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Clinical Study of Clay Pot Combined With Thunder Fire Moxibustion in the Treatment of Chronic Refractory Wounds in Department of Orthopedics

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Chronic refractory wounds in orthopedic patients not only impede physical recovery but also cause sleep disturbances due to treatment-related anxiety. This study aims to investigate the effects of combining clay pot therapy with thunder-fire moxibustion on the wound healing and sleep quality of patients with chronic refractory wounds.

Material/Methods: From June 2022 to December 2024, 60 patients in the department of orthopedics of a class III hospital in Guangdong Province were randomly divided into an observation group (n=30) and control group (n=30). The control group received conventional treatment, including anti-infective therapy for chronic wounds, debridement, measures to improve microcirculation, and neurotrophic support. The observation group received clay pot therapy combined with thunder-fire moxibustion in addition to the treatments administered to the control group. Wound healing rate, local symptom scores, pain scores, and Pittsburgh Sleep Quality Index scores were compared between the 2 groups.

Results: After the intervention, the observation group achieved a significantly higher cure rate (26.67% vs 3.33%), lower local symptom scores (5.08±1.60 vs 7.02±1.89), lower pain scores (1.89±2.06 vs 2.97±1.98), and better Pittsburgh Sleep Quality Index scores (9.58±1.56 vs 11.30±2.15), compared with the control group (all $P<0.05$).

Conclusions: Clay pot combined with thunder-fire moxibustion in the treatment of chronic refractory wounds in the orthopedics department can promote wound healing, improve sleep quality, and improve the clinical curative effect.

Keywords: 24,25-Dihydroxyvitamin D 3 • Chronic Disease • Osteoarthritis • Pain • Randomized Controlled Trial • Wounds and Injuries

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Introduction

Chronic refractory wounds are defined as wounds that fail to achieve complete structural and functional recovery within the expected timeframe despite standardized treatment and are often attributed to factors including infection, diabetes, ischemia, and inflammation [1]. Among hospitalized orthopedic patients with traumatic injuries, the incidence of chronic refractory wounds ranges from 1.5% to 20.3% and has shown a progressive upward trend in recent years [2]. The persistent ulcers and exudate associated with chronic refractory wounds impair patients' physical and psychological well-being, compromising their quality of life [3,4], and impose substantial burdens on families and society alike.

Currently, surgical intervention remains the primary management approach for chronic refractory wounds; however, its use is limited by factors such as high costs, prolonged treatment duration, and unpredictable healing outcomes. Notably, patients with chronic refractory wounds frequently experience sleep disturbances, primarily stemming from concerns regarding treatment prognosis and financial strain [5]. Traditional Chinese medicine (TCM) offers distinct advantages in addressing insomnia. For example, clay pot therapy, an enhanced form of cupping with strong adsorption capacity, can improve sleep quality by stimulating acupoints and promoting the circulation of qi and blood [6-7]. Thunder-fire moxibustion, a modified moxibustion technique incorporating medicinal ingredients, has also been clinically validated to facilitate wound healing [8]. This study aims to investigate the effects of combining clay pot therapy with thunder-fire moxibustion on wound healing and sleep quality in orthopedic patients with chronic refractory wounds, thereby providing novel insights for clinical practice.

Material and Methods

Participants

Sixty patients diagnosed with chronic refractory wounds who attended a tertiary hospital in Guangdong Province between June 2022 and December 2024 were enrolled in this study. This pilot study with 60 participants provides preliminary evidence for the integrated TCM intervention. However, the sample size limits the statistical power for subgroup analyses and may affect the generalizability of the findings.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) wounds conformed to the diagnostic criteria for chronic non-healing wounds (clinically defined as wounds caused by various internal or external factors that fail to heal within 1 month of treatment and show no tendency toward healing) [9]; (2) wounds did not require surgical intervention, or patients declined to undergo surgical treatment; (3) patients possessed clear consciousness and provided informed consent to participate in this research; and (4) age was between 18 and 60 years.

The exclusion criteria were as follows: (1) a known allergy to any of the drugs used in this study; (2) severe depression, anxiety disorders, or other mental illnesses; (3) complications including other serious diseases, such as malignant tumors; and (4) voluntary withdrawal from the study or demonstration of poor treatment compliance.

Intervention Methods

The control group of patients with chronic refractory wounds received routine treatment, including anti-infective therapy for chronic wounds, debridement, measures to improve microcirculation, neurotrophic support, and external application of wound healing yellow water (Foshan Traditional Chinese Medicine Hospital internal preparation; batch number: 1572146) [10].

