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Original Article

A retrospective comparative study of helium-neon laser combined with ultrasonic debridement in improving healing of chronic non-healing wounds

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Abstract: Objective: To evaluate the clinical value of ultrasonic debridement alone, helium-neon (He-Ne) laser therapy alone, and their combined use in the treatment of chronic non-healing wounds. Methods: A total of 272 patients with chronic non-healing wounds treated at Panzhihua Central Hospital between October 2023 and December 2024 were retrospectively selected and assigned to three groups according to treatment modality: a combined group (n=90, He-Ne laser and ultrasonic debridement), an ultrasonic debridement group (n=95, ultrasonic debridement alone), and a He-Ne laser group (n=87, He-Ne laser alone). Clinical indicators, including wound healing, Pressure Ulcer Scale for Healing (PUSH) scores, microbiological parameters, and visual analog scale (VAS) scores were assessed before treatment and at 4, 8, and 12 weeks after treatment. Adverse reactions during treatment and recurrence rates within six-month of follow-up were collected. Results: The combined group achieved better efficacy compared with the single-treatment groups at all assessment time points. At 12 weeks after treatment, the combined group demonstrated higher complete healing rates than the single-treatment groups ($P<0.05$). The combined group demonstrated higher wound area reduction rates, lower PUSH scores, lower bacterial infection rates, lower VAS scores, shorter average hospitalization stay, fewer treatment sessions, lower six-month recurrence rates, and lower adverse reaction rates compared with the single-treatment groups ($P<0.05$). Conclusion: The combined application of He-Ne laser therapy and ultrasonic debridement provides significant advantages in managing chronic non-healing wounds. This approach effectively promotes wound healing, enhances bacterial clearance, alleviates pain, shortens treatment cycles, lowers recurrence risk, and reduces treatment-related adverse reactions.

Keywords: Ultrasonic debridement, He-Ne laser, chronic non-healing wounds, combined treatment

Introduction

Chronic non-healing wounds are defined as wounds that fail to heal after more than four weeks of standard treatment. Their global prevalence in the adult population is estimated at 1.5%-20.3% [1], and the incidence is increasing with population aging and the increase in chronic diseases [2]. Chronic non-healing wounds are characterized by prolonged healing cycles, high recurrence rates, and treatment challenges, which severely impair patients' quality of life and impose a substantial medical burden. The underlying pathophysiological mechanisms primarily involve persistent inflammation, cellular dysfunction, impaired angiogenesis, and bacterial infection. As a result, wounds often remain in the inflammatory phase and fail to progress through the normal healing cascade [3]. Current clinical treatments include wound cleansing, moist dressings, pressure relief, and antibiotic treatment. However, these methods have limited efficacy in complex cases, with prolonged treatment courses and high recurrence rates.

Recently, physical therapy modalities have been increasingly applied in chronic wound management. Ultrasonic debridement removes necrotic tissue and biofilm from the wound surface through mechanical force and cavitation, thereby improving local blood circulation and creating favorable conditions for wound healing [4]. Helium-neon (He-Ne) laser, a low-energy laser with a wavelength of 632.8 nm, has been shown to promote cellular metabolism, stimu-

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late protein synthesis, promote fibroblast proliferation, facilitate collagen deposition, and improve microcirculation in the wound area [5]. Although both techniques have demonstrated efficacy, their mechanisms differ: ultrasonic debridement primarily reduces wound burden through physical removal, whereas He-Ne laser promotes tissue repair through biological stimulation. Given the complexity of chronic non-healing wounds, a single treatment is often insufficient to meet the multifaceted needs of wound healing [6].

Systematic investigations into the combined use of ultrasonic debridement and He-Ne laser therapy remain limited. Therefore, this study retrospectively analyzed clinical data to evaluate the clinical value of their combined application compared with either modality alone, aiming to provide new clinical evidence and treatment strategies for chronic non-healing wounds.

Materials and methods

Research design and case screening

This retrospective cohort research was approved by the Ethics Committee of Panzhihua Central Hospital and was conducted in accordance with the Declaration of Helsinki. Clinical data were retrieved from the electronic medical system for patients with chronic non-healing wounds who received He-Ne laser therapy, ultrasonic debridement, or their combination at Panzhihua Central Hospital from October 2023 to December 2024.

