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Original Research Article

Non-operative management of distal radius fractures by mumiaee: a randomized clinical trial

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Abstract

Objective: This placebo-controlled randomized clinical trial (RCT) aimed to compare the time of union, and radiological, and clinical outcomes between patients taking Mumiaee and those taking a placebo drug. Mumiaee is a natural mineral-rich substance that has been utilized for centuries in various traditional medical systems and is recognized in Persian medicine for its potential therapeutic role in bone healing.

Materials and Methods: This RCT was done in Mashhad University of Medical Sciences, Mashhad, Iran on 44 of patients. Subsequently, radiographic parameters such as radial height, radial inclination, and articular step were assessed, alongside clinical outcomes including visual analog scale (VAS), disability of arm, shoulder and hand (DASH), patient-rated wrist evaluation (PRWE), and Mayo Wrist Score Questionnaire.

Results: This study involved 44 patients with acute distal radius fractures (DRF) in a two-arm RCT. The intervention group (M) received daily capsules containing 250 mg Mumiaee plus 250 mg Avicel powder, while the control group (P) received capsules containing only 500 mg of Avicel powder. After 6 weeks, significant differences were observed in range of motion, grip strength, and clinical questionnaire scores between the two groups. However, no significant differences were found in radiological parameters at this time point. Also, there was a statistical variance in wrist extension, grip strength, and Mayo wrist score 12 weeks post-operation.

Conclusion: The results showed that the M group had improved grip strength, wrist extension, and Mayo questionnaire outcomes compared to the P group. Additionally, M group had shorter union time. Mumiaee may have a potential role in supporting bone repair following DRF, however, the current study included limited sample size and focused on specific types of fractures. Therefore, larger-scale studies with longer follow-up periods are needed to better evaluate the effectiveness of Mumiaee.

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Introduction

Distal radius fractures (DRFs) are some of the most commonly encountered fractures, making up 8−15% of all bony fractures in adults (Liporace et al. 2009; Meena et al. 2014). DRFs usually occur following low-energy trauma, such as falls are related to bone mineral density (BMD) (ALAH et al. 2003; McCall et al. 2007; Xavier et al. 2011). While methods such as plaster-pin immobilization, wrist splint or cast, and external and internal fixation are common for DRFs treatment, the most suitable technique for managing DRFs remains a topic of debate due to the low density of bone minerals (Daliri et al. 2024; Ermutlu et al. 2020; Ghasemi et al. 2023; Lim et al. 2021).

Mumiaee (also known as Shilajit, Mummy, Mumie, Mumijo, Momiai, Moomiaii, Brag-shun or Barakhshin, rock sap or rock juice, Asphaltum punjabinum, or mineral pitch) is an organic and mineral compound that exists as a viscous extract. It is formed through the mixing of minerals and plant fibers, as well as the oxidation of oily hydrocarbons within layers of sedimentary rocks, eventually oozing out from mountain cracks during hot weather. Mumiaee comprises benzoic acid, fatty acids, ichthyol, ellagic acid, resin, triterpenes, sterol, aromatic carboxylic acids, bioactive 3,4-benzokoumarins, amino acids, phenolic lipids, and microelements. Notably, it is rich in bioactive molecules like dibenzo-alpha-pyrones (DBPs), humic acid (HA), and fulvic acid (FA), which contribute to its strong antioxidant activity (Sadeghi et al. 2020c).

The mineral content of Mumiaee is approximately 15–20%, and it contains trace elements such as selenium. Additionally, it contains mineral salts, amino acids, proteins, lipids, steroids, carbohydrates, alkaloids, and nitrogen-containing compounds. The primary mineral components include potassium (K), calcium (Ca), magnesium (Mg), sulfur (S), and sodium (Na) (Kangari et al. 2022; Stohs et al. 2017).