In addition to the treatments administered to the control group, the observation group received clay pot therapy (a Class I medical device; registration No. Yue Guan Qi Bei 20210145) combined with thunder-fire moxibustion.

Clay Pot Therapy (Back Cupping)

Prior to treatment, the patients were instructed to assume a prone position. The clay pot therapy included 5 sequential steps: flash cupping, rubbing cupping, pushing cupping, shaking cupping, and retained cupping, as detailed below.

Flash Cupping

Two medium-sized clay pots with raised bottoms were used. One pot was applied to the patient's back, starting at the Chibian Point (BL54) along the left Bladder Meridian (BL), and flash cupping was performed clockwise from the lower to the upper back. The other pot was applied along the right Bladder Meridian, and flash cupping was performed counterclockwise from the upper to the lower back.

Rubbing cupping

The clay pot used for flash cupping was selected, and its bottom was pressed firmly against the patient's back. It was then moved along the following meridian routes: along the back meridian from top to bottom, from the Dazhui Point (GV14) to the Waiyangguan Point (GB39), and along the bilateral Bladder Meridians from top to bottom, from the Fufen Point (BL41) to the Zhibian Point (BL54). During the procedure, wrist force was

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used to keep the pot bottom pressed against the back while gently shaking it left and right.

Pushing Cupping

First, a small amount of Chen Weiliang orthopedic oil (in-hospital preparation of Foshan Traditional Chinese Medicine Hospital; approval No. Yue Yao Zhi Zi Z20070486; main ingredients: Huangbai [Phellodendri Chinensis Cortex], Diyu [Sanguisorbae Radix], Gardenia [Gardeniae Fructus], and other Chinese herbal medicines) was evenly applied to the patient's back. After kneading the pot to ensure adherence, the operator pushed the pot along the following routes, repeating the process 3 times. Along the Du Meridian (GV), the pot was moved from the Dazhui Point (GV27) to the Yaoyangguan Point (GV3) and back to the Dazhui Point (GV27). Along the bilateral Second Bladder Meridian (lateral branch of BL), the pot was moved from the associated points (Back-Shu Points) to the Changbian Point (BL53) and back to the associated points (Back-Shu Points). Along the bilateral First Bladder Meridian (medial branch of BL), the pot was moved from the Dazhu Point (BL11) to the Baihuanyu Point (BL30) and back to the Dazhu Point (BL11). Moderate force was applied during pushing, following the sequence of the Du Meridian first, then the Second Bladder Meridian, and finally the First Bladder Meridian. The treatment endpoint was mild skin redness.

Shaking Cupping

The clay pot was shaken back and forth 3 times along the bilateral Bladder Meridians of the back. The procedure followed the order of first shaking the pot from top to bottom along the distal segment of the Bladder Meridian, followed by the proximal segment from top to bottom. After the procedure, the patient's back was cleaned with a tissue.

Retained Cupping

One clay pot was placed at the Dazhui Point (GV14). Along the bilateral Bladder Meridians, approximately 10 additional pots were placed from the upper back down to the Yaoyangguan Point (GV3) for retention. After placing the pots, the operator used both hands to gently press them downward to check their adhesion. The back was then covered with a towel to maintain warmth, and the pots were retained for 5 minutes. Treatment was administered once every 3 days, twice per week, with 1 week constituting a treatment course, and 2 continuous courses completed for a total of 2 weeks. The procedure is summarized in **Figure 1**.

Local Wound Cupping

The patient was positioned comfortably on a bed covered with a sterile drape. To minimize the risk of alcohol spillage, the practitioner used sterile forceps to hold a cotton ball saturated with 75% medical alcohol, gently squeezing it to remove excess liquid before ignition. Prior to cupping, a thin layer of sterile petroleum jelly was applied to the intact skin within a 1-2 cm perimeter around the wound to create a protective barrier. The cotton ball was then ignited, inserted circularly into a transparent glass cup (to facilitate observation), and promptly removed. The cup was quickly placed over the wound site and retained for 3 to 5 minutes, during which bloody secretions were drawn in. After cup removal, the periwound area was first wiped with a sterile saline gauze to ensure no alcohol residue remained, after which the wound bed itself was cleansed with sterile water for injection, as shown in **Figure 2** in detail. The glass cup was disposed of as a sharp. This procedure was performed twice weekly (with a 3-day interval or longer) over a continuous 2-week course.

Thunder-Fire Moxibustion Treatment

Thunder-fire moxibustion sticks produced by Chongqing Zhao's Thunder-Fire Moxibustion Traditional Medicine Research Institute (25 g per stick) were used. Two forms of moxibustion were performed: acupoint moxibustion and local wound moxibustion.

