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Research Article

Multimodal Therapeutic Glove in Patients with Hand Osteoarthritis: A Phase I-II Pilot Study

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ABSTRACT

Background: Hand Osteoarthritis (HOA) is a prevalent form of osteoarthritis that leads to significant morbidity. The management of HOA typically involves a combination of nonpharmacological and pharmacological interventions, with a focus on safest therapies. Nonpharmacological interventions, such as splints or topical heat application, have shown potential benefits in reducing pain and improving grip strength.

Objective: To evaluate the safety and efficacy of a multimodal therapeutic glove (MTG) in patients with nodal HOA.

Methods: During 60 days patients received two 15 minutes sessions (before and after bedtime) with MTG. MTG delivered simultaneously heat, vibration, and joint distraction over interphalangeal joints. Effect of glove was evaluated baseline and at the end of the trial. Hand symptoms were assessed by determining Visual Analog Scale (VAS) for pain in the last 24 hours, VAS for pain in daily activities (VASda), VAS for pain during night rest (VASr), count of swollen and painful joints, Brief Pain Inventory (BPI) scores and minutes of morning stiffness. To assess hand function, Pain Disability Index 2 (PDI) and grip strength were used.

Results: Thirty-three females and 7 males (median age = 62.4 ± 9.7) with moderate to severe HOA (80% Dreisser class III or IV) ended the trial. No drop-outs or adverse effects were recorded. After 60 days, there was a significant (>50%) decrease in all pain-related measures (VAS, VASda, VASr, BPI, count of painful joints) and in PDI score. Grip strength, count of swollen joints and duration of morning stiffness also showed a relevant (but non-significant) improvement.

Conclusions: This pilot study confirms the safety of the multimodal MTG. The patent reduction of hand pain, the significant improvement of PDI score and the positive trend observed in hand function justify further trials to better determine MTG efficacy in patients with HOA.

INTRODUCTION

Hand Osteoarthritis (HOA) is a prevalent musculoskeletal disease that becomes more common with advancing age [1]. Individuals with HOA typically experience a range of clinical symptoms including pain, functional limitations, and difficulties in carrying out daily self-care, work-related, or leisure activities [2-4]. The clinical impact of HOA extends beyond functional limitations affecting physical appearance leading to

psychological disturbances, particularly, in women and individuals with severe disease or erosive osteoarthritis [5]. The primary objective in managing HOA is to alleviate symptoms and optimize hand function, ultimately enhancing activity, participation, and quality of life [6]. This goal is typically achieved through a combination of pharmacological and non-pharmacological interventions. However, current pharmacological approaches such as non-steroidal anti-inflammatory drugs (NSAIDs), Symptomatic Slow-Acting Drugs for Osteoarthritis (SYSADOAs), intra-articular injections or Disease-Modifying Anti-Rheumatic Drugs (DMARDs) often fall short of providing sustained therapeutic benefits due to various limitations. In case of NSAIDs, its use is hindered by the risk of toxicity. SYSADOAs are safe, but their efficacy remains elusive. Intra-articular injections of steroids or hyaluronic acid may provide some benefits but their widespread recommendation remains controversial. The role of DMARDs in HOA differs from other kind of inflammatory hand arthritis since there is no clinical trials that demonstrate relevant efficacy of any DMARDs or biological agents in this population [6]. In the light of this evidence, localized therapies for HOA, such as hand exercises and topical treatments, offer modest but clinically significant symptomatic relief. Moreover, many experts suggest that these therapies should be more widely utilized considering their effectiveness and the potential drawbacks of pharmacological alternatives [7].

One recommended treatment by occupational therapists is the use of therapy gloves [8]. Different types of gloves are available, including thermal gloves [9], stretch gloves [10], compression gloves [11], and vibrating gloves [12]. Emerging research has shed light on the therapeutic advantages offered by the utilization of therapy gloves in alleviating the symptoms of pain, stiffness, and swelling [13]. However, it remains unclear which specific physical attribute (thermal, vibrating, stretching, or compression) have the greatest influence on glove performance. Our hypothesis is that a single glove, that provided splinting and delivered most of the above-mentioned physical therapies (heat, vibration, and joint distraction), would straightforwardly achieve best results in alleviation of symptoms and function of patients with nodal HOA. The aim of this proof-of-concept trial is to evaluate the safety and efficacy of a multimodal intervention glove that provides external splinting and topically delivers heat, vibration and micro pulses of joint distraction in patients with HOA affecting the interphalangeal joints.