Inclusion criteria: (1) Age ≥18 years; (2) Diagnosis of chronic non-healing wounds [7], defined as wounds failing to heal after more than 4 weeks of standard treatment; (3) Receipt of He-Ne laser therapy alone, ultrasonic debridement alone, or their combination; (4) Availability of complete clinical records, including baseline data, treatment records, and follow-up data.

Exclusion criteria: (1) Inability to cooperate with treatment or complete the entire treatment course; (2) Incomplete medical records; (3) Receipt of other physical treatments (e.g., vacuum sealing drainage, hyperbaric oxygen therapy) before or during treatment; (4) Presence of severe coagulation disorders, systemic infections, or advanced malignant tumors; (5) Contraindications to ultrasound or laser treatment.

Based on the predefined inclusion and exclusion criteria, a total of 272 patients were enrolled. According to the treatment modality, eligible patients were assigned to three groups: the combined group (n=90), treated with a combination of He-Ne laser and ultrasonic debridement; the ultrasonic debridement group (n=95), treated with ultrasonic debridement alone; and the He-Ne laser group (n=87), treated with He-Ne laser therapy alone.

Treatment modality

All patients in the three groups received standard wound care, including wound cleansing, moist dressing application, and systemic antibiotics when necessary. On this basis, group-specific treatments were administered as follows:

Combined group (He-Ne laser + ultrasonic debridement): Patients first underwent ultrasonic debridement using a low-frequency ultrasonic debridement device (Lifotronic, Shenzhen; model CareMaster-E), with a frequency of 25-40 kHz and an intensity of 0.5-1.0 W/cm^2. The treatment duration was 3-5 minutes per cm^2 of wound area. Immediately following debridement, He-Ne laser therapy was applied with a device (Beijing Tuoda Laser Instrument Co., Ltd.; model HN1000L) at a wavelength of 632.8 nm and a power density of 10-15 mW/cm2. Each laser session lasted 10-15 minutes. Treatment frequency was three times per week for 4-12 weeks.

Ultrasonic debridement group: Patients received ultrasonic debridement alone with the same device, parameters, and duration as described above.

He-Ne laser group: Patients received He-Ne laser therapy alone with the same parameters, device, and treatment schedule as in the combined group.

Outcome measures and evaluation methods

Primary outcome measures: (1) Complete wound healing rate was assessed at 4, 8, and 12 weeks of treatment; (2) Wound area reduction rate was measured using digital photography and image analysis software. The calculation

Table 1. Comparison of baseline clinical data among the three groups (mean ± SD)/[n (%)]

General data	Combined group (n=90)	Ultrasonic debridement group (n=95)	He-Ne laser group (n=87)	*P*
Average age (years)	61.42±13.75	62.23±14.16	60.84±13.53	0.765
Sex (male/female)	53/37	56/39	51/36	0.994
Average BMI (kg/m^2)	26.35±4.72	25.93±4.54	26.52±4.85	0.693
Wound duration (months)	9.23±5.32	8.75±4.92	9.54±5.51	0.584
Wound area (cm^2)	19.64±8.42	20.25±8.93	19.37±8.25	0.754
Wound type				0.873
Diabetic foot ulcer	38 (42.22)	40 (42.11)	35 (40.23)	
Pressure ulcer	24 (26.67)	27 (28.42)	22 (25.29)	
Venous ulcer	18 (20.00)	19 (20.00)	20 (22.99)	
Other chronic wounds	10 (11.11)	9 (9.47)	10 (11.49)	
Comorbidities, n (%)				
Diabetes mellitus	56 (62.22)	58 (61.05)	54 (62.07)	0.984
Hypertension	49 (54.44)	52 (54.74)	48 (55.17)	0.993
Cardiovascular disease	31 (34.44)	35 (36.84)	29 (33.33)	0.883
Cerebrovascular disease	15(16.67)	17(17.89)	14 (16.09)	0.943
Renal insufficiency	13 (14.44)	15 (15.79)	12 (13.79)	0.924
Barthel index	72.51±18.91	71.82±19.33	73.22±18.63	0.883

Note: BMI: body mass index; He-Ne: helium-neon.

formula was: Wound area reduction rate = (initial area - current area)/initial area × 100; (3) Pressure Ulcer Scale for Healing (PUSH) Score [8] was employed to evaluate wound healing status based on wound area, exudate amount, and tissue type. Lower scores indicated better healing outcomes.