Mumiaee is a substance commonly used in traditional and folklore medicine to aid in the treatment of bony fractures. The typical oral dosage is 200–2000 mg per day for 1 month (Bybin and Stom 2015; Sadeghi et al. 2020c). Mumiaee facilitates bone formation through a dual mechanism, it exhibits anabolic activity and promotes the transport of minerals into bone tissue. Furthermore, it induces calcium deposition and mineralization by increasing the expression of osteocalcin, alkaline phosphatase (ALP), Runt-related transcription factors 2 (RNX2), and type I collagen, which in turn stimulate osteoblast function and improves cell survival (Lin et al. 2025). Recent studies have shown that Mumiaee is effective in accelerating the healing process in tibial fractures (Sadeghi et al. 2020b). In another study, Mumiaee was compared with phenytoin cream on wound healing. The results indicated that Mumiaee reduces inflammation and increases oxygen levels in wounds (Dehghan and Faradonbeh 2012). Furthermore, a non-interventional cohort study demonstrated that consuming Mumiaee may improve the healing of femoral and tibial fractures (Dehghan and Faradonbeh 2012; Sadeghi et al. 2020a; Shahriari et al. 2018). Therefore, Mumiaee has been found to facilitate bone fracture healing by up-regulating synthesis of collagen, and improving oxygenation to the wound area (Barouji et al. 2020). The ions present in Mumiaee play significant roles in regulating mitosis, osteogenesis, angiogenesis, and antibacterial properties, making them applicable in bone regeneration. (Jahani et al. 2025a; Jahani et al. 2025b; Kangari et al. 2022; Perez et al. 2015).

Questions/purposes: Our study aimed to evaluate the effects of oral administration of Mumiaee in managing patients with DRFs. Previous research has shown promising results in the repair of tibial shaft fractures with the oral consumption of

Mumiaee. With the increasing incidence of DRFs, exploring treatment options is becoming crucial. However, no clinical trials have been conducted to investigate the efficacy of Mumiaee in managing DRFs. Thus, we aimed to evaluate the impact of oral Mumiaee administration in DRF management.

Materials and Methods

Study setting

In a two-arm randomized clinical trial (RCT), 44 patients with acute DRF were enrolled in two hospitals between 2020 and 2021. All patients received signed written informed consent forms before enrollment to study. Ethical approval of this RCT was obtained from Mashhad University of Medical Sciences (IR.MUMS.MEDICAL.REC.1399.330). Also, our study was registered and accepted by the Iranian Registry of Clinical Trials (IRCT) (IRCT20191216045758N1, https://irct.behdasht.gov.ir/search/result?query=IR.MUMS.MEDICAL.REC.1399.330). This research adheres to the Declaration of Helsinki and follows the CONSORT guidelines.

Patients

Adult patients who were referred to emergency department with acute unstable (Fernandez type 1 and 3) unilateral DRF were recruited to the study. Patients with underlying conditions such as osteoporosis, rheumatic diseases, immune system disorders, or those presenting with pathological fractures were excluded from the study.

Study design

Orthogonal wrist imaging studies were done to determine radiological parameters, including palmar tilt, radial height, radial inclination, articular step, and wrist range of motion. An expert hand surgeon visited all patients who underwent percutaneous pining and bridging external fixator treatment and they were recruited for the study. The external fixator device and distal radius pinning were identical and followed academic guidelines.

Patients with DRF were enrolled in the study during the year 2020, adhering to specific inclusion and exclusion criteria. Inclusion criteria encompassed providing informed consent for trial participation, age ranging from 18 to 80 years, and Type 1, 2, and 3 of fractures stabilized using PCP or an external fixator. Exclusion criteria comprised bone diseases known to delay union (such as osteoporosis), a history of rheumatoid disease or immune disorders, pathological fractures, or unwillingness to continue participating in the study.