PATIENTS AND METHODS

Trial Design: This prospective, multicentre, open-label, single-arm phase I-II clinical trial was conducted to evaluate the safety and efficacy of Multimodal Therapeutic Glove (MTG) in patients with HOA affecting the interphalangeal joints and persistent hand pain that hinders their daily activities. Prior to enrolment, patients were provided with and signed a patient information sheet detailing the study's purpose and procedures.

Study cetting

Participants were recruited from November 2021 to December 2022 from outpatient rheumatology units at three private hospitals in Madrid, Spain: Hospital de La Luz, Instituto de Salud Articular ARI, and Hospital Beata María Ana.

Eligibility criteria

Inclusion criteria: Patients meeting all of the following criteria were eligible for the trial: age ≥ 40 years; diagnosis of HOA based on standard clinical or radiological criteria; duration of pain exceeding 3 months; and pain intensity of ≥ 4 on the Visual Analog Scale (VAS).

Exclusion criteria: Patients with a known allergy to plastic or leather; psoriasis; use of oral anticoagulants; severe neuropathies with hypoesthesia or sensory loss in the hands; and inflammatory arthropathies were excluded from the study.

Intervention: After obtaining informed consent, researchers ensured that each patient received a properly fitted and functional MTG. The gloves were labelled with a unique code for each hand, considering that hand pain and/or swelling could be unilateral. At this time, participants also received a written information sheet detailing the proper wear, care, and intervention protocol for the gloves. The MTG incorporates a temperature sensor and a sensor to measure the force applied by splints. It also has a microprocessor that controls various components of the device, including short-wave generating coils and heaters. The splints consist of a lattice of nitinol threads that adjust and stiffen the patient's fingers based on temperature changes.

Intervention protocol: Participants received two 15-minute sessions per day, one before bedtime and one after, for a total of 60 consecutive days. During each session, the glove

executed a preinstalled program that simultaneously combined dry heat, vibration, and micropulses of joint distraction over the interphalangeal joints. An electronic display over the dorsal aspect of the glove showed the phase of the program, heat temperature, battery level, vibration status, and massage function for each finger. At the end of each session, the glove automatically turned off. Data regarding glove usage, including session duration and number of sessions, were recorded in a memory card embedded in the glove.

Co-Interventions: Patients were allowed to use acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), Symptomatic Slow-Acting Drugs for Osteoarthritis (SYSADOAs), and Disease-Modifying Antirheumatic Drugs (DMARDs) such as methotrexate, sulfasalazine, and hydroxychloroquine. The dosage and units of these medications were recorded and included in the statistical analysis.

Adherence: Adherence to glove wear was assessed at each review appointment (days 15, 30, 45, and 60). Additionally, complete electronic data from the memory cards were analysed to evaluate adherence. Patients who did not complete at least 90% of the programmed sessions (≥108 sessions) were excluded from the statistical analysis.

Outcomes: Effect on hand function: Grip strength was assessed using the JAMAR© hydraulic hand dynamometer [14], and the Pain Disability Index 2 was used to evaluate the impact of the gloves on hand function.

Effect on hand symptoms: The following outcomes were used to assess the effect of the gloves on pain, stiffness, and swelling: Visual Analog Scale (VAS) for pain in the last 24 hours, VAS for interference of pain in daily activities (VASda), VAS for interference of pain during nighttime rest (VASr), the Brief Pain Inventory (BPI), count of swollen joints, count of painful nodules, and duration of morning stiffness.