Secondary outcome measures: (1) Bacterial clearance rate: Wound bacterial cultures were performed at baseline as well as at 4, 8, and 12 weeks of treatment. Bacterial clearance rates were compared among the three groups; (2) Pain intensity: The Visual Analog Scale (VAS, 0-10 points) [9] was used to evaluate the intensity of pain; (3) Hospitalization and number of treatments: The average length of hospital stay and total number of treatment sessions were recorded; (4) Adverse reactions: Incidence of treatment-related adverse events was documented; (5) Recurrence rate: Wound recurrence was evaluated during a six-month follow-up period after complete healing.

Statistical analysis

All statistical analyses were performed using SPSS 25.0. Continuous variables with normal distribution were expressed as mean ± standard deviation (SD). Between-group comparisons were conducted using the t-test, one-way ANOVA, or repeated-measures ANOVA, as appropriate. When overall significance was observed, pairwise post hoc comparisons were performed using the Bonferroni correction, with a corrected $P<0.05$ considered statistically significant. Categorical variables were presented as counts and percentage, and compared using the chi-square test or Fisher's exact test. When the data did not meet the assumption of sphericity, appropriate corrections were used. $P<0.05$ indicated statistical significance.

Results

Baseline characteristics

Baseline characteristics, including sex, body mass index (BMI), disease duration, wound area, wound type, and comorbidities, were collected and compared among the three groups. No statistically significant differences were observed (all $P>0.05$), indicating good comparability (**Table 1**).

Wound healing outcomes

The complete wound healing rate in the combined group was markedly higher than that in the ultrasonic debridement and He-Ne laser

Table 2. Comparison of complete wound healing rates among the three groups

Group	Number of cases	At 4 weeks	At 8 weeks	At 12 weeks
Combined group	90	45 (50.00)[a,b]	71 (78.89)[a,b]	84 (93.33)[a,b]
Ultrasonic debridement group	95	31 (32.63)	54 (56.84)	76 (80.00)
He-Ne laser group	87	22 (25.29)	40 (45.98)	61 (70.11)
χ^2	-	12.453	20.973	15.804
P	-	0.002	<0.001	<0.001

Note: Compared with ultrasonic debridement group, [a]*P*<0.05; compared with He-Ne laser group, [b]*P*<0.05. He-Ne: helium-neon.

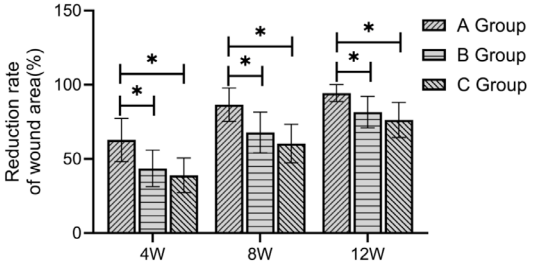

Figure 1. Comparison of wound area reduction rate after treatment among the three groups. At weeks 4, 8, and 12 of treatment, the wound area reduction rate was significantly greater in the combined group compared with the ultrasonic debridement and He-Ne laser groups (*P*<0.05). Note: 4W: 4 weeks after treatment; 8W: 8 weeks after treatment; 12W: 12 weeks after treatment; He-Ne: helium-neon. **P*<0.05. Group A received He-Ne laser combined with ultrasonic debridement, Group B received ultrasonic debridement alone, and Group C received He-Ne laser alone.

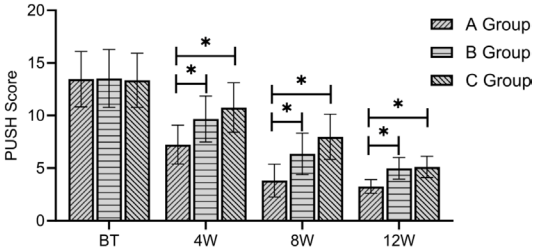

Figure 2. Comparison of PUSH scores among the three groups before and after treatment. Note: BT: before treatment; 4W: 4 weeks after treatment; 8W: 8 weeks after treatment; 12W: 12 weeks after treatment. **P*<0.05. He-Ne: helium-neon; PUSH: Pressure Ulcer Scale for Healing. Lower scores indicate better healing. Group A received He-Ne laser combined with ultrasonic debridement, Group B received ultrasonic debridement alone, and Group C received He-Ne laser alone.

groups at weeks 4, 8, and 12 of follow-up (P< 0.05, **Table 2**). Similarly, the wound area reduction rate in the combined group was markedly greater than that of the other two groups at all time points (*P*<0.05, **Figure 1**).