We randomly allocated the patients into two groups: intervention group (Group M), patients received a daily dose of 4 capsules each containing 250 mg Mumiaee plus 250 mg Avicel powder for one month. In the control group (Group P), participants received 4 capsules, each containing 500 mg of Avicel powder, which were matched in shape, color, and appearance to the capsules administered in the intervention group. The capsules consumed by patients in both groups had similar shapes, sizes, and smells. Simple random allocation is the easiest and most basic approach that provides unpredictability of treatment assignment. In simple random allocation, treatment assignment is made by chance without regard to prior allocation (that is, it bears no relation to past allocations and it is not discoverable ahead of time). Then the random allocation sequence was generated by using a computer-generated random-number table. A statistical consultant will determine the allocation of participants to each group and their order using Sealed Envelope software, with the type of concealed allocation. Blocked randomization ensures an equal number of participants in the intervention and control groups across consecutive time intervals. The table was securely stored in a notebook on a dedicated shelf within the emergency department. Once a patient provided informed consent, a designated nurse, who

was not involved in outcome assessment, accessed the table to assign the patient to the next available slot, thereby ensuring allocation concealment. Notably, both patients and the researchers involved in treatment administration and outcome assessment remained blinded to group assignments throughout the study, maintaining bilateral blinding. Outcome assessors, including those evaluating functional questionnaires, scores, and radiologic parameters, had no access to the randomization table and were therefore fully blinded to treatment allocation. This assigned patients to either the M or P groups. Patients in group M were given capsules containing Mumiaee plus Avicel powder, while those in group P received capsules containing Avicel powder only. Patients visited at 6-week and 12-week follow-up periods to evaluate their wrist range of motion and grip strength. Functional outcomes were evaluated in each follow-up visit through the completion of questionnaires, including Mayo Wrist Score, quick disabilities of the arm, shoulder and hand (Q-DASH), and patient-rated wrist evaluation (PRWE) Questionnaires. Additionally, the amount of pain is measured by visual analogue score (VAS). Radiologic parameters were measured before and at weeks 6 and 12 post-operation (post-op). To evaluate the fracture union, orthogonal wrist X-rays were performed every 2 weeks post-op unless union was achieved earlier.

In summary, the present study was a double-blind superiority clinical trial conducted in parallel, employing randomized block allocation and placebo control. Its aim was to assess the effect of Mumiaee medication on the duration of DRF union. Convenience sampling was utilized as the sampling method in this study.

Sample size

A total of 44 patients with acute DRF were enrolled in this two-arm RCT between 2020 and 2021. Participants were equally allocated to the intervention group (Group M) and the control group (Group P), with 22 patients in each group. All enrolled participants met the predefined inclusion and exclusion criteria and were randomized using block randomization with concealed allocation. The final analysis was conducted on all randomized patients.

Tools (data sources)

Radiography:

Radiographic parameters were measured twice: before initial treatment and after 6 weeks, with wrist X-rays taken every 2 weeks to determine union time.

Radial palmar tilt: This parameter is evaluated through a lateral view of wrist x-ray. It measures the angle formed by the line perpendicular to the radius shaft axis and the line connecting the volar and dorsal lips of the distal radius. The normal range of this parameter is approximately 11-12 degrees of volar tilt.

Radial height: In anteroposterior (AP) view of wrist x-ray, two parallel lines perpendicular to radius shaft were drawn. One line originates from distal ulnar head and the other from radial styloid process. The distance between these two lines was measured as radial height. The mean normal range of radial height is considered as 11-12 millimeters (Kamal et al. 2023) (Figure 1-A).

Radial inclination: It is defined as the angle formed between the perpendicular line to the radial shaft and the line connecting the distal radio-ulnar joint to the styloid process in AP view. The normal range is considered as 22-23 degrees (Athwal et al. 2003) (Figure 1-B).

Articular step: It defined any depression or protuberance in the joint surface using AP view. In this study, patients with an articular step ranging from 0-2 mm, a consistent range observed across all participants in our study.

