

## Protocol for Systematic Review of Spinal Orthoses for Vertebral Osteoporosis

### Introduction

Osteoporosis and vertebral fracture have a considerable negative impact on an individual's health related quality of life due to pain and fatigue, limitations in activity and social participation and altered mood.<sup>1</sup> Chronic back pain and limitations in daily activity often develop insidiously as a result of vertebral fractures and quality of life declines progressively as the number of vertebral fractures increases.<sup>2</sup> Vertebral fractures are most common at the thoracolumbar junction (T11-L1) followed by the mid-thoracic region and are closely related to increased thoracic kyphosis.<sup>3</sup> In turn, thoracic kyphosis with a loss of lumbar lordosis (hyper-kyphotic posture) is linked to increased loading on the anterior vertebral column and back extensor muscle weakness with a significantly increased risk of further fracture, most commonly anterior vertebral wedge or compression fracture.<sup>4,5</sup> Hyper-kyphosis is also associated with back pain and fatigue, reduced respiratory function and gait and balance disturbances as the centre of gravity is displaced anteriorly, closer to the limits of stability with a subsequent increased risk of falls and fractures as a result of falling.<sup>5,6</sup>

The optimal conservative management for people with vertebral osteoporosis and vertebral osteoporotic fracture is not known.<sup>3,7,8</sup> Besides medication a range of interventions are often used in combination including; exercise therapies, postural training and spinal orthoses or braces.<sup>2,7,9</sup> Spinal orthoses are a traditional treatment option for vertebral osteoporosis and thoracolumbar vertebral fracture and have been widely prescribed.<sup>2,7,9</sup> An orthosis is thought to reduce axial load or compression forces on the anterior spinal column and fractured vertebral body.<sup>3,7,9,10</sup> The goals of using an orthosis may vary according to clinical presentation but often overlap or enhance one another.<sup>11</sup> In the acute stage after fracture orthotic treatment aims to relieve pain and back muscle spasm and to stabilize the spine in order to promote fracture healing in a good alignment while allowing the individual to mobilise.<sup>3,7,12</sup> In the rehabilitation of chronic pain and dysfunction due to vertebral osteoporosis with or without fractures orthotics can be prescribed to relieve pain and fatigue but also to reduce excess kyphosis and improve standing posture.<sup>5,11,13</sup> In turn this aims

to facilitate back extensor muscle activity to increase strength, to improve balance, reducing the risk of falls and promoting function.<sup>5 11 13 14</sup>

### **Description of the Intervention**

A rigid orthosis is most likely to be used in the acute phase. Rigid thoracolumbar orthoses are made of metal and thermoplastics and often employ three point pressure systems; two anterior and one posterior pad together with a strap, to decrease trunk flexion and promote a more neutral thoracic and lumbar spinal alignment.<sup>7 10</sup> These orthoses are often known as hyperextension or 3-point braces; the Jewett, medi 3C, Taylor brace and cruciform anterior spinal hyperextension (CASH) orthoses are good examples.<sup>10 15</sup> Thoracolumbosacral orthoses (TLSOs) extend further and typically consist of rigid thermoplastic custom-moulded anterior and posterior shells secured by velcro straps and may be used especially for more severe or multiple fractures.<sup>12</sup> Rigid orthosis are commonly worn for 6 to 8 weeks and then slowly withdrawn.<sup>7 9 10</sup>

Whether rigid orthoses are effective is uncertain as most studies have been completed in non-osteoporotic populations.<sup>12</sup> A systematic review by Giele et al (2009) of bracing in the management of traumatic thoracolumbar fractures found no evidence for effectiveness but only retrospective studies are included and the lack of quality evidence is noted.<sup>16</sup> In contrast a prospective RCT by Stadhouders et al (2009) which grouped participants by fracture type found better outcomes in terms of pain and function for those with traumatic spinal compression fractures (n=108) treated with a rigid 3 point brace and physical therapy compared to casting or physical therapy alone.<sup>17</sup> Murata et al 2012 in a prospective observational study of 55 people with acute osteoporotic fracture suggest use of a rigid TLSO is associated with fracture healing and significant pain relief at 6 months for the majority of patients.<sup>12</sup> Here the lack of a control group is a significant limitation.

