Title: Efficacy of Quantic Nanotech® gloves on pain and function in hands with interphalangeal osteoarthritis: a prospective, multicenter, pre-post, single-arm, prospective observational study.

Type of study: Other

O**ther type of study:** prospective observational multicenter study with a commercial device in actual clinical practice (not a comparative trial, and therefore did not require CEIC approval).

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Section: Arthrosis

Key words:

- Osteoarthritis
- Therapeutic gloves
- Physiotherapy
- Quantic Nanotech Gloves

Body: Proven physical interventions (treatments) such as vibration, local heat, massage and physiotherapy are used in the treatment of pain and functional limitation of osteoarthritis of the hands.

Objective: To evaluate the effect on pain and functional disability in patients with symptomatic osteoarthritis of the interphalangeal joints of the hands, in a real clinical practice setting, of the use of Quantic Nanotech® gloves (ID WO2017032910A1). This consumer device provides heat and vibration to the fingers of the hand and is applied at the patient's own residence, in two daily sessions of 15 minutes each.

Methods: A prospective, multicenter, pre-post, observational, single-arm, multicenter, prospective study **was conducted** in consecutive patients seen in a rheumatology clinic who were recommended these gloves and agreed to participate in the follow-up. Inclusion criteria: age >40 years, clinical and radiological diagnosis of interphalangeal hand osteoarthritis, pain of

>3 months duration, pain intensity ≥5 on visual analog pain scale (VAS). Exclusion criteria: psoriasis, oral anticoagulation, thermal sensitivity or alterations due to vibration and allergy to plastic, leather or metal. Baseline and 15, 30 (telephone), 45 (telephone) and 60-day evaluations were performed. Data recorded: age, sex, race, time of evolution, analgesic medication, VAS, Brief Pain Inventory (BPI), Pain Disability Inventory (PDI), morning stiffness, examination, grip strength, tolerance and adverse effects. The Functional Index for Hand Osteoarthritis (FIHOA) is also evaluated in a subgroup of 22 patients. Statistics: comparison of baseline data and days 15, 30 and 60 with Student's t-test (parametric) and Wilcoxon rank sum (non-parametric), significance level 0.05 (p>0.05 N.S.: not significant). Analyses were performed with Stata IC v. 15.1.

Results: The results of the baseline clinical evaluations at days 15 and 60 are presented. Patients (n=42): sex: men 7 (16.6%), women 35 (83.3%); race: Caucasian 42 (100%); age 62.28±9.50 years (40-86); years of evolution: 9.74±10.34 years (1-46).

A significant and sustained reduction was observed in PDI values (baseline 22.29±11.23; 15 days 16.36±14.40; 60 days 12.02±10.20) (p<0.01), BPI (baseline 4.64±1.42; 15 days 3.53±1.76; 60 days 2.56±1.60) (p<0.001), FIHOA (n=19; baseline 13.94±6.45; 60 days 11.05±5.92) (p<0.05), morning stiffness (min) (baseline 16.83±21.75; 15 days 5.27±6.61; 60 days 5.23±6.92) (p<0.05).05±5.92) (p<0.05), morning stiffness (min) (baseline 16.83±21.75; 15 days 5.27±6.61; 60 days 5.23±6.61) (p<0.001) and improvement in non-dominant hand grip strength at 60 days (baseline 17.77±7.93; 15 days 18.59±7.38; 60 days 19.62±7.37) (p<0.05). A decrease in the number of daily doses of paracetamol (baseline 0.30±0.84; 15 days 0.19±0.57; 60 days 0.02±0.16) (p<0.05 baseline vs. 60 days) and NSAIDs (baseline 0.37±0.51; 15 days 0.21±0.48; 60 days 0.45±0.27) (p<0.05 baseline vs. 15 days) was observed. Fig. shows the evolution of the mean VAS of the last day (VAS), pain impact during activity (VAS2) and pain impact at night at rest (VAS3). No intolerance or adverse effects or dropouts were observed.

Conclusions: In patients with symptomatic hand osteoarthritis enrolled in the study, there was significant and sustained improvement over the 60-day observation period in VAS-measured pain, functional capacity and morning stiffness, as well as a reduced need for concomitant analgesia. Tolerance and adherence to treatment were excellent.

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