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Effect of Low-Level Laser Therapy Versus Shock Wave on Diabetic Foot

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) significantly impair patients' quality of life and may progress to lower limb amputation. Non-invasive modalities such as low-level laser therapy (LLLT) and shock wave therapy (SWT) have been investigated for their potential to accelerate wound healing.

Objective: This study aimed to evaluate the effects of LLLT and SWT on wound surface area (WSA), ulcer volume (UV), and health-related quality of life (QoL) among individuals with DFUs.

Patients and methods: Forty adults with chronic DFUs were randomly allocated to two equal groups selected from Abo Kir General Hospital . Group A (n = 20) received LLLT three times per week, while Group B (n = 20) received SWT twice per week, both over a four-week period. WSA was quantified via digital planimetry, , UV was assessed by the saline-instillation method, and QoL by the Diabetic Foot Ulcer Scale (DFS).

Results: Both groups demonstrated statistically significant improvements. Group A showed a 57.4% reduction in ulcer surface area and 45.0% reduction in volume, while Group B showed 32.0% and 35.6% reductions, respectively. Quality of life (DFS score) also improved in both groups: Group A increased 22.2% and Group B 9.4%. Post-treatment DFS was significantly higher in Group A compared to Group B.

Conclusion: It could be concluded that both LLLT and SWT are effective in reducing ulcer size and volume and in improving quality of life in patients with DFUs. However, LLLT demonstrated superior therapeutic outcomes compared to SWT.

Keywords: diabetic foot ulcer, low-level laser therapy, shock-wave therapy, ulcer surface area; ulcer volume ,quality of life.

INTRODUCTION

Diabetes mellitus is a group of metabolic disorders among which glucose is both underutilized as an energy source and overproduced due to inappropriate gluconeogenesis and glycogenolysis, resulting in hyperglycemia [(1)].

Among diabetes-related complications, diabetic foot ulcers (DFUs) are particularly threatening. They arise when inadequate perfusion (ischemia) or bacterial colonization - or both - impairs tissue integrity. Continuous monitoring of any active DFU is essential to forestall progressive foot destruction [(2)].

Diabetic foot disease usually manifests as ulceration, infection, or Charcot arthropathy and is the leading antecedent to lower-limb amputation. DFUs carry substantial morbidity and mortality, with a worldwide prevalence of roughly 6.3 %; they occur more often in men than women and are more common in type 2 than type 1 diabetes [(3)].

Up to 15 % of people with diabetes will experience a DFU during their lifetime. Early identification of high-risk feet and prompt intervention can avert ulceration, preserve limbs and lives, and enhance quality of life [(4)].

Cutaneous wound repair is a multistep cascade involving cell proliferation and migration, re-epithelialization, collagen synthesis, and angiogenesis. Large skin defects heal slowly because cellular resources are limited, and hyperglycemia disrupts each phase through several signaling pathways [(5)].

DFUs are frequently infected and may progress to cellulitis; if treatment is delayed or inadequate, infection can spread to the bloodstream or lead to gangrene, sometimes necessitating amputation. Complications include soft-tissue and bony infections, progressive tissue loss, accelerated cardiovascular disease, and increased mortality [(6)].

Standard DFU care combines surgical debridement, moisture-retentive dressings with exudate control, offloading, vascular evaluation, infection management, tight glycemic regulation, and patient education. Even after closure, ulcers recur in about 40 % of patients within one year. Physiotherapeutic modalities such as electrical stimulation have shown promise for enhancing wound repair [(7)].

Among adjuvant options, low-level laser therapy (LLLT) stands out as a painless, non-pharmacologic treatment that can hasten ulcer healing. Its benefits include dampening inflammation, fostering angiogenesis, and stimulating extracellular matrix production [(8)].

Extracorporeal shockwave therapy (ESWT) likewise encourages DFU healing by boosting angiogenic factors (e.g., VEGF, endothelial nitric-oxide synthase), enhancing immune responses, and promoting fibroblast

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proliferation—ultimately shrinking wound size and shortening healing times [9].

To address the paucity of direct comparisons, the present study aimed to evaluate LLLT versus ESWT in their ability to improve wound closure and patient quality of life in individuals with diabetic foot ulcers.