Follow-up and data collection: Baseline assessments and data collection included VAS for pain in the last 24 hours, BPI, Pain Disability Index, count of swollen joints, count of painful nodules, duration of morning stiffness, grip strength, and medication dosage. This was repeated at two time points during the study (at two weeks and at the end of the eight-week study period). The baseline questionnaire also included demographic factors (age, gender, and race) and condition-specific factors such as symptom duration, functional class, or time since diagnosis. At weeks 4 and 6, a telephone interview was conducted to assess patient adherence, any technical issues with the gloves, and to evaluate average pain in the last 24 hours, interference of pain in daily activities, and the impact of pain on mood using the VAS.

Statistical analysis: Statistical analysis was performed using Stata 14 software (StataCorp LLC; 4905 Lakeway Drive, College Station, Texas 77845-4512, USA). Descriptive statistics were used to analyze quantitative variables, including the range of values (minimum and maximum), measures of central tendency (mean and median), and measures of dispersion (standard deviation and percentiles 25 and 75). Qualitative variables were analyzed using frequency tables and percentage distributions. Given the small sample size and non-normal distribution of quantitative variables, paired non-parametric tests such as the Wilcoxon and McNemar tests were used for dichotomous and categorical variables, respectively. A significance level of 0.05 ($P > 0.05$ non-significant) was considered for comparisons.

RESULTS

Table 1: Baseline Description of the Sample (n=40).

Variable	Mean±SD	Median (P25-P75)	Range
Age	62,4±9,7	62,9 (55,2-69,6)	36,2-86,4
Years of evolution	9,8±10,2	6,5 (2,5-11)	1-46
24-hour pain intensity (VAS)	4,8±2,0	5,0 (3,4-6,7)	1,0-9
Pain interference with ADL (VAS)	5,2±2,3	5,7 (3,4-7)	0-9
Sleep interference (VAS)	2,2±2,8	0,5 (0-5)	0-8,8
BPI (Brief Pain Inventory)	29,4±17,5	28 (15-37,5)	6-73
Pain questionnaire	37,1±15,1	37,5 (27-47,5)	9-73
Stiffness	15,6±20,9	10 (4-20)	0-120
Number of tender joints	8,6±4,7	8 (5-11)	1-20
Number of swollen joints	3,4±2,0	3 (2-4,5)	0-9
IFP nodules	2,7±2,8	2,5 (0-5)	0-9
IFD nodules	4,2±3,2	4 (1-7)	0-10
Hand strength: right	20,7±10,0	19,4 (14,3-24,7	4,3-51,5
Hand strength: left	18,1±8,3	17,2 (12,3-4,5)	4,5-43,0
Female sex: n (%)		33 (82,5%)	
Functional class (Dreisser): n (%) • • II • • III • • IV		 12 (30%) 20 (50%) 8 (20%)	

The baseline characteristics of the sample included 82.5% females (n = 33) that referred high levels of pain (BPI scores ≈ 30, VAS ≤ 5) and significant functional limitations (50% of patients in Dreiser class III, 20% in class II, and 30% in class IV). All 40 patients (median age = 62.4 ± 9.7) completed 100% of the sessions, as confirmed by electronic tracking from the memory cards. Approximately half of the patients (47.5%) were taking painkillers (either acetaminophen or NSAIDs) before entry the study (Table 1). The procedure was well tolerated and deemed safe.

Effects on pain: Significant improvements were observed in VAS, VASda, BPI score, and count of painful nodules ($p < 0.0001$) (Figure 1,2). Morning stiffness, VASr and count of swollen and painful joints also showed improvement although it was not statistically significant (Figures 1,3). There was also a trend towards a reduction in painkiller consumption from 47.5% to 27.5% at the end of the study.

Effects on function: There was a significant reduction in the PDI2 index (Figure 4). Despite a little improvement observed in grip strength, it was not statistically significant (Figure 5).

