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Spinal compression fractures: no additional pain relief with use of back braces

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ABSTRACT A critical appraisal and clinical application of Li M, Law SW, Cheng J, Kee HM, Wong MS. A comparison study on the efficacy of SpinoMed® and soft lumbar orthosis for osteoporotic vertebral fracture. *J. Prosthet. Orthot. Int.* 2015;39(4):270-276. doi: [10.1177/0309364614528204](https://doi.org/10.1177/0309364614528204)

Keywords: osteoporotic vertebral fracture, orthosis, lumbosacral spine compression fracture

Clinical Context

Our patient was a 76 year-old female with history of osteoarthritis (status post bilateral hip arthroplasty), osteoporosis, COPD, hypertension, and depression, who presented with a seven-day history of intractable back pain following a mechanical fall from standing height. She had multiple falls during the months preceding her admission, and occasionally used a walker or cane for ambulation. She had no cognitive impairments, and prior to the onset of the pain, she conducted all of her instrumental activities of daily living independently. The patient was admitted to our inpatient medicine service and diagnosed by CT scan with compression fractures of the T11 and T12 vertebrae. Correlating the radiographic evidence with the physical exam findings, we determined this to be an acute compression fracture. The orthopedist ordered a rigid brace for spine immobilization.

Clinical Question

Do lumbosacral orthoses provide pain relief in the setting of subacute spinal compression fractures?

Research Article

Li M, Law SW, Cheng J, Kee HM, Wong MS. A comparison study on the efficacy of SpinoMed® and soft lumbar orthosis for osteoporotic vertebral fracture. *J. Prosthet. Orthot. Int.* 2015;39(4):270-276. doi: [10.1177/0309364614528204](https://doi.org/10.1177/0309364614528204)

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Literature Review

The search began in Google Scholar using the terms “spinal compression fracture,” “back brace,” and “efficacy.” The topics of first five returned papers concerned the results of kyphoplasty. The first paper related to non-operative management was a review article; the authors mentioned spinal bracing in one sentence without referencing a source for the statement.¹ Further searching resulted in another review article on non-operative management of osteoporotic vertebral fractures (OVF).² This article included photographic images of different types of braces. Because it was a non-systematic review, the search continued using the same terms in PubMed. References from an NIH non-systematic review³ were searched to locate clinical research appropriate to the clinical question. The only relevant reference from that paper described a research article on osteoporosis, but not specifically on acute fracture, making it less appropriate to answer the clinical question. Using the “see related” function, we identified a systematic review.⁴ This 2016 paper used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology, and commented that most studies were of poor quality: only three studies explored orthoses after acute osteoporotic vertebral fracture. The characteristics of these three studies were reviewed, and one study was chosen as most relevant and valid to the clinical question.⁵ This study was re-located in Google Scholar, and the related articles function was used. This revealed a relevant trial with only 13 cases, which was considered too small to add value.⁶ Keywords and MeSH were used to initiate a new PubMed search, using the search terms “orthosis vertebral fracture,” which resulted in another systematic review with meta-analysis.⁷ Only five papers were identified, one of which was previously identified by the prior systematic review. After review of the other papers, Li et al. was chosen for critical appraisal because the bracing technology was the latest version studied, and the paper included the most relevant patient-oriented outcomes (pain and Functional Independence Measure motor scores). Thus, this paper is consistent with the previously mentioned meta-analysis.

Critical Appraisal

The article reports that soft lumbar orthoses and SpinoMed® groups both had improvement in pain scores, but there was no statistical significance between the groups. The level of evidence, according to the Oxford Centre for Evidence Based Medicine Levels of Evidence classification, is 2b (low quality randomized controlled trial). Although the authors claim the patients were randomized to groups, it cannot definitively be determined whether or not the assignment of patients to treatment with SpinoMed® versus soft lumbar orthosis was truly randomized, as the method of randomization was not discussed.

The main outcome measure was the Oswestry Disability Index (ODI) score. We reviewed this measure, and all ten subscales included robust assessments of pain, making this measure relevant to our clinical question.⁸ The study patients were similar to our own. Being a female, age 76, with back pain secondary to osteoporotic vertebral fractures of the T11 and T12 vertebrae, our patient met all of the study inclusion criteria of: “female, age 55 or above, clinical diagnosis of OVF with radiographs, back pain secondary to OVF, and affected vertebra between T1 and L5”.⁵ When comparing SpinoMed® and soft lumbar orthosis, statistically significant improvements were observed for all three groups (hard brace, soft brace, and no brace) between pretreatment and post-treatment for pain. However, investigators were unable to prove a statistically significant difference between the groups. Because there was no difference between the groups compared, a NNT cannot be calculated.

The use of the SpinoMed® orthosis as described in this study is not entirely feasible in our practice. Specifically, patients cannot be closely monitored for compliance as they were in the study. Lumbosacral spinal bracing is available to patients in our hospital. However, there are different commercial types of braces available, meaning the argument for benefit must be a “class effect.” The patients were analyzed in the groups to which they were randomized, including SpinoMed® (treatment) group and soft lumbar orthosis (control group). It was not explicitly stated whether all of the original patients who entered the study were accounted for at the conclusion via post-treatment assessments. The patients and physical therapists were not, and could not have been, blinded, given the visibility of the difference between the treatment and control interventions. It was not mentioned whether the authors and other data collectors were blinded.

Aside from the experimental intervention, there are a couple of ways in which the groups may not have been treated equally. For instance, it is not known whether the three groups received identical or similar physical therapy, what additional modalities they may have been using for pain relief (other than opioids), and what level of activity in which they engaged at home. Furthermore, though it was mentioned that the SpinoMed® group wore the orthosis for three hours during physical therapy, there was no mention of how long the control group subjects wore the soft lumbar orthosis. Although the authors state that patients were closely



monitored, the results section contains no metrics related to adherence. Finally, the authors do not report sufficient detail to determine the intensity of follow-up or utilization time across the SpinoMed® and soft lumbar orthosis groups.

Clinical Application

While the medical team considered treatment options, the orthopedic surgeon ordered a hard orthosis. It was subsequently delivered to the bedside. After attempts to wear the brace, the patient decided it was too cumbersome. The patient's daughter commented that it was not a practical therapy for her mother and requested the hard orthosis be removed. Subsequently, the patient was found in bed wearing a soft lumbosacral orthosis. When asked if it was helpful, she replied, "Oh yes, the pain is better and now I can sit up." Given the data in the article reviewed, there is no way to infer a cause and effect relationship between the soft brace and pain relief.

Take Home Points:

- 1.) It is important to ask patients whether or not they think they can put on and remove the orthosis and perform their daily activities comfortably while wearing it.
- 2.) It would be helpful to allow patients to try on the device prior to it being prescribed.
- 3.) The decision whether or not to prescribe a brace should be guided by shared decision-making regarding the feasibility of using the device.

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