For acupoint moxibustion, the Shenque Point (CV8) and bilateral Sanyinjiao Points (SP6) were selected. Three thunder-fire moxibustion sticks were placed into individual single-hole moxibustion boxes and ignited. The boxes were then fixed onto a moxibustion device, and the distance between the device and the patient's skin was adjusted to approximately 2 to 3 cm, with further adjustments made according to the patient's subjective comfort to avoid burns. The 3 moxibustion boxes were applied simultaneously to the selected acupoints. Moxibustion was administered for 15 minutes per acupoint once daily. One week constituted a treatment course, and 2 consecutive courses were completed, for a total duration of 2 weeks.

For local wound moxibustion, the patient was positioned comfortably to fully expose the chronic ulcerated wound. The operator held an ignited thunder-fire moxibustion stick at a distance of approximately 5 to 10 cm from the surface of the wound. Moxibustion was administered for 15 to 20 minutes, with the endpoint determined by the patient's tolerance, specifically when a mild warming sensation was reported without pain or discomfort. The frequency and duration of treatment were consistent with those of acupoint moxibustion (once daily for 2 consecutive weeks). The procedure is illustrated in **Figure 3**.

Observation Indicators

Wound healing status was evaluated using graded criteria in accordance with the *Diagnostic and Therapeutic Criteria for*

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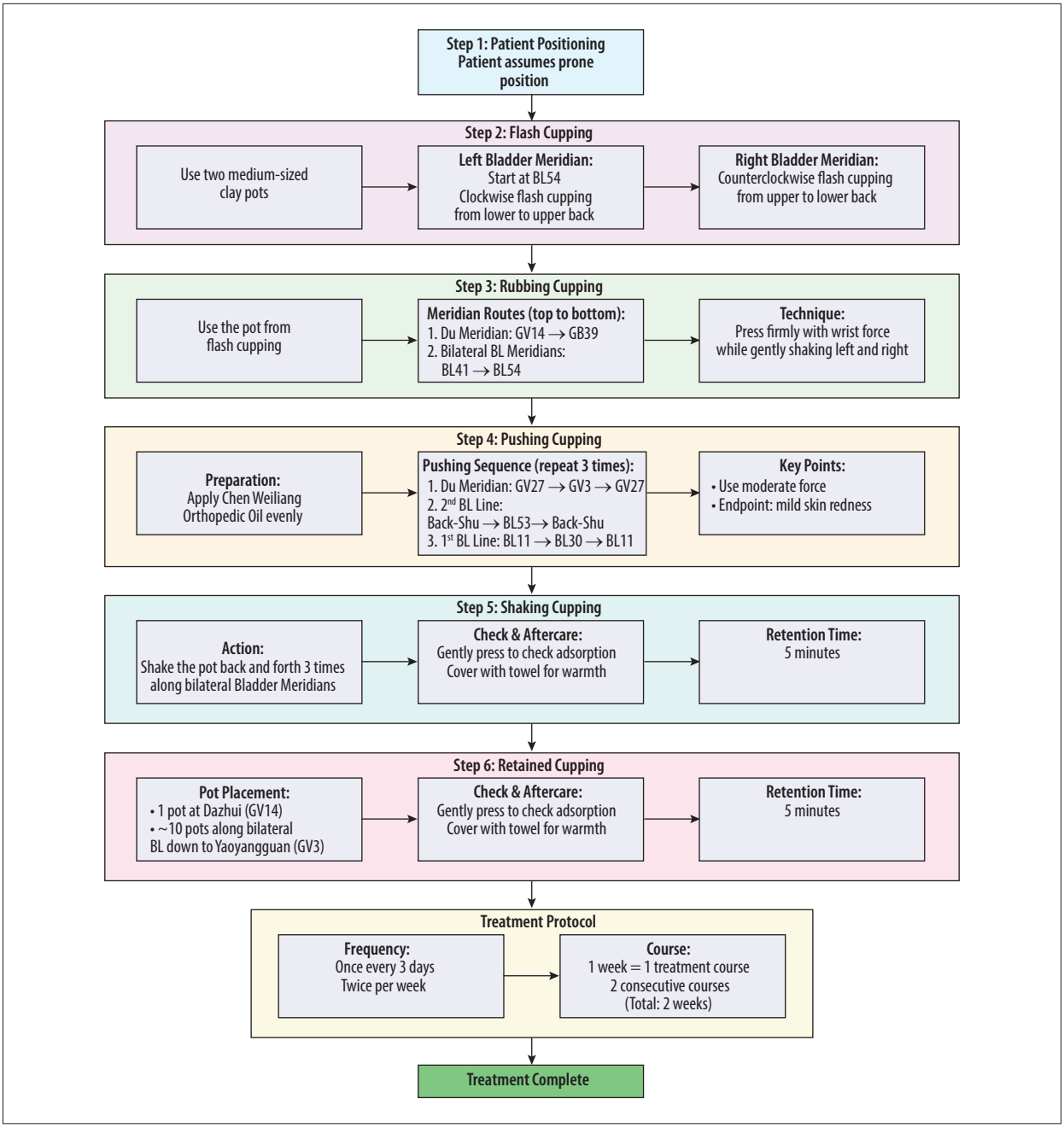