Semi-rigid orthoses are used for both for acute and longer term treatment.<sup>5 13 18</sup>

Traditional semi-rigid orthoses include various corset type orthoses made of fabric with or without elasticated panels, posterior paravertebral bars which may be shaped and shoulder straps<sup>10 18</sup> They may reduce axial load on the osteoporotic spine through increasing intra-abdominal pressure and can provide increased proprioceptive

input about posture in all directions.<sup>10</sup> Alternative semi-rigid orthoses include the Spinomed and Spinomed active orthoses<sup>13</sup> The Spinomed consists of a lightweight padded metallic back pad which can be moulded by hand to be in contact with the spine and a system of shoulder straps and pelvic belt (3 point system) that allows it to create an extension moment. It is worn like a backpack. The Spinomed active orthosis incorporates the posterior metal pad into a body suit in a pocket on the back of the garment. Tensile elements included within the elastic fabric of the suit substitute for straps and belt. Randomised controlled trials by the group that developed the Spinomed orthoses report good compliance and improvements in back extensor muscle strength, posture, pain and function after 6 months wear.<sup>13</sup> But a recent pilot RCT questions whether the Spinomed orthosis is more effective than a lumbar corset.<sup>18</sup>

Advances in fabrication have seen the introduction of other, more dynamic orthoses. The Osteo-Med orthosis (Osteomed, Thaemert Ltd, Germany) is the prime example. Here a bodysuit is combined with air sacs on the outside of the suit over the lumbosacral and thoracic areas<sup>11</sup> The suit provides proprioceptive feedback about posture in all directions and the air sacs are filled to 75% of capacity so that when the person moves the air is displaced and the orthosis provides further sensory stimulation and potential massage like effects. These orthoses may aid postural re-training and randomised controlled trials have reported positive effects on quality of life, back muscle strength and gait stability<sup>11 19 20</sup>

A final group of orthoses designed for vertebral osteoporosis are the weighted kypho-orthoses (WKO) or 'backpack' type orthoses e.g.; the posture training support (PTS)<sup>10 14 21 22</sup> These orthoses suspend a light weight exactly below the level of the inferior angle of the scapula, thereby creating an extension moment to counteract the excess flexion of the hyper-kyphotic spine, and increasing proprioceptive input about spinal alignment and posture.<sup>10 14 21 22</sup> Studies of WKO report improvements in balance and muscle strength but only include small numbers of women and most investigate the use of a WKO together with an exercise programme.<sup>14 22</sup>

Limitations of spinal orthoses are recognised in the literature but detailed information about complications is not always reported.<sup>7,9,22</sup> Orthoses can be heavy, hot and uncomfortable, difficult to don and doff and look unappealing all of which can lead to poor compliance and efficacy.<sup>10,22</sup> Care needs to be taken not to restrict respiration and they can pose risks to skin integrity especially if closely fitting and for frail individuals.<sup>7</sup> Rigid orthoses may be unsuitable for long term use, due to the risk of further atrophy of off-loaded back extensor muscles with subsequent increased risk of future fractures.<sup>2,9</sup> However both the degree to which the spine is stabilised and extensor muscle activity is reduced is debated<sup>7</sup> and rigid orthoses might be better tolerated, with fewer complications than other interventions for managing acute vertebral fracture such as casting.<sup>17</sup> Better compliance is reported in some studies of less invasive and more flexible orthoses such as the Spinomed and WKO.<sup>13,22</sup>

Despite their widespread use relatively few high quality clinical studies examine the efficacy of the available orthoses. Guidelines and review articles describe orthotic interventions as part of the package of conservative management options for vertebral osteoporosis. Recommendations vary or are inconclusive, little appraisal of study quality occurs and newer and more dynamic orthoses are not discussed.<sup>2,7-9</sup> No current systematic review exists that is focused on orthotic care for people with vertebral osteoporosis with and without fractures.