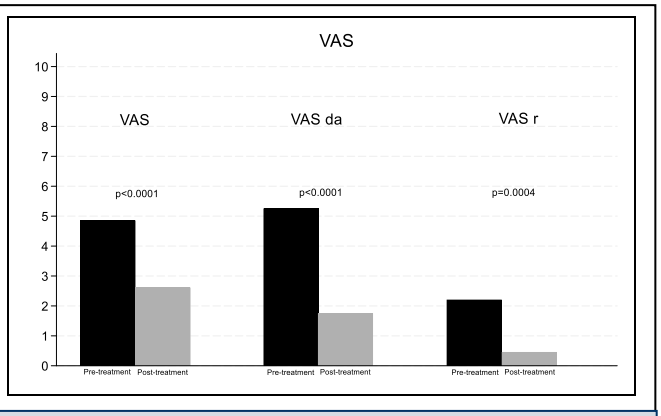

Figure 1: Visual Analog Scale for pain in the last 24 hours (VAS), in Daily Living (VASda) and during night rest (VASr) baseline and at 60 days.

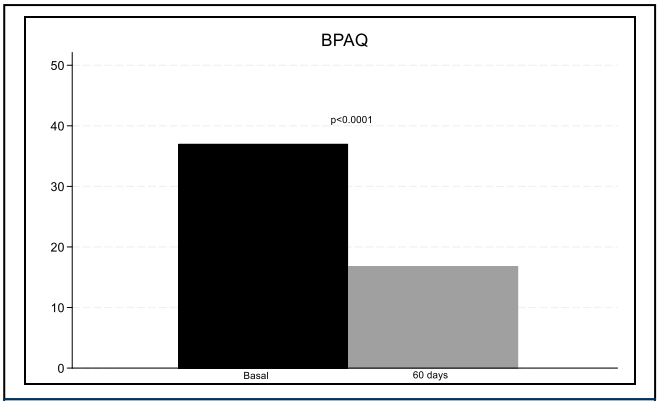

Figure 2: Changes in Brief Pain Assessment Questionnaire score (BPAQ) baseline and at 60 days.

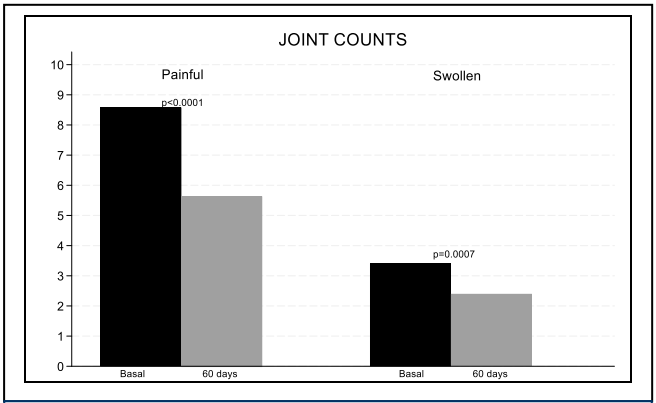

Figure 3: Change in mean joint count baseline and at 60 days.

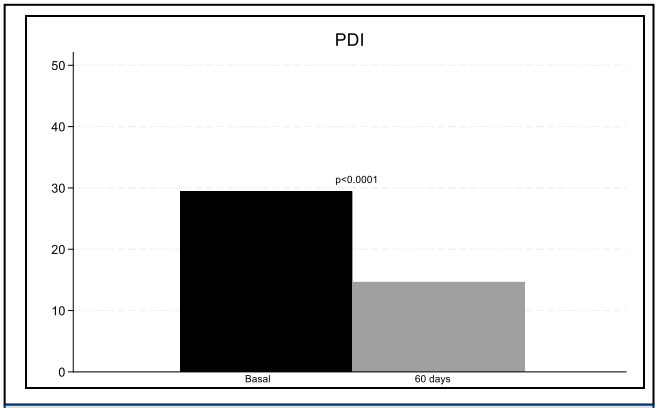

Figure 4: Changes in Pain Disability Index 2 (PDI) baseline and at 60 days.

