Methods: Our standardization process included multiple steps. A preliminary study collected force—time profiles from 9 experienced clinicians delivering HVLA-SM to 16 asymptomatic participants. Mean thrust loading durations, pre-load forces and peak thrust forces in the lumbar spine were: 308 ± 389 ms; 116 ± 69 N; and 261 ± 143 N, respectively. We trained 3 clinicians to deliver HVLA-SM to within 1 SD of the calculated means and conducted a pilot study of patients with LBP. Force—time profiles were collected at 1—3 visits on 4 participants receiving HVLA-SM and all but 1 manipulation was within the standardized force ranges. We then conducted a focus group with the 9 clinicians from our preliminary study to determine what doctor and patient characteristics they considered important when evaluating the quality of SM. This led to the inclusion of surveys in the RCT of 219 participants asking both the clinician and patient to rate their perceptions of SM quality. We video recorded HVLA-SM treatment on specified visits that were evaluated by an independent clinician.

Results: The preliminary study consisted of 16 asymptomatic participants (15 males, mean BMI 26, mean age 36). Further analysis revealed a total of 28 segments were manipulated with much variability found both amongst the clinicians and the segmental levels. Between clinicians, the thrust loading duration varied by $0 - 1940$ ms, preload range was $41 - 216$ N and peak force range was $67 - 462$ N. Preload per segment range was 64 N at L5 to 154 N at L4 and peak force range from 134 N at the sacrum to 402 N at L4. Eight clinicians delivered thrust forces with the hand and one with the leg. Pilot study clinicians stated that maintaining the specified force—time profile was difficult and limited their care. The focus group felt that the force—time profile was only one of several necessary components in high quality HVLA-SM. Analysis of 133 visits during the RCT showed that clinician and patient perceived quality of HVLA-SM delivery for the same treatment was different. Patients rated quality average 5%, very good 37% and excellent 55% of the time. Clinicians rated their own quality average 30%, very good 67% and excellent 2% of the time. Evaluation of 54 video recorded encounters focused on potential quality parameters identified by the study team showed significant variation between and within clinicians.

Conclusion: Clinicians used their judgment in applying force—time profiles and we collected qualitative data to objectively assess HVLA-SM quality. It is premature to standardize HVLA-SM based upon force—time profiles of thrusting hand alone, due to different delivery styles. More research is needed to effectively standardize HVLA-SM delivery.

Effects of Biofreeze vs. ice on acute, non-complicated neck pain[☆]

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Background: Cryotherapy has long been used by physical therapists and chiropractors in the management of acute pain and more recently it has been shown to effectively manage chronic pain. Multiple studies have demonstrated that both ice and menthol decrease blood flow and help to control pain; however, there is limited research to determine which form of cryotherapy works better on individual patients.

Methods: Fifty-one males and females between the ages of 19 and 65 (37 ± 11.2 years) with bilateral non-radicular, acute neck pain (myalgia) were given both ice and the topical analgesic Biofreeze on each side of the neck. The patients had no history of surgery in the neck nor had received a cortisone injection in the neck in the last year. The study was randomized so that the ice was on the left side of the neck and the Biofreeze was on the right side or vice versa. Thus, both sides of the neck had one cryotherapy modality. The patients were asked to rate their pain on a 0—10 Visual Analog Scale (VAS) for each side of the neck both before and immediately following the 10 min treatment. In addition, the patients were asked to answer 2 questions about which modality they would use in the future for pain control and the level of comfort of each modality during its application on a 5-point scale (1 = Very Unlikely or Very Uncomfortable and 5 = Very Likely or Very Comfortable). Finally, the patients were asked the following day whether they preferred ice or Biofreeze and which modality had a longer lasting effect.

Results: Overall, when asked to rate the comfort and preference, patients preferred Biofreeze 8 to 1 ($p < 0.001$). The average score on the 5 point Likert scale was 4.20 for Biofreeze and 2.57 for ice. In addition, 9 out of 10 subjects reported that Biofreeze lasted longer ($p < 0.001$). For actual levels of pain change, the

average pre-treatment VAS score went from 6.24 to 3.65 for Biofreeze and from 6.31 to 5.00 for ice. A paired t-test demonstrated that both ice and Biofreeze gave a significant reduction on pain levels ($p < 0.001$); however, there was nearly 2 times the reduction of pain on the Biofreeze side.

Conclusions: Both ice and Biofreeze significantly decreased pain levels; however, Biofreeze decreased pain nearly 2 times as much as ice. In addition, it was rated as substantially more comfortable, patients preferred it, and it lasted longer 9 out of 10 times. This is the first study to evaluate solely the immediate effects of two different cryotherapy methods and, as such, it is not unexpected that the results of this study would differ slightly from other published studies evaluating menthol products. Conservative care specialists are often looking for methods to improve patient satisfaction and compliance and with the results significantly favoring Biofreeze this is recommended as the primary method of cryotherapy application on the first visit.

Dose—response of spinal manipulation for low back pain: Short-term outcomes from a randomized trial[☆]

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Introduction: There is increasing evidence that suggests the efficacy of spinal manipulation for the treatment of chronic low back pain (LBP). Yet, there have been no large trials to determine optimal number of treatments with manipulation. Our pilot study suggested greater pain and disability improvement for higher doses of manipulation. The current study is the first full-scale randomized trial to evaluate optimal dose and efficacy of manipulation, while controlling attention bias, patient touch, and expectation associated with quantity of care.

Methods: 400 participants with chronic LBP were randomized to 4 doses ($n = 100$/group), using design adaptive allocation to balance baseline variables across groups. Participants were seen by one of 10 study chiropractors 18 times (3 times per week for 6 weeks). Patients received 0, 6, 12, or 18 sessions of spinal manipulation, and a light massage control on visits without manipulation. All patients received a hot pack and low intensity pulsed ultrasound at each visit.

The primary outcomes were the 100-point Modified Von Korff Pain and Disability Scales at 12 and 24 weeks. Secondary outcomes included days with pain and disability in the last four weeks, fear avoidance and SF12 physical and mental health component summaries. An intention-to-treat analysis was conducted using ANCOVA to identify linear dose effects (slope) adjusted for baseline differences between groups. Significance level was set for tests of four primary outcomes ($\hat{1} \pm .0125$). More sophisticated dose—response curve analysis will also be presented.

Results: The mean baseline pain was 67.3 (SD = 18.6), disability was 45 (SD = 22.8), days with LBP were 24.1 (SD = 5.1), and days with LBP-related disability were 6.8 (SD = 7.5). The overall mean pain and disability improvement for the sample was approximately 50% at 12 weeks and was sustained to 24 weeks. For the primary outcomes, the linear effects at 12 weeks were statistically significant and of modest magnitude favoring higher dose: pain slope = 2.7 points/group (95% CI = 1.0—4.5, $P = .002$) and disability slope = 2.3 points/group (95% CI = 0.6—4.0, $P = .009$). The linear effects were diminished at 24 weeks: pain slope = 1.2 points/group (95% CI = −0.5 to 3.0, $P = .176$) and disability slope = 1.4 points/group (95% CI = −0.3 to 3.2 to 4.5, $P = .114$). For the secondary outcomes, there were modest statistically significant linear effects for days with pain and disability at 12 weeks; the effect was sustainable to 24 weeks for days with pain. The SF12 physical component summery was statistically significant at 12 weeks. Meaningful linear effects were not found for other variables.

Conclusions: Modest linear dose—response effects favoring higher dose were found for pain and disability at 12 weeks. The linear effects were halved at 24 weeks.