Authors:

Michael Pfeifer, MD
Lisa Kohlwey, MS
Bettina Begerow, PhD
Helmut W. Minne, MD

Affiliations:

From the Institute of Clinical Osteology "Gustav Pommer" and Clinic "DER FÜRSTENHOF," Bad Pyrmont, Germany.

Correspondence:

All correspondence and requests for reprints should be addressed to: Michael Pfeifer, MD, Institute of Clinical Osteology, Am Hylligen Born 7, 31812 Bad Pyrmont, Germany.

Disclosures:

Funded by "medi Inc, Bayreuth, Germany," which also provided the orthoses used in this clinical trial. However, "medi Inc" had no control over the decision to approve or submit the manuscript for publication. Presented, in part, at the 27th annual meeting of the American Society for Bone and Mineral Research (ASBMR) in Montreal, Quebec, Canada, in September 2008 and at the 36th European Symposium on Calcified Tissues (ECTS) in Vienna, Austria in May 2009. Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

0894-9115/11/9010-0805/0
American Journal of Physical Medicine & Rehabilitation

DOI: 10.1097/PHM.0b013e31821f6df3

ORIGINAL RESEARCH ARTICLE

Effects of Two Newly Developed Spinal Orthoses on Trunk Muscle Strength, Posture, and Quality-of-Life in Women with Postmenopausal Osteoporosis

A Randomized Trial

ABSTRACT

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: a randomized trial. Am J Phys Med Rehabil 2011;90:805–815.

Objectives: We conducted a prospective randomized study to evaluate the efficacy of two newly developed spinal orthoses in patients with vertebral fractures.

Design: We conducted a prospective, randomized, cross-over study to evaluate the efficacy of two newly developed spinal orthoses in patients with osteoporotic vertebral fractures. Measurements include trunk muscle strength, angle of kyphosis, body height, body sway, and parameters of quality-of-life such as pain, well-being, and limitations of daily living.

Results: Wearing the orthosis Spinomed during a 6-mo period (results of Spinomed active are given in parentheses) was associated with a 72% (64%) increase in back extensor strength ($P < 0.01$), a 44% (56%) increase in abdominal flexor strength ($P < 0.01$), an 11% (11%) decrease in the angle of kyphosis ($P < 0.01$), a 23% (20%) decrease in body sway ($P = 0.03$ and $P = 0.02$), a 19% (18%) increase in vital capacity ($P < 0.01$ and $P = 0.03$), a 41% (47%) decrease in average pain ($P < 0.01$), an 18% (18%) increase in well-being ($P < 0.01$), and a 49% (54%) decrease in limitations of daily living ($P < 0.01$), respectively. The overall tolerability of the orthoses was good; no adverse effects were reported and the dropout rate with 7% was rather low.

Conclusions: The use of an orthosis increases trunk muscle strength and therefore improves posture in patients with vertebral fractures caused by osteoporosis. In addition, a better quality-of-life is achieved by pain reduction, decreased limitations of daily living, and improved well-being. Thereby, the use of an orthosis may represent an efficacious nonpharmacologic treatment option for spinal osteoporosis.

Key Words: Osteoporosis, Vertebral Fractures, Spinal Orthosis, Trunk Muscle Strength, Quality-of-Life, Body Sway

The incidence of vertebral fractures caused by osteoporosis is rapidly rising with aging in both sexes.[1] One-fourth of women 50 yrs or older in the general population have one or more vertebral fractures resulting in loss of height and increased kyphosis.[2] Kyphotic postural change is the most physically disfiguring and psychologically damaging effect of osteoporosis and can contribute to an increased risk of vertebral fractures and of falling.[3] In addition, spinal osteoporosis may be associated with reduced pulmonary function,[4] chronic pain for several years,[5] limitations in everyday life,[6] and emotional problems related to appearance.[7]

Therapeutic interventions with proven efficacy include various bisphosphonates,[8–11] raloxifene,[12] and parathyroid hormone (teriparatide),[13] which improve bone quality.[14] These therapeutics, however, only prevent approximately 50% of spinal fractures.[14] In addition, there is a need to improve back muscle strength because muscle atrophy parallels the decline of bone mineral density of the spine[15] and contributes significantly to kyphotic postural changes.[16] The multidisciplinary rehabilitation concept of spinal osteoporosis, therefore, includes back-strengthening exercises to counteract thoracic kyphosis in hyperkyphotic subjects.[17]