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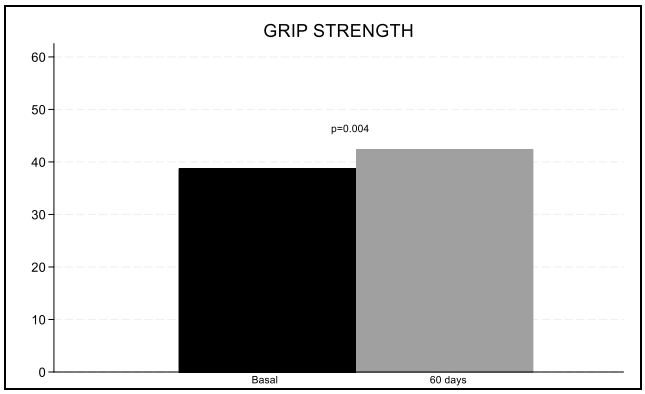

Figure 5: Changes in grip strength baseline and at 60 days. Sum of the two hands.

DISCUSSION

Osteoarthritis (OA) of the hand is a high prevalent disorder projected to increase as the population ages [14]. Unfortunately, the efficacy of pharmacological treatments used to alleviate pain and maintain independent daily activities is limited, either due toxicity [15] or suboptimal efficacy [6]. Among non-pharmacological interventions, techniques such as splinting, joint protection, local application of heat and strength training exercises have shown positive effects on pain and grip strength [16]. A common practice among occupational therapists is to prescribe therapy gloves to patients with inflammatory arthritis [8]. Several studies have investigated the mechanisms by which different therapy gloves may relief patients with arthritis of the hand. Gloves that use local compression may improve hand´s symptoms because they remove extracellular fluid, thus reducing pain, stiffness and improving finger movement. Compression may also increase blood flow, thus increasing warmth and reducing pain [17]. Gloves that deliver vibration seem also to reduce pain [12]. Proposed theories suggest selective attention and distraction, Diffuse Noxious Inhibitory Controls (DNICs), lateral inhibition within the spinal cord and stimulation of coinciding cortical coding areas involved with pain and touch in the brain [18]. Gloves that deliver heat seem to exert their benefits by decreasing pain, waning muscle spasms and diminishing inflammation [19]. Stretching gloves seem to ameliorate morning stiffness but the reasons or mechanisms remains uncertain [10]. Despite this widespread uncertainty about mechanisms of action of therapy gloves and the inconclusive evidence regarding its effectiveness, most glove users are committed to wear them due to a comfort provided by local warmth independently of other added local therapies [20]. Our results show a consistent and significant effect of MTG in all pain-related outcomes. This benefit comprises up to 90% of the sample.

Patients with Rheumatoid Arthritis seem to improve hand symptoms when using therapy gloves [13]. Our findings replicate a similar pattern of response but taken from a HOA population. We found a significant benefit in pain-related outcomes (that was accompanied with a relevant reduction in painkillers consumption), but we did not find a complete improvement in functional outcomes. Many reasons may contribute to explain this efficacy discordance. First, boundaries related to the sample such as the small size, the advanced HOA stage of the sample (mainly class III and class IV patients) or the high percentage of patients that, besides nodal OA, also have first carpo-metacarpal joint OA (CMC OA). Second, restrictions related to outcomes chosen to assess function. It is conceivable that a more complete core of standardized measures that includes AUSCAN, Cochin or FIHOA Index [21], would contribute to a more reliable functional result. Third, a most accurate optimization of parameters that influence the performance of the gloves such as the length of time wearing gloves or glove fitting [7]. Lastly, limitations inherent to a non-randomized open-label design such as the absence of control group, the heterogeneity of the sample or the short follow-up.

The results of this trial met its predefined endpoints indicating that the intervention was safe, feasible with relevant clinical improvements. Whether this improvement is due only to warmth or to the combination of different physical therapies, is difficult to ascertain in absence of controlled conditions. Likely, a better understanding of the mechanisms by which MTG exerts their analgesic effect would be achieved in further controlled trials that include arms exempting local warmth application. Despite the limitations inherent to trial design, the consistent results found over pain-related-outcomes and the positive trend observed in the improvement of hand function, encourage further trials to better clarify the efficacy of this novel non-pharmacological therapy for HOA.

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