### **Question**

The purpose of this systematic review is to investigate the effectiveness of spinal orthoses on physical functioning and quality of life for adults with vertebral osteoporosis with or without vertebral fractures.

### **Methods**

#### **Search Strategy**

From June 2014 to locate articles for the review one reviewer will complete a search of the following electronic databases; PubMed, EMBASE, AMED, CINAHL, PEDro (the physiotherapy evidence database) and the Cochrane library including CENTRAL (Cochrane register of controlled trials). A search of clinical trial registers via [www.controlled-trials.com/](http://www.controlled-trials.com/) will be completed. The electronic search will be

complemented with citation tracking and searches of the International Orthotics and Prosthetics journal will be completed for the past 5 years.

Terms related to the populations of interest will be searched and linked with the use of 'OR' e.g.; osteoporosis, thoracolumbar fracture etc. Terms related to the intervention both generally and specifically will be searched and linked with the use of 'OR' e.g.; rehabilitation, physiotherapy, conservative management, spinal orthoses, kypho-orthosis. It is recognised that using more general terms such as "osteoporosis" will access a wider range of studies, some of which will be irrelevant to the review e.g.; studies of rehabilitation following osteoporotic hip fracture, however it was felt that relevant studies could be missed if more restrictive population terms were used.

The searches will be restricted to title, abstract and keywords except where indexed (MeSH) terms are employed. No language restrictions will be used as it is recognised that publications related to osteoporosis orthotic care are likely to be within non-English literature. A conservative date limit will be set to recognise the change in clinical practice and fabrication of spinal orthoses over time in order that the review reflects more current practice but does not fail to capture relevant material. Articles published before 1995 will not be included. Using the term AND the first and second searches will be combined. The result will be limited to adult human studies when possible. See Appendix 1 for the exact search syntax.

### **Selection**

#### Population

Studies of men and women with a confirmed diagnosis of primary osteoporosis or osteopenia that affects the vertebral column will be eligible. Those with and without osteoporotic vertebral fractures will be included. Those younger than 16 years and adults with osteoporosis secondary to any other condition e.g.; rheumatoid arthritis, malignancy, renal disease will be excluded. Those with spinal fractures due to trauma will be excluded. As osteoporosis is a systemic disease it is recognised that participants are likely to have low bone mass in other areas or a history of other fragility fractures e.g. fractured neck of femur. However, the purpose of this review is to examine the use of spinal orthoses so studies will be excluded where the primary

focus and population is osteoporosis and other types of fragility fracture e.g.; hip or wrist fracture or the provision of other types of orthoses e.g. hip protectors.

### Types of studies

It is recognised that in this area well conducted randomised controlled trials may be scarce. Consequently Class I studies: randomised controlled trials (RCT's) and pilot RCT's of orthotic interventions for vertebral osteoporosis and Class II studies: controlled clinical trials without true randomisation and observational studies with prospective control groups will be included e.g.; case controlled studies.

Observational studies without control groups: cross-sectional studies, before and after repeated measures studies, retrospective studies, case series, single case reports and expert opinion studies will not be included. Quality assessments will reflect the different study designs and study synthesis will be stratified by both design and quality. The review will only include RCT's of high quality in any statistical meta-analysis.