PATIENTS MATERIALS AND METHODS

This randomized controlled prospective study included a total of 40 patients diagnosed with type 2 diabetes mellitus for more than five years, attending at Department of Diabetic Foot, Abu Qir General Hospital, Alexandria, Egypt, during the period from July 2023 to October 2024.

Inclusion criteria: Patients of both sexes, aged 45 to 60 years, with type 2 diabetes mellitus for more than 5 years; presence of chronic foot ulcers classified as Wagner grade 1 or 2; ulcer dimensions between 0.5 cm and 5 cm in any direction; ulcers unresponsive to standard conservative treatment for at least three months; glycated hemoglobin (HbA1c) > 48 mmol/mol; and willingness to comply with the treatment protocol and attend follow-up visits.

Exclusion criteria: Presence of local infection, cellulitis, osteomyelitis, or gangrene; systemic illnesses such as malignancy, renal or hepatic failure; ankle-brachial index (ABI) < 0.7; severe malnutrition or anemia; or pregnancy.

The included subjects were randomly divided into two groups; **Group A** (n = 20) received low-level laser therapy (LLLT) and **Group B** (n = 20) underwent extracorporeal shock-wave therapy (ESWT).

Sample Size Calculation

Using G*Power 3.1, an a priori calculation was conducted assuming a moderate effect size (f = 0.25), an alpha level of 0.05, statistical power of 0.80, and two measurement occasions (pre- and post-intervention). The analysis indicated that a minimum of 40 participants—20 in each group—was required to adequately power the study.

Ethical Considerations

This study was ethically approved by the Ethical Committee of the Faculty of Physical Therapy, Cairo University, Egypt, in 2024 (Approval No. P.T.REC/012/003891). Written informed consent was obtained from all participants. The study protocol adhered to the principles of the Declaration of Helsinki, the ethical standard of the World Medical Association for research involving human subjects.

Evaluation Procedures

Assessments were conducted before treatment initiation and after the 4-week intervention period. These included detailed medical history, ulcer surface area and volume measurement, and quality of life assessment using the Diabetic Foot Ulcer Scale (DFS). Baseline data were collected via clinical interview and chart review, including diabetes duration, HbA1c, prior foot treatments, and relevant comorbidities. Each participant's data were documented in individualized case sheets to ensure consistency and eligibility compliance.

Ulcer Surface Area

Wound surface area was measured using a transparent grid overlay method. The ulcer was outlined with a sterile marker on transparency film and digitized via flatbed scanner. Adobe Photoshop CS6 software was used to calculate area in cm² through pixel mapping and calibration against a known reference grid [10].

Ulcer Volume

Ulcer volume was measured via the saline-filling method. After cleansing and covering the ulcer with adhesive film, sterile saline was injected using a 20 cm³ syringe until the wound cavity was completely filled. The total volume required to reach skin level was recorded in cm³, providing a reproducible measurement of wound depth [11].

Quality of Life

Quality of life was assessed using the DFS questionnaire. A trained therapist assisted participants in a quiet environment, particularly those with low literacy or vision impairment. The questionnaire evaluated domains such as physical functioning, emotional well-being, and ulcer-specific burden. Standardized scoring was used to calculate pre- and post-intervention scores [12].

Intervention Procedures

Group A – Low-Level Laser Therapy (LLLT)

Participants in Group A received LLLT using a red-light laser device (660 nm wavelength, 50 mW/cm² power density). The ulcer site was disinfected, and the laser probe was positioned perpendicularly at a short distance. A total energy dose of 3–6 J/cm² was delivered, based on wound size, over 30–80 seconds per session. Treatment was administered three times per week for 4 weeks (total of 12 sessions). No adverse events were reported during or after therapy [13].

Group B – Extracorporeal Shock Wave Therapy (ESWT)

Participants in Group B received ESWT twice weekly for four weeks (eight sessions total). After disinfection, the ulcer was covered with transparent film, and ultrasound gel was applied. The probe was positioned perpendicular to the wound area. Each ulcer received 100 pulses/cm² at 0.11 mJ/cm² energy flux density. Post-treatment inspection confirmed safety and tolerability of the procedure [14].

