43.8 ± 7.9 to 30.7 ± 7.5 points, marking a substantial 20.00% improvement. In this aspect, study by Wolf et al⁴⁹ identified a significant correlation between the initial WBS and wound area, a finding consistent with our own study (including post-ESWT evaluation). The authors advocate for further research to elucidate the mechanisms by which ESWT promotes wound healing.

The timing of assessments is crucial in understanding the dynamics of wound healing. In this study, evaluations were conducted at two specific time-points: before the initiation of ESWT treatment (M0) and one week after the treatment (M1). These time-points were strategically chosen to capture the baseline condition of wounds and to assess the immediate impact of ESWT. The one-week interval allows for a relatively short-term observation of changes in wound parameters, providing insights into the early response to shockwave therapy. However, it's important to note that longer-term follow-ups could offer a more comprehensive understanding of the sustained effects and overall progress in wound healing over time.

In the realm of ESWT parameters and sessions, our study aligns with the grand narrative only to the extent that it prompts evaluation in controlled clinical trials. However, our exclusive focus on radial ESWT in the context of pressure

ulcers redefines the discourse. With specific parameters — 300 baseline pulses + 100 additional pulses per square centimeter, a pulse pressure of 2.5 bars, a pulse energy of 0.15 mJ/mm², and a pulse frequency of 5 Hz — our study sets a benchmark for future investigations. Notably, our study hints at the transformative potential of radial ESWT, challenging the status quo and paving the way for a more targeted, nuanced approach in chronic wound management.

Study Limitations

This paper has certain potential limitations. First of all, it is recommended to validate the experiment through the inclusion of a control group within the protocol. It is important to note that ESWT treatment applications may require 3-5-10 sessions for stronger results, or treatment may need to continue until complete wound closure is achieved. Additionally, follow-up observations should be considered to assess long-term effects and the comprehensive journey of wound healing from intervention to closure.

Clinical Implications

This study offers compelling evidence endorsing the practicality of utilizing radial ESWT applications in the treatment of chronic wounds among geriatric patients. This finding holds potential benefits for both researchers and clinical practitioners in their pursuit of safe and efficient treatment approaches to facilitate wound healing of such demanding group of patients. It is important to take into account the essential methodological factors associated with the ESWT procedure, with particular attention to maintaining aseptic conditions throughout. The delivery of the procedure should be conducted meticulously and with the use of sterile materials. During the ESWT session, the applicator head makes direct contact with the wound, facilitated by sterile ultrasound gel and a sterile polyurethane film. ESWT application should commence from the wound's edges, moving gently towards the center while meticulously treating the entire wound surface. Special attention is necessary when working near any bone structure, which should be avoided. [Figure 6](#) provides an illustration of a treatment session employing radial ESWT. The potential complications, such as general discomfort during ESWT application, local pain sensations, transient increase in wound drainage, and the rare risk of infection, tissue damage or the possibility of local bleeding, should be thoroughly considered and reported to ensure the comprehensive understanding of the therapy's impact on patients and to prevent any deterioration in their clinical condition.

Research Directions

It should be pointed out that ESWT currently lacks widespread adoption in routine clinical practice. Our study, along with others in this domain, seeks to provide evidence supporting the effectiveness and feasibility of ESWT in wound healing. These investigations are essential for developing practical guidelines and facilitating the integration of ESWT into routine wound care protocols. We value the chance to offer valuable insights into this emerging therapeutic approach. Future studies should be focused into optimizing treatment protocols, such as shockwave intensity, frequency, and duration, through iterative studies can help identify the optimal parameters for maximizing therapeutic benefits. Collectively, these future research directions aim to establish ESWT as a reliable and effective modality in the holistic management of wounds, providing evidence-based guidelines for its incorporation into clinical practice. Also, mechanistic studies at the molecular and cellular levels can deepen our understanding of how ESWT influences wound healing processes and explaining the biological mechanism of its action.

Conclusion

The ESWT may potentially serve as a clinically effective, non-invasive, and safe adjunctive biophysical therapy to enhance the healing of chronic wounds in older adults. Nonetheless, the outcomes of this initial clinical study should be approached with caution, and further well-designed RCTs involving a larger patient cohort, including placebo ESWT sessions, should be considered, particularly for PUs.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author, [R.D.], upon reasonable request.

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Disclosure

The authors report no conflicts of interest in this work.

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