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A Prospective, Randomized, Double Blind, Placebo Controlled Clinical Trial Assessing the Effects of Applying a Force to C5 by a Mechanically Assisted Instrument (MAI) on Referred Pain to the Shoulder.

Hardas GM[1], Murrell GA.

Author information

Abstract

STUDY DESIGN: Randomized, prospective, double blind, placebo controlled clinical trial.

OBJECTIVE: To determine the effects of applying a force to C5 of the spine by a mechanically assisted instrument (MAI) in patients with referred shoulder pain.

SUMMARY OF BACKGROUND DATA: Manipulating C5 of the spine is a chiropractic treatment for referred shoulder pain, there are no clinical trials evaluating its efficacy. Outcome measures were patient ranked questionnaires and independent examiner findings. One hundred and twenty five patients were diagnosed with referred shoulder pain of cervical origin; sixty five were in the treatment cohort and sixty in the placebo cohort.

METHODS: This was a prospective, randomized, double blind, placebo controlled trial assessing the effects of applying a force to C5 by a MAI to patients with referred shoulder pain. The treatment cohort had the MAI set at the maximum setting to transmit a force into the spine; the placebo cohort had the MAI turned off. Primary outcome measures were frequency and severity of extreme shoulder pain obtained via a patient reported questionnaire; secondary outcome measures were patient ranked pain and functional outcomes as well as examiner assessed range of motion and strength. Assessment procedures were completed at 24 weeks post treatment and data were analyzed with intent to treat protocol.

RESULTS: There was a reduction in the frequency but not severity of extreme shoulder pain in the treatment cohort, average ranking reducing from weekly to monthly ($p<0.05$). Patients treated with the MAI had 10N ($p=0.04$) better internal rotation strength after 6 months post-treatment. No differences with any other outcome measures between the two cohorts at the 24 week study period.

CONCLUSION: The major effect of applying a MAI to the level of C5 of the spine in referred shoulder pain is improved shoulder strength for internal rotation in this randomized double-blinded clinical trial.

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2015, English, Thesis edition:

A prospective, randomized, double blind, placebo controlled clinical trial assessing the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) on referred pain to the shoulder.

Hardas, George, Clinical School - St George Hospital, Faculty of Medicine, UNSW

Title	• A prospective, randomized, double blind, placebo controlled clinical trial assessing the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) on referred pain to the shoulder.
Author	• Hardas, George, Clinical School - St George Hospital, Faculty of Medicine, UNSW
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Physical Description	• Masters Thesis
Subjects	• C5 facet joints orthopaedics neck cervical spine UNSW • referred shoulder pain medicine research double blind randomized • mechanically assisted instrument chiropractic shoulder manipulation
Summary	• Background: Manipulating the C5 facet joints is a popular chiropractic treatment for referred shoulder pain, however there are no clinical trials evaluating its efficacy. Aim: To determine the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) in patients presenting with referred shoulder pain. Methods: This was a prospective, randomized, double blind, placebo controlled trial to assess the effects of applying a force to the C5 facet joints by a MAI to patients with referred shoulder pain. For this trial; the treatment cohort had the MAI set at the maximum setting (5 rings) to transmit a force into the spine; the placebo cohort had the MAI turned off (0 ring). Primary outcome measures were frequency and severity of extreme shoulder pain obtained via a patient reported questionnaire; secondary outcome measures were patient ranked pain and functional outcomes as well as examiner assessed range of motion and strength. Assessment procedures were completed at 24 weeks post treatment and data were analysed with an intent to treat protocol. Results: One hundred and twenty-five patients were

recruited for this trial, sixty five were in the treatment cohort and sixty in the placebo cohort. There was a reduction in the frequency but not severity of extreme shoulder pain in the treatment cohort, with average ranking reducing from weekly to monthly ($p<0.05$). Patients treated with the MAI had 10 N ($p=0.04$) better internal rotation strength after 6 months post-treatment. There were, however, no differences with any other outcome measures between the two cohorts at the 24 week study period. Conclusion: The major effect of a MAI over placebo applied to the C5 facet joints two times per week for six weeks, then once a week for three weeks in patients who presented with referred shoulder pain was improved shoulder strength in internal rotation at 24 weeks ($p=0.04$).

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2015 AAOS Annual Meeting

Presentation Abstract

Session:	556-570-Spine V
Session Time:	Thursday, Mar 03, 2016, 10:30 AM -12:30 PM
Location	Room W304A
Presentation Time:	11:54 AM - 12:00 PM
Presentation Number:	Paper 567
Title:	Effects of Mechanical Stimulation of C5 for Referred Shoulder Pain: A Randomized Double-Blinded Clinical Trial
Classification:	+Nonoperative/functional restoration/injections (Spine)
Keywords:	Cervical; New Technique / Device; Instrumentation; Outcomes
Author(s):	**George Hardas**, Sutherland, Australia

Abstract:

INTRODUCTION: Manipulating the C5 facet joints is a popular chiropractic treatment for referred shoulder pain, however there are no clinical trials evaluating its efficacy. The aim of this study was to determine the effects of applying a force to the C5 facet joints by a mechanically assisted instrument (MAI) in patients presenting with referred shoulder pain.

METHODS: A prospective, randomized, double blind, placebo controlled trial was conducted to assess the effects of applying a force to the C5 facet joints by a MAI to patients with referred shoulder pain. The treatment cohort had the MAI set at the maximum setting (5 rings) to transmit a force into the spine; the placebo cohort had the MAI turned off (0 ring). Primary outcome measures were frequency and severity of extreme shoulder pain obtained via a patient reported questionnaire; secondary outcome measures were patient ranked pain and functional outcomes as well as examiner assessed range of motion and strength. Assessment procedures were completed at 24 weeks post-treatment and data were analyzed with an intent to treat protocol.

RESULTS: A total of 125 patients were recruited for this trial, 65 were in the treatment cohort and 60 in the placebo cohort. There was a reduction in the frequency but not severity of extreme shoulder pain in the treatment cohort, with average ranking reducing from weekly to monthly ($p<0.05$). Patients treated with the MAI had 10 N ($p=0.04$) better internal rotation strength after 6 months post-treatment (figure 1). There were, however, no differences with any other outcome measures between the two cohorts at the 24-week study period.

DISCUSSION AND CONCLUSION: The major effect of applying a MAI to the C5 facet joints in referred shoulder pain is improved shoulder strength for internal rotation in this randomized double-blinded clinical trial.