Figure 1. Clay pot therapy (back cupping) procedure flowchart.

Traditional Chinese Medicine Diseases [11]. Wounds were classified as follows: (1) recovery, defined as complete epithelial coverage with a firm scar and no re-ulceration after 1 week of observation; (2) marked effect, defined as a reduction in wound area of more than 75% with significant relief of clinical symptoms and the presence of fresh granulation tissue; (3) improvement, defined as a reduction in wound area of 25% to 75% with improved granulation tissue and partial symptom relief; and (4) no effect, defined as a reduction in wound area of less than 25%, limited granulation tissue growth, and incomplete relief of clinical symptoms despite some improvement in wound appearance. The significant recovery rate was calculated as the sum of recovered cases and cases with marked effect divided by the total number of cases, multiplied by 100%.

Local symptoms were quantitatively assessed based on 9 core parameters: wound size, necrotic tissue, purulent discharge, redness, erosion, exudation, itching, pain, and fetid odor. A 4-point scale was used for each parameter (0, no symptoms; 1, mild symptoms, not affecting daily activities; 2, moderate

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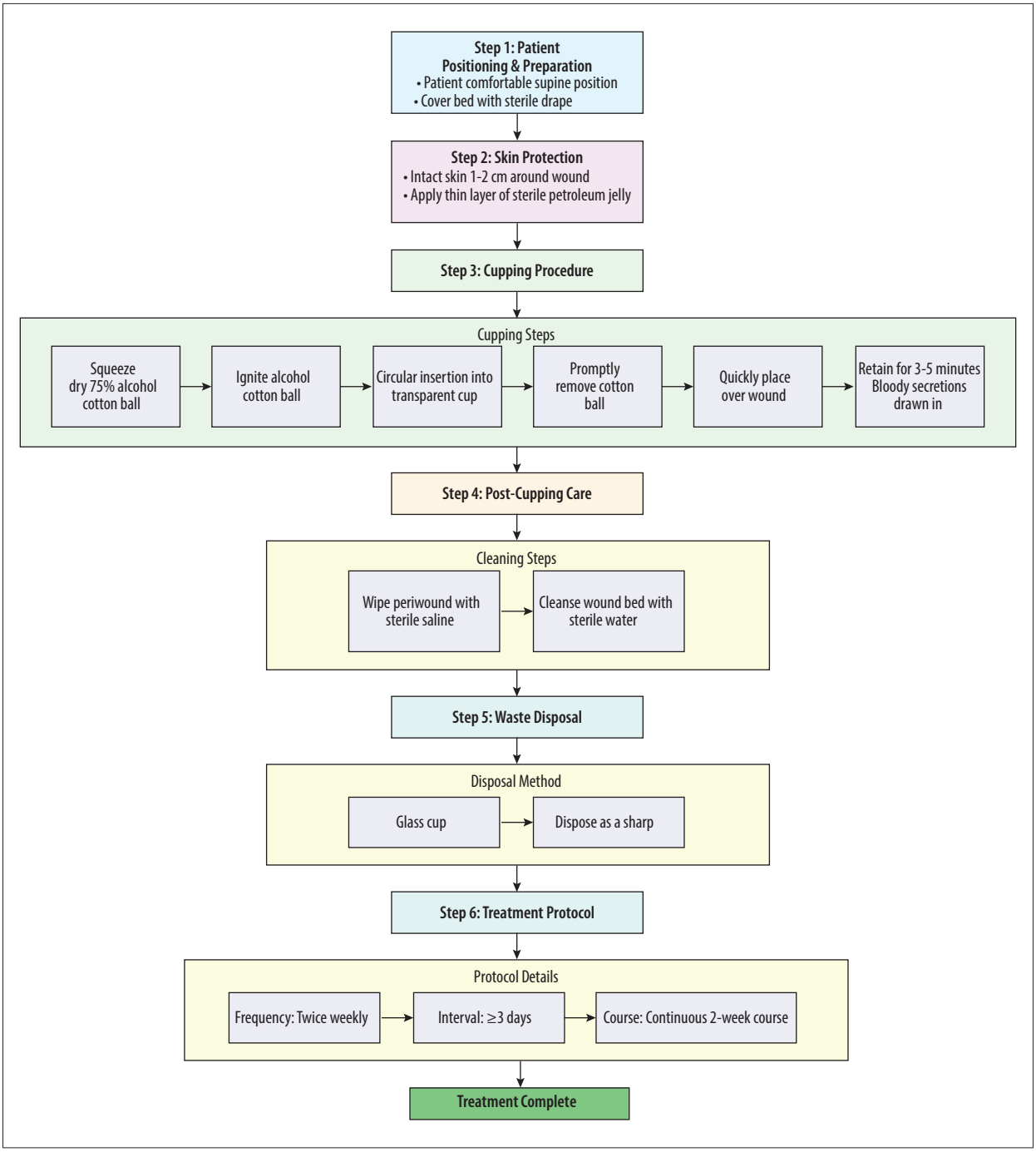