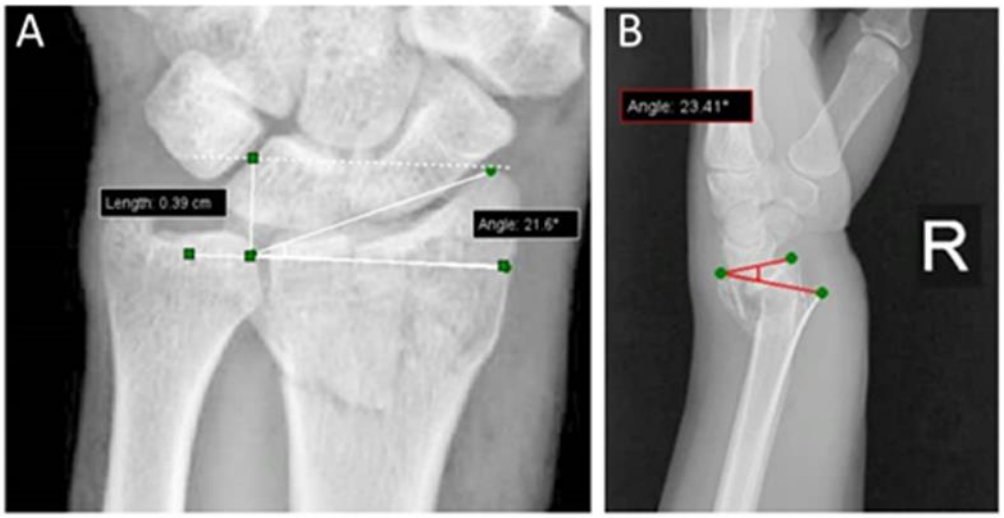

Figure 1. Pre-operative radiological parameters measurements: radial height and radial inclination (A). Radial palmar tilt (B)

Goniometry:

Range of motion of the wrist, consisting of flexion, extension, pronation, supination, radial deviation, and ulnar deviation, was evaluated by utilization of goniometry.

Dynamometry:

With the patients in a seated position, grip strength was evaluated three times with the flex of the elbow at 90 degrees and the forearm and wrist in a neutral position by using a hand-held dynamometer (HHD), and the mean value was recorded.

PRWE Questionnaire:

This score assesses three aspects: wrist pain, disability in daily and special functions. It included 15 steps and each step has 10 items; based on the step of PRWE questionnaire, the number of scores is evaluated from 0 (indicating pain-free) to 100 (indicating extreme pain or acute pain) based on individual item scores (Mehta et al. 2015). We utilized the validated Persian-translated version of the score (Fadavi-Ghaffari et al. 2017).

DASH Questionnaire:

This questionnaire evaluates both symptoms and the capacity to perform specific activities. In contrast to the original 30 steps in the original DASH, the Quick DASH employs 11 steps to gauge physical function and symptoms in individuals with any or multiple musculoskeletal disorders of the upper limb. The score ranges from 0 (indicating ability) to 100 (indicating the critical limitation)(Jester et al. 2005). We used the validated Persian-translated version of this score (Ebrahimzadeh et al. 2015).

Mayo wrist score questionnaire:

It evaluates four aspects of pain, the active flexion/extension, wrist range of motion, and grip strength. The scale of the score is from 0 to 100 points. Scores between 90 and 100 are considered “excellent” functions, 80-89 are “good”, 65-79 are “intermediate” and a score below 65 is classified as “poor” (Dacombe et al. 2016). This questionnaire is filled out by the physician.

VAS Score:

The pain intensity was assessed using the VAS score that is scored from 0 (indicating pain-free) to 10 (indicating acute pain) (Hawker et al. 2011).

Statistical analysis

Data is presented as mean ± SD. Initially, the demographic data of the patients were delineated by descriptive statistical methods consisting of the central index, dispersion index, and frequency distribution. In this following, the relationship among different qualitative variables was evaluated by Chi-square and Fisher's exact tests. The student t-test was

employed for the comparison of quantitative variables between the two groups Also, the Kolmogorov- Smirnov test was employed to evaluate the normality or non-normality of the distribution of quantitative data. To compare variables across various periods, the paired t-test was applied in instances of normal distribution, while the Wilcoxon test was utilized in the case of abnormal distribution. All p-values below 0.05 were evaluated as statistically significant. The analysis was conducted using SPSS software, version 19 (SPSS Inc., Chicago, USA).