Traditionally, spinal orthoses have been used in the management of thoracolumbar injuries treated with or without surgical stabilization. Most orthoses, however, is used in patients with low back pain.[18] In the United States alone, more than 250,000 corsets are prescribed each year.[19] We have not been able to find any reports in the literature of these orthoses having never been tested under standardized conditions. Especially, no reports of prospective, randomized controlled clinical trials are available to document efficacy according to the criteria of evidence-based medicine. This is also the case for osteoporosis, where approximately one-fourth of women 50 yrs or older have one or more vertebral fractures.[20] The orthotic treatment modality in the management of vertebral fractures caused by osteoporosis remains subjective because to our knowledge, no objective data are available on the effectiveness of orthoses in stabilizing osteoporotic vertebral fractures.[21] Furthermore, the use of rigid thoracolumbar braces in osteoporosis is limited by factors such as the atrophy of trunk muscles and restricted respiration leading to low compliances.[22]

Therefore, a new orthosis was developed, especially taking into account the needs of patients withvertebral osteoporosis. In a preliminary pilot study, we have shown that this orthosis may improve trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis.[23] Now, we further developed our concept and we would like to investigate the efficacy of two completely new designed orthotic devices.

METHODS

Study Participants

We studied ambulatory, community-dwelling women 60 yrs or older who were recruited through newspaper advertisements. The inclusion criteria were at least one clinical vertebral fracture caused by osteoporosis within the last 6 mos and an angle of kyphosis above 60 degrees as measured using stereo-photomorphometry. Exclusion criteria were disorders affecting bone mineral metabolism (e.g., renal disease, hyperthyroidism, primary hyperparathyroidism, hypercortisolism, and osteomalacia) and severe degenerative diseases of the spine such as osteoarthritis, scoliosis, and malignancies.

Initially, 1386 interested subjects were prescreened through a standardized telephone interview. Fifty-five percent (763 subjects) were invited to a screening visit at our clinic. Three hundred twenty-two subjects were excluded because of abnormal laboratory findings, suggesting secondary osteoporosis, and another 115 potential participants were excluded because the date of their vertebral fracture(s) could not be determined. Finally, 108 subjects were included and evaluated using isometric back extensor strength, body sway, angles of thoracic kyphosis, pulmonary function, vertebral fractures, and quality-of-life at baseline and at 3, 6, 9, and 12 mos, respectively (Fig. 1).

Evaluation

At study entry, we assessed the subjects' medical history, including the circumstances and dates of the diagnosis, number and severity of falls within the previous 2 yrs, and the first bone densitometry test, and we performed radiography to identify or confirm the fractures of the spine. We performed an extensive physical examination of the spine and whole body as well as routine laboratory tests to exclude secondary osteoporosis. In addition, we recorded concurrent and earlier medication, use of analgesics, dietary habits including alcohol consumption and nicotine use, previous diseases associated with immobilization phases, and family history.

We calculated the loss of body height as the difference between body height at the age of 25 yrs,

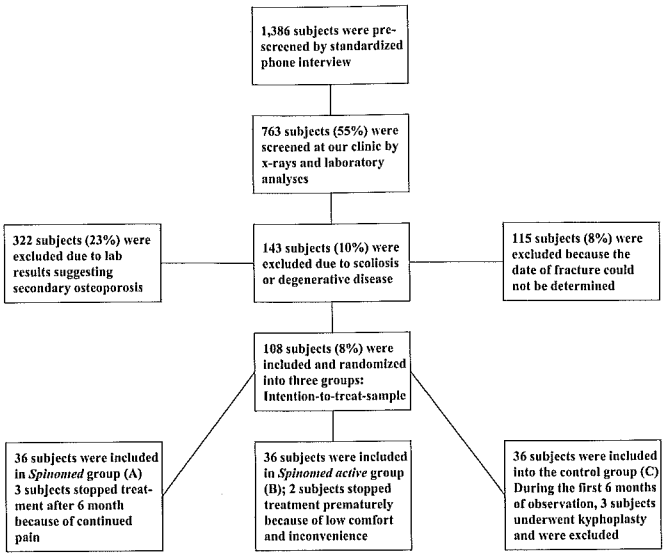

FIGURE 1 *Flowchart describing screening and randomization process. Initially, 1,386 interested subjects were prescreened by a standardized telephone interview. Fifty-five percent (763 subjects) were invited to a screening visit at our clinic. Three hundred twenty-two subjects were excluded because of abnormal laboratory findings, suggesting secondary osteoporosis and another 115 potential participants were excluded because the date of their vertebral fracture(s) could not be determined. Finally, 108 subjects were included and randomized into three groups: Group A started wearing Spinomed from baseline until month 12. Group B also began wearing Spinomed active from baseline until month 12. Group C served as the control group from baseline to month 6 and started wearing Spinomed thereafter.*

as documented in the subjects' passports, and the current measured height, which we determined using a stadiometer under standardized conditions between 8:00 and 9:00 a.m.