Figure 2. Local wound cupping treatment procedure flowchart.

symptoms, interfering with daily activities; and 3, severe symptoms, markedly affecting daily activities). Total local symptom scores were calculated for each patient before and after the intervention, to evaluate changes in symptom severity [12].

Pain was assessed using the visual analogue scale. Patients rated their pain on a scale from 0 to 10, with the aid of facial expression diagrams. Higher scores indicated greater pain intensity. Pain severity was categorized as follows: 0, no pain; 1 to 3, mild pain (tolerable and not affecting daily life or sleep); 4 to 6, moderate pain (noticeable and affecting sleep); and 7 to 10, severe pain (intense and intolerable, affecting both appetite and sleep).

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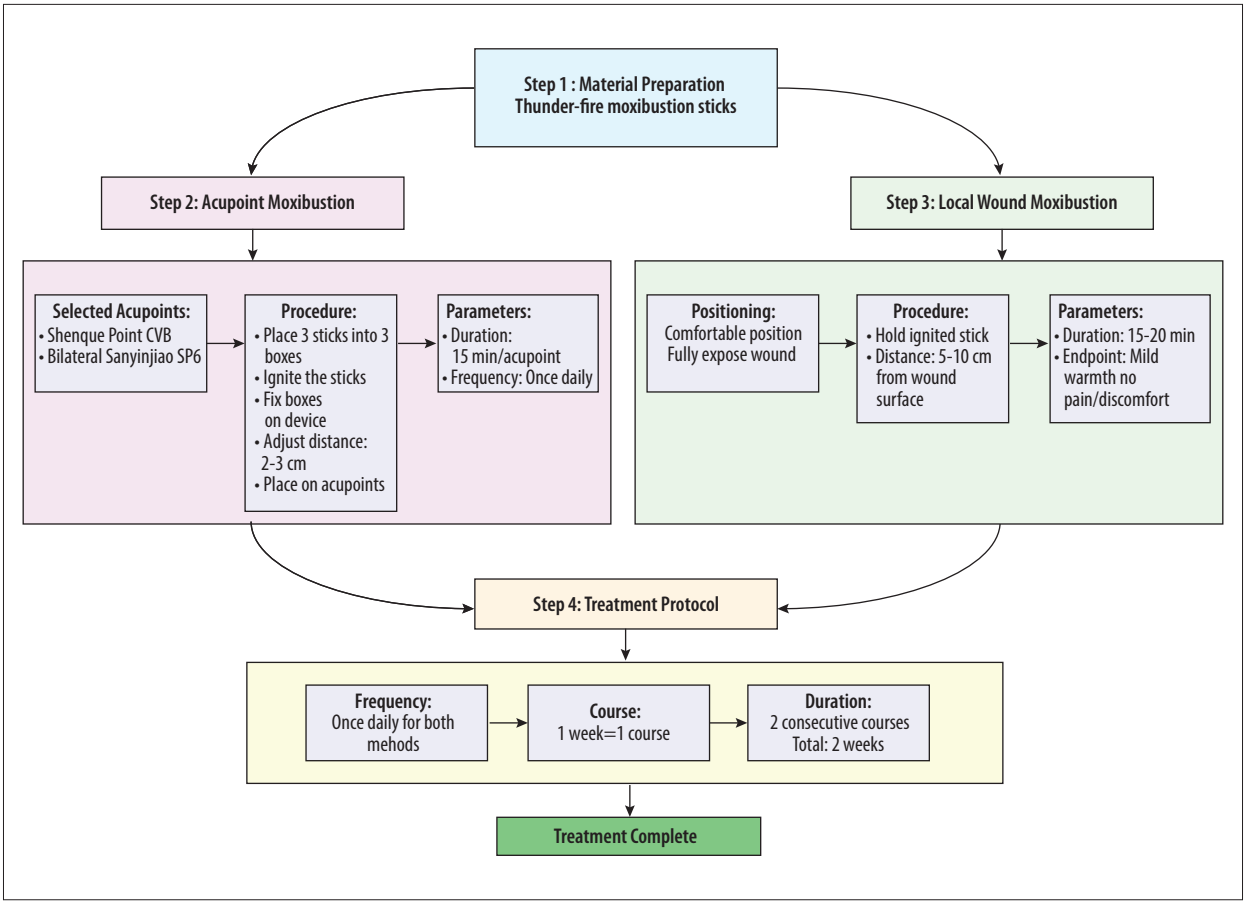