PUSH scores

At baseline, the three groups showed no significant differences in PUSH scores (*P*>0.05). At 4, 8, and 12 weeks of treatment, the combined group showed markedly lower PUSH scores compared with the ultrasonic debridement and He-Ne laser groups (*P*<0.05, **Figure 2**).

Bacterial culture results and infection status

Before treatment, no significant differences in positive bacterial culture rates were observed among the three groups (*P*>0.05). After 4, 8, and 12 weeks of treatment, the combined group demonstrated significantly lower positive culture rates compared with the ultrasonic debridement and He-Ne laser groups (*P*<0.05, **Figure 3**). At 12 weeks, the combined group demonstrated markedly lower detection rates of Staphylococcus aureus *(S. aureus)*, *Pseudomonas aeruginosa (P. aeruginosa)*, *Escherichia coli,* and *Staphylococcus epidermidis* compared to the other two groups (*P*<0.05, **Figure 3**).

Overall treatment outcomes

Before treatment, there were no marked differences in VAS scores among the three groups (*P*>0.05). At 4, 8, and 12 weeks after treatment, patients in the combined group reported markedly lower VAS scores compared with those in the ultrasonic debridement and He-Ne laser groups (*P*<0.05, **Figure 4**). Furthermore, the combined group showed markedly shorter hospitalization stay and fewer treatment sessions compared with the ultrasonic debridement and He-Ne laser groups (*P*<0.05). During the six-month follow-up, the wound recurrence rate in the combined group was markedly lower than that in the other two groups (*P*<0.05, **Table 3**).