We selected a change in isometric back extensor strength as a primary endpoint of the study. Secondary endpoints included isometric abdominal flexor strength, body height, angle of kyphosis, body sway, lung function as determined by vital capacity, and parameters of quality-of-life assessed using questionnaires such as pain, limitations of daily life, and well-being.

Measurements

We determined the isometric maximum strength of trunk muscles on subjects sitting in a standardized position with the angles of knee and hip at 90 degrees, with the pelvis fixed using a seatbelt (Digi-Max, mechaTronic, Germany).[24] For assessment of back extensor strength, we requested the subjects to press the upper part of their body against the fixed pad in the back of the measurement chair (isometric maximal back extensor strength). We measured maximal abdominal flexor strength in the same position with the subjects pressing forward against a fixed pad. Afterward, we determined strength electronically using a pressure gauge. We performed three measurements each and we included the highest value in the analysis. The coefficients of variance were 2.2% for back extensor strength and 2.4% for abdominal flexor strength, respectively.[24]

We measured body sway using a sway meter recording displacements of the body at waist level in 30-sec periods.[25] The device consists of a rod attached to the subject at waist level by a firm belt and a digitizing tableau on an adjustable height table which is positioned behind the subject. The rod is 40 cm in length and extends behind the subject. We adjusted the height of the table so that the rod is on a horizontal plane and the tip of a pen can draw the movements of the subject via the digitizing tableau to a computerized system. We recorded the displacements of the body in the frontal and sagittal directions to measure total path length (sway distance), and to calculate mean sway velocity. Both parameters have been shown to predict the risk for falls and fall-related fractures.[26] In our trial, the coefficients of variance were 1.6% (sway distance) and 1.8% (sway velocity).[27]

The angles of thoracic kyphosis were quantified via three-dimensional photomorphometry of the back while the subject was standing in a standardized position at a defined distance from a computerized camera (Jenoptik Co., Germany).[5] The coefficients of variation were 1.7% for intraobserver and 1.9% for interobserver variability.[5]

We estimated pulmonary function by measuring expiratory relaxed vital capacity and the forced expiratory volume in 1 sec (microlab; Heiland Co., Germany).[4] The coefficients of variation were 2.3% for intraobserver and 2.1% for interobserver variability.[4]

We verified all vertebral fractures using spinal x-rays. A fracture was defined as a height reduction of a vertebra of more than 20% at any site or at least 4 mm, according to Food and Drug Administration guidelines. In addition, a semiquantitative visual approach described by Genant et al.[28] was used to identify vertebral fractures. All assessments were carried out by an experienced radiologist.[29] The differences in magnification were avoided using a constant film-focus distance of 115 cm.

We collected data on various aspects affecting the quality-of-life using questionnaires. Limitations in everyday life we assessed using a questionnaire developed by Leidig-Bruckner et al.[6] This measure has been validated for patients with osteoporosis and has been shown to be reliable for this sample of patients. The questionnaire provides a disability score based on six items dealing with motion in general and a score on impairment of self-care, also handling six items (see "APPENDIX").

We judged the perception of average pain using Miltner's rating scale, which had been developed within a German-speaking environment and had been proven to be reliable for osteoporosis.[5] The score is easy to apply and independent of age.[5] The patients were requested to mark their intensity of perceived pain on a scale rated from 1 to 4 whereby 1 indicates low; 2, moderate; 3, severe; and 4, very severe pain.[5]

We assessed the patients' well-being using the well-being scale devised by Begerow et al.[5] (see "APPENDIX"). We selected this scale because it had been developed and validated within the German-speaking area and has been shown to be reliable. The scale consists of 16 opposing pairs of adjectives that characterize actual states and moods but not personality traits. The patients were requested to select the mood they felt best described themselves out of seven gradations, of which the two opposites are at either end of the scale. Scores may range from 16 to 112, with a higher score indicating a higher degree of well-being. Normal values from a representative population were available (mean, 98.8 ± 20.5 for the total scale).[5]

Intervention

After the initial evaluation, the subjects were randomized into three groups: Group A started wearing Spinomed from baseline until month 12; Group B begun wearing Spinomed active also from baseline until month 12; and Group C served as control from baseline to month 6 and started wearing Spinomed thereafter (Fig. 1). We asked the subjects to wear the orthosis for approximately 2 hrs per day and to keep a diary to verify compliance. The protocol was approved by the responsible ethics committee, and written informed consent was obtained from each subject.

