**Conclusions:** Forty percent of eligible patients agreed to participate in the study. This number is similar to earlier surgical placebo controlled trials from other countries. A high proportion of these patients were later excluded due to the absence of a medial meniscus lesion on MRI, confirming a poor correlation between clinical signs and MRI findings.

This study confirms the feasibility of recruiting patients for surgical placebo controlled trials but highlights the challenges of recruiting to surgical RCT's. Future studies should emphasize the oral information given at the initial screening and the importance of the study for future patients.

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PREVALENCE OF CLINICAL DIGITAL OSTEOARTHRITIS (HEBERDEN AND BOUCHARD NODES) IN A SELECTED POPULATION OF PATIENTS WITH SEVERE OBESITY: A PROSPECTIVE STUDY

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**Purpose:** Hand osteoarthritis (HOA) is the most frequent form of osteoarthritis (60%). The main risk factors of HOA are: age above 40, women, obesity, heredity and work. A recent meta-analysis seems to indicate that obesity (through the systemic release of pro inflammatory mediators such adipokines) is a risk factor of HOA (OR=1.9). However, results of studies analyzing obesity as a risk factor of HOA are mixed and focused on radiological HOA. If obesity is a substantial risk factor of HOA, we hypothesize that patients with severe obesity may present a high prevalence of this disease. The aim of the present was to study the prevalence of HOA which is defined as Heberden nodes in a prospective observational study in a population of patients with severe obesity (BMI>35 kg/m2) followed in specialized clinical nutrition department at a university hospital in Paris, France (Pitié Salpêtrière).

**Methods:** A senior rheumatologist collected demographic information (personal and familial histories, current treatment, hand pain), questionnaires of hand disability (DREISER and Cochin) and performed a complete detailed physical examination. Heberden and Bouchard nodes were diagnosed by a physical examination of hand joints and knee OA was confirmed by previous medical history. We studied the association (Fisher's exact test) between knee and hand osteoarthritis to explore if obesity is a risk factor of multiple osteoarthritis.

**Results:** We studied 112 patients: 65% of women, average age 47.1 years and average BMI 45.9 kg/m2 (30.8-69.1). We found a high proportion of Heberden nodes (16.1%), noteworthy particularly in the second and third fingers and a prevalence of Bouchard nodes of 1.8%. A third of patients with clinical hand osteoarthritis had hand pain and did not report hand disability. Knee osteoarthritis was reported in 23.2% of subjects. We found a significant link between knee and hand osteoarthritis (p=0.006). Multivariate analysis (taking into account age, sex, BMI, diabetes mellitus, hypertension and cholesterol serum level) showed that age was a significant risk factor of HOA [OR=1.11 (IC 95%: 1.04-1.17)] and knee osteoarthritis [OR=1.08 (IC 95%: 1.02-1.15)]. Univariate analysis showed that patients with knee osteoarthritis more often had diabetes mellitus (57.6% vs 26.7%, p=0.003), hypertension (73.1% vs 32.6%, p=0.006) and dyslipidemia (42.3% vs 4.7%,  $p=5.10^{-5}$ ).

**Conclusions:** In comparison with the known prevalence of clinical HOA in other series of patients aged over 55 years (4% to 14.9%), we found a high prevalence of Heberden nodes in this selected population of relatively young patients (mean age 47 years) with severe obesity, suggesting a systemic participation of adipose tissue. Moreover disturbances that are part of the metabolic syndrome could participate in the development of knee osteoarthritis which is otherwise linked to HOA.

## 343 NON-INVASIVE ELECTROMAGNETIC FIELD THERAPY PRODUCES RAPID AND SUBSTANTIAL PAIN REDUCTION IN EARLY KNEE OSTEOARTHRITIS: A RANDOMIZED DOUBLE-BLIND PILOT STUDY.

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**Purpose:** Pulsed electromagnetic fields (PEMF) have been employed for treatment of knee Osteoarthritis (OA) with varied success. PEMF signals

have been shown to modulate CaM-dependent signaling pathways that orchestrate the release of cytokines and growth factors in cellular responses to injury. This study was designed to determine if PEMF configured to modulate CaM/NO/cGMP signaling would reduce pain in early knee OA.

Methods: This IRB approved double-blind, placebo-controlled, randomized pilot study used VAS pain scores on a 0-10 cm scale with respect to baseline as an outcome measure for each cohort. Patient selection was knee pain for at least 3 months with an imaging study confirming cartilage loss, an initial VAS score  $\geq 4$ , and at least 2 hours of daily standing activity in a physical occupation. Patients with rheumatoid arthritis, gout, pregnancy, cortisone injections, surgery, or viscosupplementation were excluded. The PEMF signal consisted of a 7 msec burst of 6.8 MHz sinusoidal waves repeating at 1burst/sec delivering a peak induced electric field of 34  $\pm$  8 V/m in the knee. The light-weight portable battery operated device was used 15 minutes twice daily, and ould be easily placed over the knee with clothing. Blinding was maintained because this PEMF can only be detected with specialized equipment. Un-blinding occurred after all data was collected. Patients self-reported maximum daily VAS pain scores on an unmarked horizontal 10 cm line (0 = no pain, 10 = worst possiblepain) at baseline (day 0), daily for the first 14 days and from day 29 to day 42. Results were analyzed using the Student's t-test or one way repeated measures ANOVA with Holm-Sidek post hoc analysis, as appropriate. Significance was  $P \le 0.05$ . Data is displayed  $\pm$  SEM.

**Results:** There were no adverse effects and the devices were well tolerated. There were no significant baseline differences in mean age, body mass index (BMI), or Kellgren-Lawrence (K-L) radiographic scores, between active and sham cohorts. Thirty four patients started treatment. Of these, 19 (14F, 5M) were shams, and 15 (10F, 5M) were actives. All enrolled patients received PEMF treatment to day 14. Thereafter, 3 active and 7 sham patients dropped out of the study by day 42, citing lack of perceived benefit as the reason, confirmed by VAS scores. The PEMF signal caused  $50\% \pm 11\%$  decrease in mean maximum VAS vs mean baseline VAS for the treated group on day 1, persisting to day 42 (P < 0.001). There was no significant decrease in was maximum VAS in the sham group (P = 0.227). The overall decrease in VAS scores from baseline was  $2.7 \pm 0.57$  (P < 0.001) for the active group vs  $1.5 \pm 0.41$  (P = 0.168) for the sham group. There was no significant difference in mean start VAS between active and sham groups.

**Conclusions:** This non-thermal, non-invasive PEMF, when configured to dose CaM/NO/cGMP signaling, has a significant and rapid impact on pain from early knee OA. The PEMF effect on pain is consistent with the known rapid effect of NO signaling on reduction of effusion. The intervention is novel because it is non-pharmacological, and the patient population did not have end stage OA and was required to be on their feet at least two hours a day.

## PEMF Effect on Early Knee OA Pain