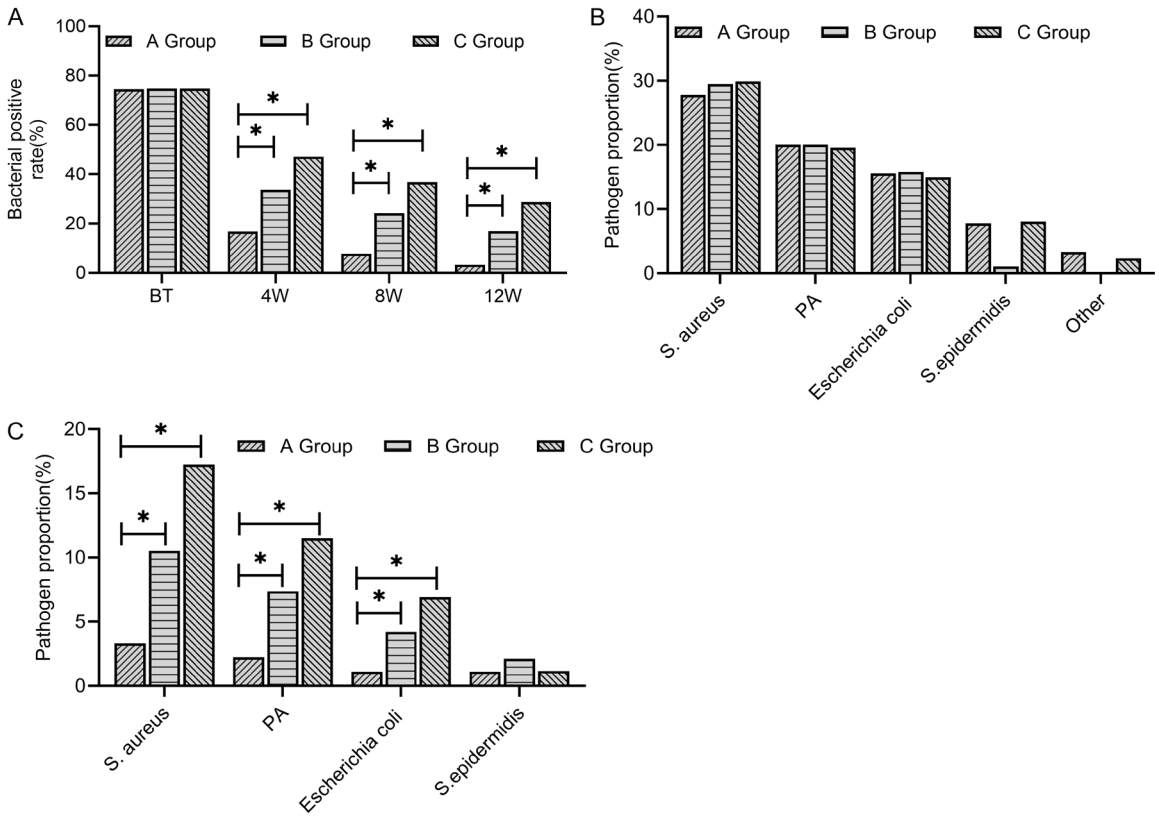

Figure 3. Comparison of bacterial infection among the three groups before and after treatment. A: Comparison of positive bacterial infection rates among three groups before and after treatment; B: Comparison of pathogenic bacteria distribution among the three groups before treatment; C: Comparison of pathogenic bacteria distribution among the three groups after 12 weeks of treatment. Note: BT: before treatment; 4W: 4 weeks after treatment; 8W: 8 weeks after treatment; 12W: 12 weeks after treatment; *S. aureus*: *Staphylococcus aureus*; PA: *Pseudomonas aeruginosa*; *S.epidermidis: Staphylococcus epidermidis;* He-Ne: helium-neon. *P<0.05. Group A received He-Ne laser combined with ultrasonic debridement, Group B received ultrasonic debridement alone, and Group C received He-Ne laser alone.

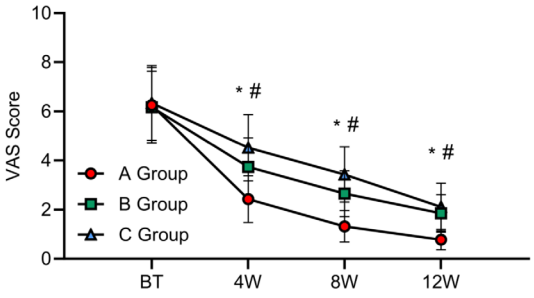

Figure 4. Comparison of VAS scores among the three groups before and after treatment. Note: BT: before treatment; 4W: 4 weeks after treatment; 8W: 8 weeks after treatment; 12W: 12 weeks after treatment; He-Ne: helium-neon; VAS: visual analog scale. *P<0.05, compared with Group B, and #P<0.05, compared with Group C. Group A received He-Ne laser combined with ultrasonic debridement, Group B received ultrasonic debridement alone, and Group C received He-Ne laser alone.

Incidence of adverse reactions

The combined group showed a lower rate of local bleeding compared with the ultrasonic debridement group, and significantly lower rates of secondary infection, wound deterioration, and treatment interruption compared with the He-Ne laser group (P<0.05, **Table 4**).

Treatment efficacy across different wound types

Patients were further stratified by wound types for subgroup analysis. In diabetic foot ulcers, pressure ulcers, venous ulcers, and other types of ulcers, the combined treatment demonstrated significantly higher complete wound healing rates than either ultrasonic debridement or He-Ne laser therapy alone (P<0.05, **Table 5**).

Table 3. Comparison of length of hospital stay, number of treatment sessions, and recurrence rates among the three groups

Group	Number of cases	Length of stay (days)	Number of treatments	Six-month recurrence rate (%)
Combined group	90	12.35±3.64[a,b]	15.64±4.25[a,b]	5 (5.56)[a,b]
Ultrasonic debridement group	95	16.73±4.86	19.82±5.16	13 (13.68)
He-Ne laser group	87	19.57±5.34	24.25±5.75	18 (20.69)
F/χ^2	-	12.533	11.516	9.635
P	-	<0.001	<0.001	<0.001

Note: Compared with ultrasonic debridement group, [a]*P*<0.05; compared with He-Ne laser group, [b]*P*<0.05. He-Ne: helium-neon.