### Intervention

The intervention of interest is the use of spinal orthoses for people with osteoporosis. To be included the aims of the study must include to prescribe a spinal orthosis and to measure the effects of this treatment. The orthosis must be designed to apply or remove forces over the thorax, the thoracolumbar or lumbosacral regions with the aim of affecting at least one of the outcomes of interest, namely fracture consolidation, pain, posture, back muscle strength, physical function, health-related quality of life or participation. All forms of spinal orthoses will be eligible i.e.; both customised and 'off the shelf' orthoses, made from any material. The orthoses may be prescribed and worn in a variety of settings e.g.; the community, hospital or at home. Studies where spinal orthoses are applied for a single sessions and programmes of orthotic wear of any length, frequency and duration will both be included. Studies which compare these orthotic interventions against a control condition, which compare one spinal orthosis with another or compare one dose of orthotic wear with a different dose of the same orthosis, will all be included. Interventions that combine orthotic prescription with other rehabilitation approaches where all participants (both those in the intervention and control group) receive the background rehabilitation will be

included e.g.; exercise training plus orthotic prescription compared to exercise training alone.

Studies in which participants are prescribed a spinal orthosis following trauma or surgical interventions e.g.; vertebroplasty or kyphoplasty will be excluded. Other interventions for osteoporosis or vertebral osteoporotic fracture that do not include spinal orthotic treatment will be excluded. This includes all kinds of spinal surgery and pharmacological treatments and studies whose primary purpose is to examine physical rehabilitation interventions such as exercise or manual therapy, hydrotherapy, tai chi, education, advice, psychological support or the use of electrotherapy treatments, including vibration therapy. Studies in which all participants (those in both the intervention and control group) have pharmacological treatments or have undergone surgery or physical rehabilitation will be included but studies which compare orthotic treatment with pharmacological treatments or surgery or physical rehabilitation only will not be eligible.

### Outcomes

The review is interested in the potential effect of spinal orthoses on people with osteoporosis at all levels of impairment, activity and participation. Relevant outcomes encompassing these areas will be eligible. The particular outcomes of interest are measures of body structure and impairment including: fracture consolidation, pain, spinal range of movement (ROM), spinal posture, muscle strength, balance, measures of physical activity and function e.g.; walking speed, activities of daily living (ADL's) and measures of participation e.g.; health related quality of life, social limitations. The review is also interested in collecting any information about adverse events and side effects e.g.; discomfort, pressure areas and interested in how acceptable people with osteoporosis find spinal orthoses in terms of aesthetics, tolerability and compliance as understanding the likely use of any prescribed device is important in any analysis of its potential benefit.

### Data collection and Risk of Bias Assessment

To track searches and document the flow of studies through the review investigators will use standardised proforma for search documentation and End Note. The exact search terms used in each database will be recorded. The retrieved studies will be

initially screened by title then abstract using a pre-determined eligibility checklist. If this does not provide sufficient information to decide eligibility and where potentially relevant studies are identified the full-length article will be retrieved for screening. Where eligibility remains unclear two reviewers (MN, KB) will independently review the full-length article and come to a consensus on inclusion through discussion. Where studies of interest are identified but data is missing or incomplete the authors of studies conducted in the past 10 years will be contacted by email to request further information. A 10 year cut off point was chosen pragmatically and in line with policies linked with data protection, recognising that older study data would be unlikely to be available.

### Data Extraction

Each reviewer (MN, CML) will independently extract information using separate, standardised pre-prepared forms. Data will be extracted about study design, participants, setting, type and dose of intervention, the comparator arm, the assessment schedule, measures used and study findings including compliance and any adverse events.

### Evaluation of Risk of Bias

The quality of each study will be assessed independently by two reviewers one of whom (CML) will be blinded to the article's author(s), affiliation(s), publication date, and journal. A domain based, risk of bias assessment approach will be adopted. Pre-prepared, data extraction forms will be developed based on the guidelines published by the Cochrane collaboration for assessing risk of bias in parallel group trials and following the PRISMA guidelines for good practice in conducting systematic reviews.<sup>23 24</sup>