Figure 3. Thunder-fire moxibustion treatment protocol flowchart.

Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI), developed by Buysse et al [13], was used to assess the patients' subjective sleep quality. This scale consists of 18 items and 7 dimensions: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of hypnotic drugs, and daytime dysfunction. Each dimension is scored on a scale from 0 to 3, and the total score of the scale is the sum of scores of the 7 dimensions, ranging from 0 to 21 points. A higher total score indicates more severe sleep problems [14]. The scale was translated into Chinese by Liu et al [15], and its Cronbach's α coefficient in the Chinese population is 0.84, indicating good reliability and validity. Clinical judgment criterion were applied, with a total PSQI score greater than 7 points indicating poor sleep quality [16].

Due to the distinctive nature of the physical interventions (clay pot therapy and thunder-fire moxibustion), blinding of the treating practitioners and patients to group assignment was not feasible. However, to minimize assessment bias, the outcome assessors responsible for measuring wound healing rates, taking wound photographs, and scoring the PSQI were blinded to the group allocation of the participants. Furthermore, the primary objective outcome was based on predefined, observable criteria to reduce subjectivity.

Statistical Methods

All statistical analyses were performed using SPSS version 21.0. Measurement data were expressed as mean±standard deviation ($\bar{x}\pm s$). For intragroup comparisons, the paired-samples *t* test was used, whereas intergroup comparisons were conducted using the independent-samples *t* test. A 2-tailed *P* value <0.05 was considered to indicate statistical significance.

Results

Baseline Data Between the 2 Groups of Patients

There were 18 men and 12 women in the control group, with a wound duration of 56.12±10.76 days. The type of wound was trauma in 20 cases and an unhealed surgical incision in 10 cases. There were 19 men and 11 women in the observation group, with a wound duration of 58.11±11.23 days. The

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Table 1. Comparison of wound healing rates between the 2 groups of patients.

Item	Number	Complete recovery	Marked effect	Effective	Ineffective	Marked recovery
Observation group	30	16 (53.33)	12 (40.00)	2 (6.67)	0	28 (93.33)
Control group	30	9 (30.00)	8 (26.67)	13 (43.33)	0	17 (56.67)
χ^2						10.756
P						0.001*

* Indicates *P*<0.05, and the difference is statistically significant.

Table 2. Comparison of local symptom scores and pain scores between the 2 groups of patients.

Item	Sample	Observation group	Control group	*t*	*P*
Symptom score					
Before intervention	30	15.60±1.91	15.63±1.50	0.085	0.940
After intervention	30	5.73±1.62	7.67±1.73	-4.473	0.000*
Pain score					
Before intervention	30	5.66±1.48	5.56±1.12	-0.308	0.759
After intervention	30	2.47±2.21	4.17±2.31	2.753	0.008*

* Indicates *P*<0.05, meaning the difference is statistically significant.

Table 3. Comparison of Pittsburgh Sleep Quality Index (PSQI) scores between the 2 groups of patients before and after treatment.

Item	Sample	Observation group	Control group	*t*	*P*
Control group	30	12.85±2.03	11.30±2.15	3.550	0.001*
Observation group	30	13.06±1.86	9.58±1.56		

* Indicates *P*<0.05, meaning the difference is statistically significant.

type of wound was trauma in 18 cases and an unhealed surgical incision in 12 cases. There was no statistically significant difference in general information, injury time, and wound type between the 2 groups of patients.