Results

Descriptive data

Forty-four patients were included in the study, with 22 patients in each group (intervention and placebo). Demographic data including age, gender of patient, and basic radiological factors including radial inclination, radial height, volar tilt, articular step and wrist alignment were gathered. The mean age was 41.50±13.35 and 42.31±12.72 years in Mumiaee and placebo groups, respectively. There were non-significant difference between the two groups in age, gender, and fracture side.

Pre-operation, quantitative data between the two groups were examined. Initially, the Kolmogorov-Smirnov test was employed to assess the normal distribution of the data. Subsequently, it was established that the studied radiological and clinical variables followed a normal distribution, allowing for parametric tests to compare them between the two groups. The clinical demographic variables and preoperative radiology were compared between the two study groups, and are presented in Table 1.

According to Table 1, the non-significant variance in pain (based on VAS score) and radiological parameters between the M and P groups before operation except for radial height**.**

Table 1. Demographic and radiological parameters data before surgery (N=44)

Parameters	Group M (N=22), Mean ± SD	Group P (N=22), Mean ±SD	p-Value*
Sex (male)	59.09%	63.64%	0.20
Age (Year)	41.50 ± 13.35	42.31 ± 12.72	0.50
Involved side % (Right)	54.55%	54.55%	1.0**
Fracture type (%)			
Shaft	45.45	54.55	-
articular	54.55	45.45	
VAS pain score	5.86 ± 1.93	5.90 ± 1.84	0.93
Radius height	3.31 ± 2.31	2.27 ± 1.90	0.01
Palmar tilt	21.04 ± 14.13	17.54 ± 10.27	0.20
Radial inclination	16.86 ± 6.29	18 ± 6.94	0.57
Wrist alignment	16.50 ± 7.76	17.31 ± 8.21	0.20
Time of union	36.90 ± 6.81	42.31 ± 6.09	-
Articular step	0.31 ± 0.47	0.27 ± 0.45	0.52

Independent T-test*, Chi-square**. M: Intervention group; P: Control group; SD: Standard deviation

Outcome measures (6 weeks post-op: primary outcome)

There were statistically significant differences in wrist extension (p=0.01), grip strength (p=0.02), and Mayo wrist score (p=0.03). However, no significant differences were found in radiological parameters, range of motion, grip strength, and clinical scores. Additionally, there was a significant difference in the time of union exhibited between the M and P groups (p=0.01) (Table 2).

Outcome measures (12 weeks post-op: secondary outcome)

The results displayed in Table 2 demonstrate the disparities in range of motion, grip strength, and clinical questionnaire scores between the M and P groups. Although statistical differences were observed in the Mayo wrist score, wrist extension, and flexion ($p<0.05$), no significant differences were detected in radiological and other clinical parameters between the two groups after 12 weeks.

Table 2. The comparison of clinical scores and wrist range of motion between M and P groups after the operation

