

Original Research

Efficacy of Periosteal Stimulation for Chronic Pain Associated With Advanced Knee Osteoarthritis: A Randomized, Controlled Clinical Trial

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ABSTRACT

Background: Because of morbidity associated with painful knee osteoarthritis (OA) and commonly prescribed analgesics, patients often pursue complementary and alternative modalities (eg, acupuncture). Clinical trials have demonstrated modest therapeutic efficacy of traditional Chinese acupuncture for knee OA pain, and patients with advanced disease have largely been excluded. We have previously demonstrated preliminary short-term tolerability and efficacy of periosteal stimulation therapy (PST) (ie, electrical stimulation of the periosteum facilitated by acupuncture needles) for older adults with advanced knee OA.

Objective: This study evaluated the sustained efficacy of PST and boosters for treating chronic pain with advanced knee OA.

Methods: One hundred ninety participants age > 50 years with Kellgren-Lawrence grade 3 or 4 knee OA and chronic pain were randomized to (1) PST (once a week for 10 weeks) followed by PST boosters for 6 months (once every 2 weeks 2 times, then once a month), (2) control PST (ie, periosteal needles and brief electrical stimulation of control points) once a week for 10 weeks, or (3) PST for 10 weeks followed by control PST boosters for 6 months. Change in the Western Ontario and McMaster Universities Osteoarthritis Index pain score immediately after the 10-week intervention and at 6-month follow-up (9 months after baseline) was the

primary outcome. OMERACT-OARSI (Outcome Measures in Rheumatology Clinical Trials–Osteoarthritis Research Society International) criteria also were evaluated. Secondary measures of outcome included (1) physical performance (Short Physical Performance Battery, gait speed, Timed Up and Go, and timed stair climb); (2) psychological factors (depressive symptoms measured with the Center for Epidemiologic Studies–Depression scale, coping measured with the catastrophizing subscale of the Coping Strategies Questionnaire, and self-efficacy measured with the Arthritis Self-Efficacy Scale); (3) health-related quality of life measured with the Medical Outcomes Study 36-Item Short-Form Health Survey; (4) rescue pain medication use tracked with diaries; and (5) health care utilization and interim physical activity were monitored via monthly telephone calls.

Results: After adjustment for pain at baseline, the PST and control booster did not differ from controls at 10 weeks (difference, 1.3; 95% CI, –0.10 to 2.8; $P = 0.0683$) or 9 months (difference, 1.1; 95% CI, –0.32 to 2.6; $P = 0.13$). The PST and PST booster group had similar improvement compared with

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controls at 10 weeks (baseline adjusted difference, 1.1; 95% CI, -0.34 to 2.5; $P = 0.1369$) but significantly more improvement at 9 months (baseline adjusted difference, 1.5; 95% CI, 0.069 to 3.0; $P = 0.0401$). Baseline depressive symptoms, low self-efficacy, higher difficulty performing daily activities, and greater knee stiffness predicted a lower likelihood of response.

Conclusion: PST plus PST boosters in patients age > 50 with advanced knee OA were well-tolerated and modestly reduced pain. ClinicalTrials.gov identifier: NCT00865046. (*Clin Ther.* 2013;35:1703–1720) Published by Elsevier HS Journals, Inc.

Key words: acupuncture, chronic pain, knee osteoarthritis, older adults, periosteal stimulation.

INTRODUCTION

Approximately 20 million Americans have chronic pain associated with knee osteoarthritis (OA).¹ Lower-extremity OA is the most common cause of difficulty with walking or climbing stairs, thus preventing an estimated 100,000 elderly Americans from independently walking from bed to bathroom. Osteoarthritis of the knee and/or hip is associated with limitations in physical activities, mobility, and self-care, as well as with loss of earnings and work disability.²

The 2012 American College of Rheumatology guidelines recommend nonpharmacologic interventions, such as weight loss and exercise, as the first-line treatment for knee OA pain.³ Many patients also rely on oral analgesics for pain management, such as acetaminophen, nonsteroidal anti-inflammatory drugs, and opioids. These medications are often associated with serious adverse effects, however, including renal impairment, cerebrovascular accidents, heart failure, and gastrointestinal bleeding with nonsteroidal anti-inflammatory drugs^{4,5} and delirium, falls, and hip fractures with opioids.^{6–8} Glucosamine, chondroitin, and intra-articular hyaluronic acid injection have met with mixed results.^{9–11} Intra-articular glucocorticoid injections may provide modest, typically transient benefits.¹² Neither arthroscopic debridement nor lavage is recommended for pain management.¹³ The standard-of-care fallback intervention for those with recalcitrant pain and functional compromise is knee replacement surgery. Older adults with limiting comorbidities may not be surgical candidates, and advanced age is the major predictor of mortality after these joint replacement procedures.¹⁴ Further, few patients appear willing to undergo such surgery.¹⁵ Clearly, for older

adults with advanced OA and chronic pain, safe and effective analgesic options are needed.

Because of the limitations associated with traditional therapeutics, use of complementary and alternative medicine (CAM) interventions has increased steadily. An estimated 3 million Americans have used acupuncture, most commonly for chronic pain.¹⁶ The efficacy of traditional Chinese acupuncture for the treatment of knee OA has been examined in the context of 3 large randomized clinical trials, but participants with advanced disease (ie, Kellgren-Lawrence [KL] grade 4) were largely excluded.^{17–19} In addition, the magnitude of pain reduction in the most rigorous of the 3 trials was very modest (0.87 points lower on the Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] pain scale in the acupuncture group compared with the sham acupuncture group), and no long-term follow-up was performed.¹⁷ Two recent trials of acupuncture for knee OA have not included radiographic data (ie, unknown disease severity among participants).^{20,21} Extrapolating from these trials and a recent meta-analysis,²² traditional Chinese acupuncture (TCA) is associated with modest pain reduction in patients with early and moderately advanced knee OA. A 2010 Cochrane review concluded that acupuncture provides clinically insignificant pain reduction for appendicular OA and that observed benefits are likely related to expectancy-mediated placebo analgesia.²³

Periosteal stimulation therapy (PST) is a technique that delivers high-frequency electrical stimulation to periosteum using acupuncture needles. It has been hypothesized that PST exerts its effect primarily by stimulating sympathetic fibers in proximity to the periosteum, which in turn stimulates a local increase in blood flow that then modifies vascular sympathetic and segmental nerve responses.^{24–26} Electrical stimulation of acupuncture needles is associated with decreased levels of the proinflammatory cytokine interleukin 6²⁷ and with release of endogenous opioids^{28–31} that may have anti-inflammatory effects on peripheral receptors.^{32,33} Because inflammation plays a central role in OA pathogenesis,^{34–36} this may be a target for the intervention. Although PST is typically administered by acupuncturists using acupuncture needles, the technique and underlying principles that guide PST are distinct from those of TCA. Traditional Chinese acupuncture involves placing needles at precise points (that may be near or far the site of pain) along channels called meridians and manipulating the needles until “te chi” is achieved

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