Comparison of Wound Healing Rates Between Groups Before and After Intervention

As shown in **Table 1**, the healing rate of the observation group after intervention was 93.33%, compared with a rate 56.67% in the control group. The difference was statistically significant (*P*<0.05).

Comparison of Local Symptom Scores and Pain Scores Between Groups Before and After Intervention

As shown in **Table 2,** before the intervention, the local symptom scores of the control group and the observation group were 15.63±1.50 points and 15.60±1.91 points, respectively, with no statistically significant difference between the 2 groups (*P*>0.05). After the intervention, the symptom score of the observation group (5.73±1.62) was significantly better than that of the control group (7.67±1.73). Also, before the intervention, there was no statistically significant difference in the pain score between the observation group (5.66±1.48) and the control group (5.56±1.12). After the intervention, the pain score of the observation group was significantly lower than that of the control group (*P*<0.05).

Comparison of PSQI Scores Between Groups Before and After Intervention

As shown in **Table 3**, before the intervention, there was no statistically significant difference in the PSQI scores between the 2 groups (*P*>0.05). After the intervention, the PSQI scores of both groups were significantly improved (*P*<0.05), and the

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observation group was significantly better than the control group in improving the PSQI scores, with a statistically significant difference (P>0.05).

Discussion

Traditional Chinese Medicine Theory and Modern Mechanisms of Cupping Therapy in Promoting Wound Healing

This study showed that cupping therapy can effectively facilitate the healing of chronic refractory orthopedic wounds. Consistent with this finding, previous research has also validated its efficacy in managing infectious and exudative wounds, including furuncles, abscesses, and chronic sinus tracts [18,19]. From the perspective of TCM theory, chronic refractory wounds are typically attributed to local stagnation of qi and blood, which further evolves into stasis and accumulation and eventually transforms into noxious heat. The application of cupping therapy at the wound site helps to dredge the stagnated local qi and blood, thereby exerting therapeutic effects, such as clearing heat, resolving toxicity, promoting blood circulation, and dissipating blood stasis [20].

In terms of its mechanism of action, the negative pressure generated during cupping elicits multiple physiological effects. First, the suction effect of negative pressure enables the timely removal of exudate, pus, and necrotic tissue from the deep layers of the wound, effectively cleansing the wound cavity and eliminating dead space. Second, negative pressure induces local tissue hyperemia, which enhances microcirculation and increases blood and oxygen supply to the wound bed, and thus promotes the proliferation of granulation tissue. Modern research further indicates that cupping therapy can reduce systemic inflammatory markers, such as white blood cell count, C-reactive protein, and procalcitonin, while downregulating the expression of inflammatory cytokines, including interleukin 4 (IL-4) and IL-5 [21]. This suggests that cupping may alleviate the body's inflammatory response by improving local qi and blood circulation and accelerating the clearance of inflammatory mediators. Additionally, accumulating evidence proposes that its anti-inflammatory effects may be associated with the regulation of the coagulation-complement-mast cell activation axis and the inhibition of mast cell degranulation [22].

Mechanisms and Synergistic Effects of Thunder-Fire Moxibustion in Promoting Wound Healing

Thunder-fire moxibustion is prepared with medicinal herbs, including agarwood, costus root, and frankincense, all of which possess the properties of activating and dispersing qi, promoting blood circulation, and unblocking meridians. Compared with conventional moxibustion, it exhibits stronger thermal penetration and yields more profound and extensive therapeutic effects [23]. Research indicates that thunder-fire moxibustion can downregulate the expression of inflammatory factors, such as hypoxia-inducible factor-2α and prostaglandin E2, thereby alleviating the body's inflammatory response. In this integrated treatment protocol, cupping is applied first to induce local capillary dilation; subsequent administration of thunder-fire moxibustion then facilitates the deeper penetration of herbal components. Meanwhile, the thermal radiation generated by thunder-fire moxibustion transfers heat to deeper tissues, which further enhances vasodilation, improves local blood circulation, and accelerates the absorption of wound exudate [24]. Clinical studies have also confirmed that thunder-fire moxibustion can effectively relieve symptoms such as pain and itching in ulcerated wounds and expedite the wound healing process [25].