Statistical Analysis

Statistical processing was performed with IBM SPSS Statistics, version 26. Data normality was examined through the Shapiro–Wilk test and visual inspection of histograms. Continuous variables that met parametric assumptions (e.g., ulcer area, volume, and DFS scores) are reported as mean ± standard deviation. Differences between the two groups were evaluated using independent-samples (unpaired) t-tests, whereas pre- versus post-intervention changes within each group were analyzed with paired-samples t-tests. Categorical variables were compared by Chi-square or, when expected counts were small, Fisher's exact test. A two-sided p-value of 0.05 or less denoted statistical significance.

RESULTS

Baseline demographics did not differ significantly between groups. Average age was 51.35 ± 4.89 years in the LLLT group and 51.00 ± 4.38 years in the ESWT group ($p = 0.813$). Sex distribution was similar as well, with a 1:1 male-to-female ratio in Group A and a 9:11 ratio in Group B ($p = 0.752$). Details are presented in Table 1. The average duration of diabetes was 11.05 ± 3.55 years for Group A and 12.30 ± 4.22 years for Group B ($p = 0.317$). Mean HbA1c values were likewise comparable—66.07 ± 6.86 % versus 65.47 ± 5.65 % ($p = 0.763$). Wagner grading showed most participants in both cohorts had Grade 2 ulcers, with no significant difference between groups.

Table 1: Demographic data of the studied groups

		Group A (n=20)	Group B (n=20)	P value
Age (years)	**Mean ± SD**	51.35 ± 4.89	51 ± 4.38	0.813
	Range	45 - 60	45 - 60	
Sex	**Male**	10 (50%)	9 (45%)	0.752
	Female	10 (50%)	11 (55%)	

Wound Surface Area (WSA)

The mean pre-treatment wound surface area was 3.29 ± 1.00 cm^2 in Group A and 2.81 ± 0.77 cm^2 in Group B ($p = 0.096$). After 4 weeks of treatment, both groups showed significant reductions in ulcer size: Group A reduced to 1.4 ± 0.71 cm^2 and Group B to 1.91 ± 0.89 cm^2 ($p < 0.001$ within both groups). Although the post-treatment difference between groups was not statistically significant ($p = 0.051$), Group A exhibited a larger mean reduction. These results are shown in Table 2 and visually depicted in Figure 1.

Table 2: Ulcer surface area (cm^2) of the studied groups

		Group A (n=20)	Group B (n=20)	P value‡
Pre	**Mean ± SD**	3.29 ± 1	2.81 ± 0.77	0.096
	Range	1.45 - 4.7	1.73 - 4.63	
Post	**Mean ± SD**	1.4 ± 0.71	1.91 ± 0.89	0.051
	Range	0.08 - 2.64	0.42 - 3.66	
P value†		**<0.001***	**<0.001***	

‡: P value between group A and group B, †: P value between pre and post therapy within the same group, *: significant as P value ≤ 0.05.

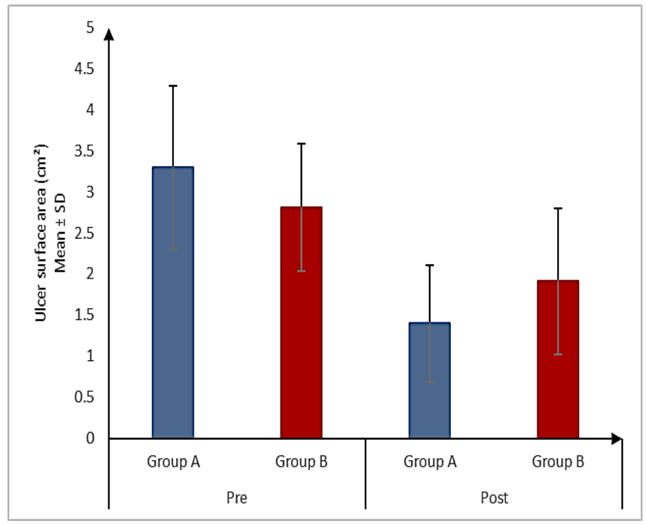

Figure 1: Ulcer surface area of the studied groups.

Wound Volume (WV)

Wound volume also decreased significantly in both groups. Group A showed a drop from 5.51 ± 1.99 cm^3 to 3.03 ± 1.55 cm^3, while Group B improved from 5.9 ± 1.56 cm^3 to 3.8 ± 1.62 cm^3 ($p < 0.001$ in both groups). Between-group differences were not significant at either time point. These findings are summarized in Table 3 and illustrated in Figure 2.