Parameters	Scores	Follow-up	(Mean ± SD)		Improvement (Mean ± SD)		p value
			Group M	Group P	Group M	Group P	
Clinical Scores	DASH	6 weeks	30.36 ± 20.56	47.18 ± 21.26	-20.45 ± 13.59	-33.58 ± 14.01	0.48
		12 weeks	9.91 ± 8.89	13.52 ± 11.26			0.24
	PRWE	6 weeks	36.34 ± 18.77	37.75 ± 17.21	-21.68 ± 9.38	-21.00 ± 8.30	0.79
		12 weeks	14.65 ± 11.08	16.75 ± 11.08			0.59
	MAYO	6 weeks	63.18 ± 21.52	50.22 ± 17.62	16.81 ± 11.39	17.27 ± 9.09	0.03
		12 weeks	80.00 ± 13.62	67.50 ± 13.25			0.01
	VAS	6 weeks	3.54 ± 2.80	3.68 ± 2.10			0.85
		12 weeks	1.04 ± 1.61	1.04 ± 1.32	-2.50 ± 2.24	-2.63 ± 1.43	0.83
Wrist range of motion	Radial inclination	6 weeks	21.90 ± 4.02	22.81 ± 3.54	-	-	0.90
		12 weeks	-	-			-
	Flexion	6 weeks	52.27 ± 13.15	45.68 ± 14.49			0.12
		12 weeks	57.27 ± 8.82	49.31 ± 12.17	5.00 ± 7.71	3.63 ± 6.39	0.01
	Extension	6 weeks	45.45 ± 14.38	31.59 ± 14.75			0.01
		12 weeks	51.59 ± 12.08	36.81 ± 12.77	6.13 ± 8.98	5.22 ± 8.23	0.01
	Radial deviation	6 weeks	19.09 ± 5.69	19.77 ± 5.22	0.90 ± 2.94	2.72 ± 3.69	0.68
		12 weeks	20.00 ± 5.11	22.50 ± 3.70			0.07
	Ulnar deviation	6 weeks	37.27 ± 8.41	34.31 ± 10.72			0.28
		12 weeks	36.81 ± 9.06	34.77 ± 9.93	-0.45 ± 5.32	0.45 ± 4.33	0.28
	Pronation	6 weeks	64.09 ± 14.36	56.59 ± 14.25			0.08
		12 weeks	66.13 ± 13.44	59.31 ± 10.26	2.04 ± 5.26	2.72 ± 6.31	0.06
	Supination	6 weeks	65.90 ± 15.24	60.45 ± 14.79	2.04 ± 7.81	3.18 ± 4.23	0.23
		12 weeks	67.95 ± 12.69	63.63 ± 14.57			0.30
Union	Grip strength	6 weeks	29.81 ± 9.41	21.59 ± 13.10			0.02
		12 weeks	34.00 ± 8.46	24.13 ± 14.20	4.18 ± 4.81	2.54 ± 4.70	0.08
	Time of union	6 weeks	36.90 ± 6.81	42.31 ± 6.09	-	-	0.01
		12 weeks	-	-			

Independent T-test*, Chi-square*. DASH :Disabilities of the arm, shoulder, and hand; PRWE: Patient-rated wrist evaluation; MAYO: Mayo wrist score; VAS: Visual analog scale; The estimated power is ≈ 70%

Discussion

In this double-blinded placebo-controlled clinical trial, the efficacy of Mumiaee in clinical parameters of patients with DRF was assessed at 6 and 12 weeks post-op intervals. DRF is one of the most common fractures and its management is crucial, often depending on the patient's BMD and clinical outcome. Initial management DRFs typically involves immobilization, pain control, and follow-up with orthopedic specialists (Gullborg et al. 2024). Treatment strategies range from non-operative approaches such as casting, to external or internal fixation, depending on fracture severity, patient's age, overall health, and the surgeon's expertise (Jafari et al. 2023). The primary goal of DRF management is to restore functional mobility and strength in the affected limb, allowing patients to resume pre-injury activities. Traditional medicine has a long history in the treatment of fractures and other bone injuries. Topical herbal formulations are commonly used based on the premise that their bioactive components penetrate tissues and enhance local metabolism, thereby promoting tissue repair (Lin et al. 2025). Mumiaee has been suggested to potentially increase the strength and mass of muscles and recuperative powers. It has been suggested to improve muscle strength, mass, and recuperative capacity, and studies indicate that combining Mumiaee with stem cells may accelerate bone tissue regeneration, highlighting its potential in cell-based therapies for bone defects (Abadi et al. 2025; Kangari et al. 2024). Evidence from nonintervention cohort study in Iran demonstrated that Mumiaee consumption enhances the healing of femur, tibia, and other long bone fractures (Sadeghi et al. 2020c). Oral consumption of Mumiaee has been associated with reduced fracture healing time, particularly in tibia shaft fractures, while *in vitro* studies demonstrate that it can increase osteoblast proliferation and enzyme expression, suggesting a direct effect on bone formation (Abbasi et al. 2019).