For each study items relevant to its internal validity will be reviewed. Each item will be graded as 'adequate' (low risk of bias), 'inadequate' (high risk of bias) or 'unclear' (uncertain risk).<sup>23</sup> The direction of any potential bias detected (to under/overestimate results) will be compared with overall findings. Selection bias will be considered by assessing recruitment and allocation processes, including whether eligibility criteria were specified, and where relevant sequence generation and concealment of the



allocation sequence. For all studies the following areas will be reviewed; intervention integrity, blinding of participants, intervention providers and outcome assessment, completeness of outcome data and intention to treat analysis, data analysis including statistical methods, sample size considerations and any suggestion of unplanned analyses or selective reporting of outcomes.<sup>23-26</sup> Blinding of participants and intervention providers is not always feasible in a rehabilitation intervention and lack of blinding here will be rated as low risk. Blinding of outcome measurement is judged feasible and to recognize that the risk of bias due to lack of blinding will vary according to the measure; blinding of objective and subjective outcome measures will be considered independently i.e.; a measure of back muscle strength using a isokinetic dynamometer is thought less likely to be exposed to observer bias through unmasking than a clinician rating muscle strength. Studies will be checked for any other sources of bias and rated as free or at least one other source of bias present. This includes; were the measures used reliable and valid.

Any items which are judged differently by reviewers (MN, CML) will be discussed and initial disagreements will be resolved during consensus meetings. A third person will be available in the event of consensus not being reached (KB). In this review studies will be judged as high quality where all items are rated as low risk, judged as moderate quality where items are rated as low or unclear risk (when those of unclear risk are unlikely to alter study findings) and judged as low quality when they include any item rated as high risk.

### Data Synthesis and Analysis

Class I and class II studies will be considered separately in any data synthesis. Only Class I studies of high quality where the patient populations and orthotic care provided are significantly homogenous will be included in any explanatory meta-analysis. If a meta-analysis is conducted a fixed effect model will be used and heterogeneity will be investigated ( $I^2$ ). A funnel plot will be used to investigate publication bias.

It is more likely that the review retrieves studies of varied orthotic devices, involving different patient populations e.g.; those immediately post fracture, those undergoing longer term rehabilitation. In this case a narrative or descriptive synthesis is planned.

**Reference:**

1. Bruyere O, C.D. C, R. D, Reginster J. Bone mineral density and health related quality of life: a 3 year follow-up study of osteoporotic postmenopausal women. *The Open Geriatric Medicine Journal* 2009;2.:44-52.
2. Francis RM, Aspray TJ, Hide G, A.M. S, Wilkinson P. Back pain in osteoporotic vertebral fractures. *Osteoporosis International* 2008;19:895-903.
3. Kim DH, Vaccaro AR. Osteoporotic compression fractures of the spine; current options and considerations for treatment *The Spine Journal* 2006;6:479-87.
4. Huang M-H, Barrett-Connor E, Greendale G, Kado D. Hyperkyphotic posture and risk of future osteoporotic fractures: The Rancho Bernado Study. *Journal of Bone and Mineral Research* 2006;21:419-23.
5. Valentin GH, Nymann Pedersen L, Maribo T. Wearing an active spinal orthosis improves back extensor strength in women with osteoporotic vertebral fractures. *Prosthetics and orthotics international* 2014;38(3):232-38.
6. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength. *Osteoporosis international* : 2005;16(8):1004-10.
7. Longo UG, Loppini M, Denaro L, Maffulli N, Denaro V. Conservative management of patients with an osteoporotic vertebral fracture: A review of the literature. *Journal of Bone & Joint Surgery, British Volume* 2012;94(2):152-58.
8. Esses SI, McGuire R, Jenkins J, Finkelstein JS, Woodard E, Watters WC, et al. American Academy of Orthopaedic Surgeons Clinical Practice Guideline on The Treatment of Osteoporotic Spinal Compression Fractures. *Journal of Bone and Joint Surgery America* 2011;93:1934-6.
9. Bonaiuti D, Arioli G, Diana G, Franchignoni F, Giustini A, Monticone M, et al. SIMFER Rehabilitation treatment guidelines in postmenopausal and senile osteoporosis. *Eura Medicophys* 2005;41(4):315-37.
10. Meade KP, Malas BS, Patwardhan AG, Gavin TM. Orthoses for Osteoporosis. In: Hsu AT, editor. *AAOS Atlas of Orthoses and Assistive Devices*. Fourth Edition ed. Philadelphia: Mosby Elsevier, 2008:155-63.
11. Vogt L, Hubscher M, Brettmann K, Banzer W, Fink M. Postural correction by osteoporosis orthosis (Osteo-med): a randomized, placebo-controlled trial. *Prosthetics and orthotics international* 2008;32(1):103-10.
12. Murata K, Watanabe G, Kawaguchi S, Kanaya K, Horigome K, Yajima H, et al. Union rates and prognostic variables of osteoporotic vertebral fractures treated with a rigid external support. *Journal of neurosurgery. Spine* 2012;17(5):469-75.
13. Pfeifer M, Kohlwey L, Begerow B, Minne HW. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis. *American Journal of Physical Medicine and Rehabilitation* 2011;90(10):805-15.
14. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Significant reduction in risk of falls and back pain in osteoporotic-kyphotic women through a Spinal Proprioceptive Extension Exercise Dynamic (SPEED) program. *Mayo Clinic proceedings* 2005;80(7):849-55.
15. Denaro V, Longo UG, Denaro L. Vertebroplasty versus conservative treatment for vertebral fractures... *Lancet*. 2010 Sep 25;376(9746):1085-92. *Lancet* 2010;376(9758):2071-73.