Table 3: Ulcer volume (cm^3) of the studied groups

		Group A (n=20)	Group B (n=20)	P value‡
Pre	**Mean ± SD**	5.51 ± 1.99	5.9 ± 1.56	0.498
	Range	2.22 - 9.09	3.11 - 9.41	
Post	**Mean ± SD**	3.03 ± 1.55	3.8 ± 1.62	0.133
	Range	0.17 - 6.05	0.04 - 7.81	
P value†		**<0.001***	**<0.001***	

‡: P value between group A and group B, †: P value between pre and post therapy within the same group, *: significant as P value ≤ 0.05

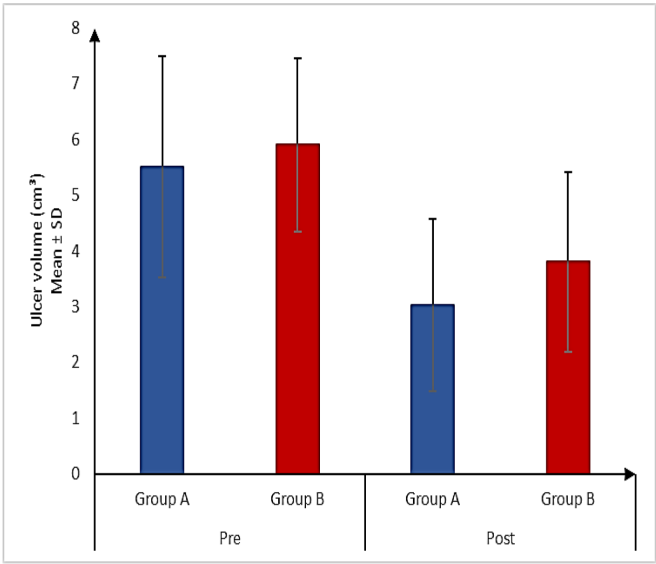

Figure 2: Ulcer volume of the studied groups.

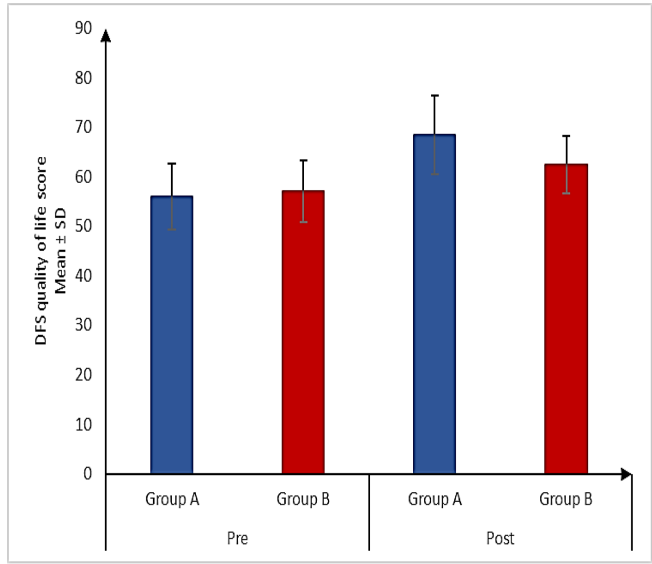

Figure 3: DFS quality of life score of the studied groups.

Quality of Life (DFS Score)

Quality of life significantly improved in both groups. DFS scores in Group A rose from 55.99 ± 6.64 to 68.4 ± 7.98 ($p < 0.001$), while Group B improved from 57.01 ± 6.17 to 62.35 ± 5.82 ($p = 0.007$).

Post-treatment DFS was significantly higher in Group A compared to Group B ($p = 0.009$), indicating greater patient-perceived benefit. These outcomes are presented in Table 4 and visually represented in Figure 3.

Table 4: DFS quality of life score of the studied groups

		Group A (n=20)	Group B (n=20)	P value‡
Pre	Mean ± SD	55.99 ± 6.64	57.01 ± 6.17	0.620
	Range	43.75 - 67.29	48.54 - 76.79	
Post	Mean ± SD	68.4 ± 7.98	62.35 ± 5.82	**0.009***
	Range	55.32 - 85.2	49.61 - 73.76	
P value†		**<0.001***	**0.007***	

DFS: diabetic foot ulcer scale, ‡: P value between group A and group B, †: P value between pre and post therapy within the same group, *: significant as P value ≤ 0.05.