The randomization of study subjects was performed externally by a statistical consultant bureau (see "Statistical Analyses"). After completion of the first 6 mos, group C should be provided with the orthosis, whereas groups A and B should serve as controls. The beneficial course of the first intervention phase, however, led to the fact that the participants in groups A and B refused to stop wearing the orthosis.

Back Orthoses

We developed the thoracolumbar orthoses A and B ("Spinomed" and "Spinomed active") in cooperation with patients experiencing severe back pain caused by osteoporosis with vertebral fractures. Orthosis A consists of a supportive back rod, which is workable as a cold material and a system of belts with Velcros (Fig. 2 left). This allows adjustments for individual sizes by an experienced orthopaedic technician. Orthosis A weighs 450 g and is worn with a supportive back rod. Orthosis B looks like a so-called body suit, in which a supportive back rod will be inserted into a pocket sewed on the back of the body suit (Fig. 2 right). The system of belts is substituted by textile traction elements around the pelvis to fix the orthosis and around the shoulders to remind the patients to bring themselves in an upright position.

Statistical Analyses

Quality assurance was conducted by a statistical consultant bureau (Lazarescu Statistics, Bad Pyrmont, Germany). Statistical calculations were conducted using the statistical software of IDV (Gauting, Germany) using the Tesimate part of the program (Test & Estimation, version 5.2.). All study subjects, who were initially randomized and received an orthosis, had been included into the analysis (intention-to-treat analysis). To determine the sample size, we used the software package NCSS-PASS 1.0. We expected for our primary endpoint ("back extensor strength) a difference between groups A and C of 40%–60% of the standard deviation.[23] To

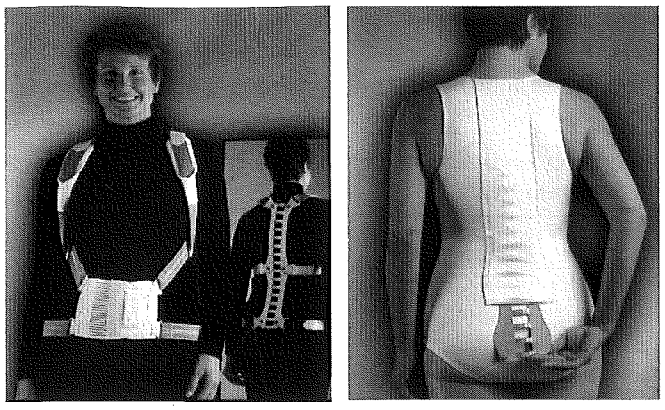

FIGURE 2 *The back orthosis Spinomed on the left consists of a supportive back rod, which is workable as a cold material and a system of belts with Velcros. This allows adjustments for individual sizes by an orthopedic technician. The orthosis weighs 450 g and is worn like a supportive back rod. The back orthosis Spinomed active on the right includes a supportive back pad, which is removable according to different daily activities. The system of belts is substituted by textile elements within this so-called "body suit" and thus allows wearing the orthosis completely invisible under clothes.*

prove a difference of 50% of the standard deviation with a power of 80%, 32 subjects per group were needed. Assuming a dropout rate of 10%, we included 36 subjects in each group. Thirty-five subjects in group A, 34 persons in group B, and 34 persons in group C completed 12 mos of the study and were included into the intention-to-treat analysis. We assumed a normal distribution to the pretreatment and posttreatment differences between groups A and C, B and C, as well as between groups A and B. In this case,