16. Giele BM, Wiertsema SH, Beelen A, van der Schaaf M, Lucas C, Been HD, et al. No evidence for the effectiveness of bracing in patients with thoracolumbar fractures  
A systematic review. *Acta Orthopaedica* 2009;80(2):226-32.
17. Stadhouders A, Buskens E, Vergroesen DA, Fidler MW, de Nies F, Oner FC. Nonoperative Treatment of Thoracic and Lumbar Spine Fractures: A Prospective Randomized Study of Different Treatment Options. *Journal of orthopaedic trauma* 2009;23:588-94.
18. Li M, Law SW, Cheng J, Ho-man K, Wong MS. A comparison study on the efficacy of Spinomed and soft lumbar orthosis for osteoporotic vertebral fracture. *Prosthetics and orthotics international* 2014:1-7.
19. Hubscher M, Schmidt K, Fink M, Vogt L, Banzer W. [Prospective evaluation of the effects of a spinal orthosis on physical function and quality of life in women with osteoporosis] [German] Prospektive Evaluation funktions- und lebensqualitätsbezogener Effekte einer Wirbelsäulenorthese bei Frauen mit Osteoporose. *Zeitschrift für Orthopädie und Unfallchirurgie* 2010;148(4):443-47.
20. Schmidt K, Hubscher M, Vogt L, Klinkmüller U, Hildebrandt HD, Fink M, et al. [Influence of spinal orthosis on gait and physical functioning in women with postmenopausal osteoporosis]. *Der Orthopäde* 2012;41(3):200-5.
21. Ishida H, Watanabe S, Yanagawa H, Kawasaki M, Kobayashi Y, Amano Y. Immediate effects of a rucksack type orthosis on the elderly with decrease lumbar lordosis during standing and walking. *Electromyography Clinical Neurophysiology* 2008;48:53-61.
22. Kaplan RS, Sinaki M, Hameister MD. Effect of back supports on back strength in patients with osteoporosis: a pilot study. *Mayo Clinic proceedings* 1996;71(3):235-41.
23. Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions*. West Sussex, England: Wiley- Blackwell, 2008.
24. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, J.P.A. I, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration *BMJ (Online)* 2009;339(b2700).
25. Egger M, Smith GD, Altman D, editors. *Systematic Reviews in Health Care: Meta-analysis in context*. Second edition ed. London: BMJ Publishing Group, 2001.
26. Schulz K, Altman D, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *Annals Internal Medicine* 2010;152.