DISCUSSION

Diabetic foot ulcers (DFUs) represent some of the most disabling sequelae of diabetes, commonly resulting in protracted healing times, potential limb loss, and diminished quality of life. Adjunctive approaches, particularly low-level laser therapy (LLLT) and shock-wave therapy (SWT), have been introduced as innovative options to enhance treatment outcomes [15].

This randomized controlled trial compared the impact of LLLT and SWT on wound surface area, wound volume, and patient-reported quality of life in individuals with chronic DFUs.

Both therapies produced statistically significant reductions in ulcer surface area. Although the average decrease was greater in the LLLT cohort, the difference between groups did not achieve statistical significance. This observation aligned with the findings of **Mathur *et al.*** [15] who documented faster epithelial regeneration and substantial ulcer shrinkage following LLLT in diabetic patients. Conversely, it diverged from the work of **Vitese *et al.*** [16] who observed no significant benefit of LLLT over placebo in chronic leg ulcers, indicating that the efficacy of LLLT may depend on wound type and patient population.

Concerning SWT, our findings were consistent with those of **Omar *et al.*** [14] who demonstrated that shock wave therapy effectively reduced ulcer surface area and improved healing rates in DFU patients, supporting its therapeutic potential. In contrast, **Jeppesen *et al.*** [17] found no statistically significant difference in wound size reduction between SWT and conventional treatment, although improvements in tissue oxygenation were observed.

Both LLLT and SWT significantly reduced ulcer volume (UV) in this study, with no significant difference between the groups. This supports the concept that each therapy contributes positively to tissue regeneration and wound cavity reduction. This outcome was consistent with the findings of **Wadee *et al.*** [18] who reported that LLLT resulted in a meaningful decrease in ulcer depth and promoted granulation in chronic diabetic wounds. On the other hand, **Darmaputri *et al.*** [19] found that variations in energy density during LLLT did not produce statistically significant reductions in wound volume, suggesting that dosing parameters may influence therapeutic outcomes. SWT also showed promising results in this study. **Snyder *et al.*** [20] similarly found that extracorporeal SWT facilitated wound closure in treatment-resistant DFUs in a large multicenter trial.

In terms of patient-reported quality of life, both LLLT and SWT led to significant improvements, with LLLT showing a more favorable impact post-treatment. This finding is supported by **Brandão *et al.*** [21] who found that LLLT contributed to enhanced physical and psychological well-being by promoting faster healing and pain reduction in DFU patients. With regard to SWT, Hitchman et al. [9] reported that shock wave therapy was well tolerated and led to improvements in both wound size and patient-reported outcomes, including quality of life. Nonetheless,

Both LLLT and SWT appeared to be effective adjuncts for managing diabetic foot ulcers. While LLLT may confer greater improvements in quality of life, SWT remains a viable alternative, particularly in cases where laser therapy is contraindicated or unavailable. These findings support the inclusion of both modalities within multidisciplinary treatment programs for DFU care.

LIMITATIONS AND FUTURE DIRECTIONS

This study had some limitations, including a relatively short follow-up duration and a limited sample size, which may restrict the generalizability of the findings. Future research should explore long-term outcomes and examine the potential synergistic effects of combining LLLT and SWT. Additionally, exploring the molecular and cellular mechanisms underlying each therapy could aid in developing personalized treatment protocols to optimize healing outcomes in patients with DFUs.

CONCLUSION

This randomized controlled study demonstrates that both Low-Level Laser Therapy (LLLT) and Shock Wave Therapy (SWT) significantly improve clinical outcomes in patients with diabetic foot ulcers, as evidenced by reductions in ulcer surface area and volume, as well as improvements in quality of life. While both interventions are effective, LLLT shows superior outcomes compared to SWT.

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Conflict of Interests

Authors declare no potential conflicts of interests.