Mumiaee has been found to contain approximately 20–40% mineral content, which may contribute to its therapeutic effects. However, in processed Mumiaee, this value is approximately 10-15%, implying about 2-3 mg of minerals per 200 mg of Mumiaee. It is rich in nutrients such as mineral salts, amino acids, and humic acids. The mineral content of Mumiaee is 15–20%, along with trace elements including selenium. Additionally, Mumiaee has been shown to have increasing effects on the proliferation rate and enzyme expression of human osteoblast-like cells, indicating its potential impact on bone health (Abbasi et al. 2019; Mishra et al. 2019). More than 90% of the mineral content in Mumiaee is attributed to Calcium (Ca), phosphorus (P), copper (Cu), and Magnesium (Mg). Additionally, the major chemical ingredients of Mumiaee are HA, FA, DBPs, and DBP chromoproteins. Mumiaee has been implicated as a contributing factor in various diseases such as digestive diseases, diabetes, Alzheimer's, oligospermia, sexual dysfunctions, neurological disorders, and obesity. The inorganic components, the minerals existing in Mumiaee, may have ameliorating functions in bone diseases (Kanikkannan et al. 1995). The diverse biological functions and medicinal properties of Mumiaee are attributed to the presence of FA and HA, along with other chemical components (Schepetkin et al. 2003).

Experimental studies also highlight the broader regenerative and anti-inflammatory potential of Mumiaee. In osteoarthritis models, aqueous extracts improved cartilage degeneration and reduced synovial inflammation. In wound healing studies, Mumiaee decreased inflammation and enhanced oxygenation, comparable to or complementing effects seen with phenytoin cream (Allah Tavakoli et al. 2003; Azizi et al. 2018). Kangari et al.

reported the effect of Mumiaee on the osteogenic differentiation of adipose-derived mesenchymal stem cells (ASCs). The results demonstrate that DBPs enhance the osteogenic differentiation of ASCs, promoting collagen deposition, mineralization, and osteoblast activity, thereby providing insights into their mechanisms of action in bone regeneration (Kangari et al. 2022). It is crucial to consider that Cu and Mg ions in Mumiaee play crucial roles in both the process of angiogenesis in the bone repair process (Perez et al. 2015). The potential antioxidant activity of Mumiaee may contribute to the bone union process. The antioxidant activity of Mumiaee supports the optimal functioning of osteoblasts, facilitating the mineralization process, or aiding in the reduction of osteoclast activity (Sheweita and Khoshhal 2007). Mumiaee may contribute to osteogenesis via anabolic activities, including the enhancement of protein and nucleic acid synthesis, as well as the transportation of minerals into bone tissue (Barouji et al. 2020).

In our randomized double-blinded placebo-controlled clinical trial, the impact of Mumiaee on distal radius fracture repair was assessed. All participants received uniform clinical and radiologic evaluations including imaging, assessments of range of motion and grip strength, VAS pain scoring, completion of functional questionnaires, and measurement of essential radiographic parameters at baseline and at 6 and 12 weeks post-op. This study reported non-significant variance in radiological variables between the Mumiaee (M) and placebo (P) groups at 6 weeks post-op. However, significant distinctions were observed in clinical parameters, including wrist extension, grip strength, Mayo questionnaire scores, and the duration of union. At 12 weeks post-op, a comparative analysis revealed significant differences between the intervention and control groups in clinical criteria and questionnaire scores for variables such as wrist flexion, extension in wrist range of motion, and the Mayo questionnaire score. There were no significant differences in the remaining clinical variables and questionnaire scores between the two groups during the 12 weeks following surgery. It should be noted that the significant differences observed between the two groups in pain and patient-reported functional scores are inherently subjective and can be substantially influenced by psychological factors, including treatment expectations, beliefs about the efficacy of the intervention, and the patient's overall treatment experience. Although double-blinding was implemented, the possibility of a placebo effect cannot be entirely excluded, as receiving any intervention may enhance the patient’s perception of attention from the treatment team or foster expectations of faster recovery, potentially leading to a subjective reduction in pain. Previous studies have also shown that the placebo effect can play a significant role in improving pain in the short term, without necessarily causing any real change in the biological process of healing. Therefore, part of the observed difference in pain scores between the two groups may be due to this effect, and not the pure effect of the Mumiaee. This is particularly important since other more objective outcomes, such as radiological indices, did not show significant differences at week 6 post-op. Consequently, Mumiaee has been shown to promote bone healing when applied for therapeutic purposes. While its application may explain the enhanced healing observed in the intervention group, it is important to acknowledge that subjective responses and placebo effects may also have contributed to the observed reduction in pain. Nevertheless, further research is needed to provide more definitive insights into the efficacy of Mumiaee.