Thunder-Fire Moxibustion and Its Potential Synergy With Modern Photothermal Therapy

In recent years, the mechanisms underlying modern hyperthermia have been further elucidated. Research by Xie et al [26,27] demonstrates that photothermal therapy using nanomaterials (eg, black phosphorus and borophene) acts directly on diseased tissues and modulates the local immune microenvironment via thermal effects. For instance, it can recruit monocytes and macrophages and promote their polarization toward a reparative phenotype. This finding provides a novel perspective for interpreting the therapeutic mechanism of thunder-fire moxibustion: its wound-healing effects may partially stem from thermal stimulation regulating the phenotypes of local immune cells, thereby driving the transition of chronic inflammatory wounds toward a reparative state. Future research could further explore the integration of TCM thermal therapies with modern nanomaterials featuring precise thermal properties. Such investigations would not only clarify the scientific basis of traditional therapies but also contribute to the development of innovative wound treatment strategies with well-defined mechanisms and controllable therapeutic outcomes.

Improvement Effect and Mechanism of Combined Cupping and Thunder-Fire Moxibustion on Sleep Quality in Patients with Chronic Refractory Wounds

Chronic refractory wounds are characterized by a prolonged disease course and poor therapeutic response, often imposing significant psychological burden and triggering sleep disturbances in patients. Research indicates that these patients frequently experience insomnia due to concerns about wound healing [28], and their psychological and social adaptation levels related to the disease are generally unsatisfactory [29]. From the perspective of TCM theory, qi is the commander of

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blood, and blood is the mother of qi. The sufficiency of qi and blood serves as the fundamental basis for wound healing, while sleep constitutes a crucial period for the transformation of qi and blood as well as bodily repair. Chronic insomnia, in turn, can lead to qi and blood deficiency, thereby delaying the wound healing process.

This study showed that the combined application of cupping and thunder-fire moxibustion can effectively improve sleep quality in such patients. Mechanistically, cupping stimulates nerve endings under acupuncture points, promotes the release of neurotransmitters such as serotonin, regulates emotional states, alleviates anxiety, and thus exerts a sleep-improving effect [30-32]. In TCM, insomnia falls into the category of sleeplessness, and the therapeutic principles advocate tonifying deficiencies, reducing excesses, regulating Zang-fu organs, and balancing qi, blood, yin, and yang. The clay pot cupping method, a specific form of cupping therapy, can be integrated with local manipulation techniques (such as flash cupping, shaking, and rotating) to regulate the entire spine, unblock the Bladder Meridian, facilitate the smooth circulation of qi and blood, balance yin and yang, and thereby soothe the mind and promote sleep.

Thunder-fire moxibustion uses moxa floss blended with various nourishing Chinese herbs, and its deeply penetrating thermal effect achieves therapeutic outcomes such as supporting healthy qi, consolidating the body's foundation, and harmonizing qi and blood. In terms of acupoint selection, Shenque is adopted to nourish essence and strengthen the constitution, and it is combined with Sanyinjiao to calm the mind and regulate mental state – these acupoints work synergistically to enhance sleep quality. *The Yellow Emperor's Inner Canon* states, "When lying down, blood returns to the liver," implying that adequate sleep helps regulate liver blood flow and promote tissue repair. Therefore, improving sleep quality not only acts as a key factor in enhancing patients' quality of life but also holds positive significance for the healing of chronic refractory wounds.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, as a single-center clinical efficacy trial with 60 participants, the modest sample size may restrict the statistical power for detecting subtler therapeutic effects and limit the generalizability of results to broader populations. Second, while outcome assessors for wound healing evaluation were blinded to group allocation, the distinctive nature of the physical interventions (clay pot therapy and thunder-fire moxibustion) precluded blinding of both the practitioners and patients, which may have introduced performance bias and influenced subjective outcomes, such as pain scores and sleep quality assessments. Third, the study design focused on clinical efficacy endpoints and did not include collection of biospecimens (eg, serum, wound exudate) to monitor objective molecular changes, such as fluctuations in inflammatory cytokines (eg, IL-6, TNF-α). While our discussion provides a theoretical mechanistic link based on existing literature, the absence of direct biomarker data limits our ability to conclusively delineate the underlying molecular pathways involved in the observed therapeutic effects. Future research should prioritize larger-scale, multi-center randomized controlled trials with rigorous blinding strategies and integrated biomarker assessments to validate these preliminary findings and elucidate the precise mechanisms of action.

Conclusions

In summary, the integration of clay pot therapy (using balanced cupping techniques) and thunder-fire moxibustion exhibited a notable synergistic effect in the management of chronic refractory wounds among orthopedic patients. This combined TCM intervention accelerated wound healing rates, mitigated local symptoms and pain, and substantially enhanced patients' sleep quality.

Ethical Approval

This study was reviewed and approved by the Ethics Committee of Foshan Traditional Chinese Medicine Hospital, with the ethical approval number KY [2022] 108.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Data Availability

The datasets used and analyzed during the present study are available from the corresponding author upon reasonable request.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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