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REFERENCES

1. **Sacks B, Arnold M, Bakris L (2023):** Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem., 69(8):808–68.
2. **Das K, Roy P, Mishra K (2022):** Recognition of ischaemia and infection in diabetic foot ulcer: a deep convolutional neural network based approach. Int J Imaging Syst Technol., 32(1):192–208.
3. **Ugwu E, Adeleye O, Gezawa I *et al.* (2019):** Burden of diabetic foot ulcer in Nigeria: Current evidence from the multicenter evaluation of diabetic foot ulcer in Nigeria. World J Diabetes., 10(3):200–11.
4. **Alavi A, Sibbald G, Mayer D *et al.* (2014):** Diabetic foot ulcers: part II. Management. J Am Acad Dermatol., 70(1):21–4.
5. **Brydges T, McDonnell G, Nasr Y *et al.* (2023):** The impact of youth-onset type 2 diabetes on postoperative wound healing complications. Wound Repair Regen., 31(2):187–92.
6. **Hoke D, Ramos C, Hoke N *et al.* (2016)**: Atypical diabetic foot ulcer keratinocyte protein signaling correlates with impaired wound healing. J Diabetes Res., (1):86–92.
7. **Game L, Apelqvist J, Attinger A *et al.* (2016):** Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: a systematic review. Diabetes Metab Res Rev., 32:154–68.
8. **de Medeiros L, Araújo-Filho I, da Silva N *et al.* (2017):** Effect of low-level laser therapy on angiogenesis and matrix metalloproteinase-2 immunoexpression in wound repair. Lasers Med Sci., 32(1):35–43.
9. **Hitchman H, Totty P, Cai P *et al.* (2023):** Extracorporeal shockwave therapy for diabetic foot ulcers: a feasibility study. J Wound Care, 32(3):182–92.
10. **Li N, Li H, Wu L *et al.* (2012):** A cost-effective transparency-based digital imaging for efficient and accurate wound area measurement. PLoS One, 7(5):38–69.
11. **Singh M, Singh S, Uttam S (2022):** A comparative study showing effect of local insulin injection on wound vascularization seen in color Doppler imaging in patients with diabetic foot ulcer disease before and after therapy. Asian J Med Sci., 13(12):73–8.
12. **Abetz L, Sutton M, Brady L *et al.* (2002):** The Diabetic Foot Ulcer Scale (DFS): a quality of life instrument for use in clinical trials. Pract Diabetes Int., 19(6):167–75.

13. **Santos D, Rocha D, Hazime A *et al.* (2021):** A systematic review and meta-analysis of the effects of low-level laser therapy in the treatment of diabetic foot ulcers. Int J Low Extrem Wounds, 20(3):198–207.
14. **Omar T, Alghadir A, Al-Wahhabi K *et al.* (2014):** Efficacy of shock wave therapy on chronic diabetic foot ulcer: a single-blinded randomized controlled clinical trial. Diabetes Res Clin Pract., 106(3):548–54.
15. **Mathur K, Sahu K, Saraf S *et al.* (2017):** Low-level laser therapy as an adjunct to conventional therapy in the treatment of diabetic foot ulcers. Lasers Med Sci., 32:275–82.
16. **Vitse J, Bekara F, Byun S *et al.* (2017)**: A double-blind, placebo-controlled randomized evaluation of the effect of low-level laser therapy on venous leg ulcers. Int J Low Extrem Wounds, 16(1):29–35.
17. **Jeppesen M, Yderstraede B, Rasmussen B *et al.* (2016):** Extracorporeal shockwave therapy in the treatment of chronic diabetic foot ulcers: a prospective randomised trial. J Wound Care, 25(11):641–9.
18. **Wadee N, Fahmy M, Bahey El-Deen A (2021):** Low-level laser therapy (photobiomodulation) versus hyperbaric oxygen therapy on healing of chronic diabetic foot ulcers: a controlled randomized trial. Phys Ther Rev., 26(1):73–80.
19. **Darmaputri P, Nusdwinuringtya N, Murdana N *et al.* (2020):** Comparison Low-Level Laser Therapy (LLLT) of 10J/cm² and 5 J/cm² Energy Density for Healing Diabetes Foot Ulcer. J Indones Med Assoc., 70(2):16–22.
20. **Snyder R, Galiano R, Mayer P *et al.* (2018):** Diabetic foot ulcer treatment with focused shockwave therapy: two multicentre, prospective, controlled, double-blinded, randomised phase III clinical trials. J Wound Care, 27(12):822–36.
21. **Brandão A, Ximenes M, Ramalho O *et al.* (2020):** Effects of low-level laser therapy on the healing of foot ulcers in people with diabetes mellitus. Braz J Enterostomal Ther., 18(3):1–8.