Table 4. Comparison of adverse events among the three groups

Group	Combined group (n=90)	Ultrasonic debridement group (n=95)	He-Ne laser group (n=87)	*P*
Local skin irritation	9 (10.00)	7 (7.37)	6 (6.90)	0.700
Treatment-associated pain	15 (16.67)	22 (23.16)	11 (12.64)	0.141
Local bleeding	5 (5.56)[a]	12 (12.63)	3 (3.45)	0.040
Peri-wound erythema and swelling	7 (7.78)	9 (9.47)	8 (9.20)	0.902
Burning sensation of the skin	4 (4.44)	2 (2.11)	6 (6.90)	0.282
Local allergic reaction	2 (2.22)	3 (3.16)	3 (3.45)	0.872
Secondary infection	3 (3.33)[b]	8 (8.42)	11 (12.64)	0.041
Wound deterioration	1 (1.11)[b]	5 (5.26)	7 (8.05)	0.032
Treatment interruption	2 (2.22)[b]	7 (7.37)	9 (10.34)	0.046

Note: Compared with ultrasonic debridement group, [a]*P*<0.05; compared with He-Ne laser group, [b]*P*<0.05. He-Ne: helium-neon.

Table 5. Comparison of complete healing rates among the three groups stratified by wound type

Group	Combined group (n=90)	Ultrasonic debridement group (n=95)	He-Ne laser group (n=87)	*P*
Diabetic foot ulcers	32/38[a,b]	27/40	19/35	0.015
Pressure ulcers	20/24[a,b]	18/27	13/22	0.043
Venous ulcers	16/18[a,b]	13/19	12/20	0.032
Other types	9/10[a,b]	6/9	5/10	0.031

Note: Compared with ultrasonic debridement group, [a]*P*<0.05; compared with He-Ne laser group, [b]*P*<0.05. He-Ne: helium-neon.

Discussion

This retrospective study analyzed clinical data from 272 patients with chronic non-healing wounds and systematically evaluated the clinical value of He-Ne laser combined with ultrasonic debridement. The findings revealed that compared with either treatment alone, the combined treatment demonstrated significant advantages in promoting wound healing, controlling infection, alleviating pain, and improving overall clinical outcomes. This provides new clinical evidence and potential treatment strategies for the comprehensive management of chronic non-healing wounds.

Promoting effect of combined treatment on wound healing

In this study, the combined group achieved markedly higher wound healing rates than the ultrasonic debridement and He-Ne laser groups. The wound area reduction rate was also consistently higher in the combined group at all time points, and by 12 weeks, the difference was most pronounced. The improvement in PUSH scores further confirmed the superiority of the combined treatment.

The enhanced efficacy of the combined treatment may be attributed to the complementary mechanisms of the two modalities. Ultrasonic

debridement mainly removes necrotic tissue and biofilm through mechanical force and cavitation, thereby reducing wound burden and facilitating healing [10], whereas He-Ne laser promotes cell metabolism, enhances protein synthesis and fibroblast proliferation, and stimulates collagen deposition through biostimulation [11]. Our findings are consistent with those of previous studies. Jiang et al. [12] reported that ultrasonic debridement effectively removed biofilms, reduced bacterial colonization, and created favorable conditions for subsequent healing. In another study, Jiang et al. [13] also demonstrated that He-Ne laser upregulated the expression of vascular endothelial growth factor and transforming growth factor-β1 in fibroblasts, thereby promoting angiogenesis and tissue regeneration. Extending these findings, our study confirmed the efficacy of the combined application of ultrasonic debridement and He-Ne laser across a wider range of chronic non-healing wounds, including diabetic foot ulcers, pressure ulcers, and venous ulcers.

Advantages of combined treatment in controlling infection

Infection control is a key component in the management of chronic non-healing wounds. This study observed that the positive bacterial culture rate in the combined group was significantly lower than in the single-treatment groups at 4, 8, and 12 weeks after treatment. The clearance of common pathogens such as *S. aureus* and *P. aeruginosa* was particularly effective in the combined group. These findings are consistent with previous studies. Zhao et al. [14] reported that laser-triggered photothermal therapy significantly improved antibacterial efficacy and reduced damage to surrounding normal tissues through covalent coupling with bacterial lipopolysaccharides. Plattfaut et al. [15] further demonstrated that different wavelengths of blue light exhibited variable antimicrobial activity, with blue light >455 nm showing reduced cytotoxicity to human skin cells, thereby improving safety.

The antimicrobial effects of ultrasonic debridement may involve several mechanisms, including bacterial biofilms disruption, enhanced antibiotic penetration, and direct cellular damage. Biofilms are complex polysaccharide structures formed on wound surface that shield bacteria from host immune responses and antibiotic therapy, constituting a major cause of persistent infection in chronic wounds [16]. Ultrasonic energy destroys these biofilms through cavitation and microfluidic effects, exposing bacteria and enhancing antibiotic sensitivity. In parallel, He-Ne laser therapy exerts certain photodynamic antimicrobial effects while improving local microcirculation and immune function [17]. Thus, the combined use of the two treatment methods provides a comprehensive anti-infective strategy, integrating physical biofilm removal with immune enhancement, which may explain the superior infection control observed with the combined treatment.