According to the scarcity of RCTs investigating the efficacy of Mumiaee in treating DRF, further RCTs are imperative to establish definitive conclusions. The limited sample size in current RCTs hinders the establishment of Mumiaee as an

effective treatment for DRF. Moreover, these studies primarily focus on specific fracture types, such as tibial shaft fractures, necessitating further investigation into Mumiaee efficacy for other bone fractures. Additionally, the short follow-up duration in existing research underscores the necessity for longer-term studies to evaluate Mumiaee sustained effects on fracture healing. Hence, while initial findings suggest promise, comprehensive research encompassing various fracture types and longer follow-up periods is crucial to ascertain Mumiaee broader effectiveness in fracture management. Also, certain patient conditions, such as tobacco product usage, occupational and domestic activity levels, attitudes towards life, and social engagement, are factors that could influence pain levels, satisfaction, and functional outcomes. However, due to constraints within this study, it was not feasible to explore these aspects comprehensively.

Distal radius fractures (DRFs) are recognized as common and prevalent injuries in orthopedics, and traditional therapeutic approaches continue to draw interest for their potential to support bone repair. One of the commonly used medications for bone healing is Mumiaee, a traditional medicinal substance, has long been used for its presumed osteogenic properties. In this randomized double-blinded controlled trial involving 44 adults with DRFs, patients receiving oral Mumiaee demonstrated greater improvements in grip strength, wrist extension, and Mayo scores at 6 weeks postoperatively, along with a shorter union time compared with controls. At 12 weeks, wrist flexion and extension, as well as functional scores, also favored the intervention group. These findings suggest that Mumiaee may hold potential as an adjunctive therapy to enhance postoperative recovery following DRF surgery. However, given the modest sample size and relatively short follow-up, the results should be interpreted cautiously. Larger, well-designed studies with extended observation periods are needed to more firmly establish its therapeutic value and to determine whether Mumiaee can be incorporated into evidence-based guidelines for accelerating bone healing after DRF surgery.

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Conflicts of interest

None

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Ethical Considerations

Ethical approval for this study was obtained from the Research Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (approval number: IR.MUMS.MEDICAL.REC.1399.330).
This research was conducted in full compliance with the codes of ethical conduct from the 1964 Declaration of Helsinki.

Submission declaration

It is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or any other language, including electronically without the written consent of the copyright-holder.

Code of Ethics

The clinical trial protocol was registered and approved in the Iran Randomized Clinical Trial (IRCT) center (IRCT20191216045758N1)

Authors' Contributions

Kimia Emami: Investigation, Manuscript writing.
Afsaneh Jahani: Investigation, Manuscript writing, Proofreading.
Hassan Rakhshandeh: Resource, Study design.
Mahla Daliri: Review & Editing.
Amin Rezaeian: Data Curation.
Hassan Mehrad-Majd: Statistical analysis.
Farshid Bagheri: Conceptualization, Resource.
Naeemeh Kalali: Investigation, Review & Editing.
Ali Moradi: Conceptualization, Supervision, Methodology.
Nafiseh Jirofti: Conceptualization, Supervision.

Declaration of generative AI in scientific writing

None

Declaration of informed consent

All participants were informed of the experiment and were asked to fill out a voluntary consent form. Also, they were informed that not participating in the study would not affect their treatment process.

Statement of the location

Present study was performed in the Orthopaedics Research Center, Ghaem Hospital, Mashhad University of Medical Sciences (MUMS).

Data availability

Correspondence and requests for materials should be addressed to Nafise.jirofti@gmail.com, Moradial@mums.ac.ir.

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