Effects of combined therapy on symptom relief and quality of life

Pain is a common symptom among patients with chronic wounds and significantly impairs their quality of life. In our study, the combined group had markedly reduced VAS scores compared to the single-treatment groups at 4 and 8 weeks of treatment. This analgesic effect may be partly attributed to He-Ne laser therapy. Previous studies [18] have shown that laser therapy can relieve pain by inhibiting nociceptive fiber activity, promoting the release of endogenous opioids, and attenuating local inflammation. Although ultrasonic debridement may cause temporary discomfort during treatment, it contributes to long-term pain relief by removing necrotic tissue and reducing inflammation. The complementary effects of the two modalities likely account for the superior pain relief observed in the combined group. Additionally, the combined group experienced significantly shorter average hospital stays and required fewer treatment sessions compared with the single-treatment groups. This not only alleviated patients' economic burden but also reduced the consumption of medical resources. A reasonable explanation is that the combined therapy accelerates wound healing, reduces complications, thereby shortening the treatment course and improving therapeutic efficiency.

Clinical value of combined therapy across different wound types

An important finding of this study is that the combined therapy was effective across different types of chronic non-healing wounds. In the combined group, complete healing rates for

diabetic foot ulcers, pressure ulcers, venous ulcers, and other types of wounds were markedly higher than those in the single-treatment groups. These findings suggest that, despite differences in etiology, pathophysiological mechanisms, and therapeutic challenges, combined physical therapy provides an integrated strategy, capable of addressing multiple barriers to healing, thereby achieving favorable outcomes across a broad spectrum of wound types. Specifically, in diabetic foot ulcers, the combined treatment may improve local ischemia and hypoxia, enhance control infection, and promote tissue regeneration [19]. In pressure ulcers, ultrasonic debridement facilitates the removal of necrotic tissue, while laser therapy enhances local blood flow, with their synergistic effect accelerating wound healing [20]. In venous ulcers, the combined treatment improves microcirculation and modulates local inflammation, thereby accelerating ulcer closure [21].

Safety assessment

In this study, the combined group had lower overall incidence of adverse reactions compared with the single-treatment groups. In particular, the incidence of important adverse reactions was markedly lower in the combined treatment group. The mechanism of the above phenomenon may be related to the synergistic effects of the combined treatment, which accelerates wound healing, more effectively controls infection, and reduces inflammatory response. Consistent with previous studies [22, 23], ultrasound debridement alone can induce local stimulation and adverse effects, whereas He-Ne laser therapy helps counterbalance these reactions, thereby improving the overall treatment experience. Furthermore, during the six-month follow-up, the recurrence rate in the combined group was markedly lower compared to the single-treatment groups. This also suggests that combined treatment not only promotes wound healing and alleviates pain, but also improves the quality of healing and lowers the risk of recurrence, which is crucial for enhancing patients' long-term quality of life.

Research limitations and future prospects

Although this study provides valuable evidence for the clinical treatment of chronic non-healing wounds, several limitations should be acknowledged. First, the retrospective design and relatively small sample size may limit the generalizability of the findings. Second, critical treatment parameters - such as laser power density, irradiation duration, and the intensity and frequency of ultrasound debridement - were not systematically analyzed, restricting further mechanistic interpretation. Future research should include prospective, large-scale randomized controlled trials to validate the efficacy and safety of combined therapy. In addition, optimizing treatment parameters and developing individualized therapeutic protocols for different wound types will be essential to refine clinical practice and provide more precise guidance for the management of chronic non-healing wounds.

Conclusion

Combined use of He-Ne laser therapy and ultrasound debridement provides significant benefits in treating chronic non-healing wounds, such as promoting wound healing, controlling infection, alleviating pain, and improving patients' quality of life, with a favorable safety profile. As a comprehensive physical therapy strategy, the combined treatment exerts synergistic effects on multiple aspects of the wound healing process. These findings highlight its potential as a promising therapeutic option for chronic non-healing wounds and provide support for its broader application in clinical practice.

Disclosure of conflict of interest

None.

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