TABLE 1 Baseline clinical characteristics of the 108 study subjects

Characteristic	Value		
	Group A (n = 36)	Group B (n = 36)	Group C (n = 36)
Age, yrs	72.8 ± 7.1	72.3 ± 6.7	69.7 ± 8.9
Age range, yrs	61–86	60–81	60–83
Current height, mm	1566 ± 67	1588 ± 73	1562 ± 56
Loss of height, cm[a]	8.9 ± 5.0	7.6 ± 3.9	8.8 ± 3.5
Weight, kg	64.2 ± 10.4	64.3 ± 10.0	66.0 ± 12.0
Vertebral fractures, n[b]	2.0 ± 2.7	1.6 ± 2.8	2.1 ± 2.4
Nonvertebral fractures, n[c]	0.9 ± 1.1	1.0 ± 1.3	1.1 ± 1.2
Falls, n[d]	2.7 ± 1.5	2.8 ± 1.4	2.5 ± 1.3
Physical activity, %			
Daily	3	3	6
Weekly	48	42	40
Monthly	3	9	11
Sporadic	46	46	15
Concomitant diseases, n (%)			
Cardiovascular (mild hypertension)	14 (39)	12 (33)	15 (42)
Pulmonary (asthma)	3 (8)	1 (3)	1 (3)
Central nervous, neurologic	2 (6)	0 (0)	1 (3)
Musculoskeletal system (arthritis)	4 (11)	2 (6)	2 (3)
Concomitant medication, n (%)			
Benzodiazepine use	1 (3)	0 (0)	1 (3)
Thyroidtherapy for goiter	11 (31)	12 (33)	9 (25)
Cardiovascular drugs	14 (39)	12 (33)	13 (36)
Corticoids (inhalation only)	3 (8)	1 (3)	1 (3)

Values for age, height, loss of height, weight, fractures and falls are expressed as mean ± SD.

There was no statistically significant difference between any of the variables at baseline.

[a]Difference of the body height at the age of 25 yrs and measured current height.

[b]Number of vertebral fractures as assessed using x-rays according to Food and Drug Administration guidelines.

[c]Nonvertebral fractures were verified using x-rays or medical records.

[d]Falls within the previous 2 yrs as reported by study subjects.

a two-sided t test for independent samples was applied. If a significant deviation from normality was found, we used the Wilcoxon's test and the Mann-Whitney U test and set type I statistical error at 0.05. In addition, we performed Cox regression analyses providing a 95% confidence interval.

TABLE 2 Initial values of efficacy endpoints and changes at 6 mos in 108 study subjects, according to study group (intention-to-treat)

Index and Study Group	Initial Value	Change, Absolute Values (95%CI)
Back extensor strength, N		
Group A (intervention, n = 36)	260 ± 130	+189 ± 141 (RR[a] = 182; CI, 125.1–238.9; $P < 0.01$)
Group B (intervention, n = 36)	273 ± 112	+166 ± 120 (RR[a] = 175; CI, 137.4–212.3; $P < 0.01$)
Group C (observation, n = 36)	263 ± 122	+7 ± 55
Abdominal flexor strength, N		
Group A (intervention, n = 36)	161 ± 72	+94 ± 71 (RR[a] = 71; CI, 41.2–100.8; $P < 0.01$)
Group B (intervention, n = 36)	158 ± 73	+135 ± 83 (RR[a] = 89; CI, 63.4–115.7; $P < 0.01$)
Group C (observation, n = 36)	157 ± 66	+23 ± 46
Body height, mm		
Group A (intervention, n = 36)	1566 ± 67	+5.3 ± 6.3 (RR[a] = 5.7; CI, 2.93–8.47; $P < 0.01$)
Group B (intervention, n = 36)	1588 ± 73	+6.1 ± 5.0 (RR[a] = 6.0; CI, 3.08–8.95; $P < 0.01$)
Group C (observation, n = 36)	1562 ± 56	−0.4 ± 4.7
Angle of kyphosis, degrees[b]		
Group A (intervention, n = 36)	74.2 ± 9.8	−7.9 ± 4.9 (RR[a] = −6.3; CI, −3.71 to −8.89; $P < 0.01$)
Group B (intervention, n = 36)	72.7 ± 10.2	−8.1 ± 10.5 (RR[a] = −6.4; CI, −3.52 to −9.03; $P < 0.01$)
Group C (observation, n = 36)	70.8 ± 9.9	−1.6 ± 5.5
	Initial Value	**Change, Absolute Values (95%CI)**
Body sway path length, mm		
Group A (intervention, n = 36)	80.4 ± 31.2	−20.4 ± 40.2 (RR[a] = −18.7; CI, −37.6 to −3.2; $P = 0.03$)
Group B (intervention, n = 36)	78.7 ± 26.3	−17.2 ± 35.6 (RR[a] = −16.5; CI, −35.4 to −4.8; $P = 0.02$)
Group C (observation, n = 36)	77.9 ± 28.5	−1.6 ± 37.8
Body sway velocity, mm/sec		
Group A (intervention, n = 36)	16.4 ± 5.6	−5.9 ± 7.2 (RR[a] = −6.0; CI, −12.2 to −2.3; $P = 0.03$)
Group B (intervention, n = 36)	16.7 ± 7.1	−6.2 ± 7.4 (RR[a] = −5.6; CI, −12.5 to −2.9; $P = 0.02$)
Group C (observation, n = 36)	15.8 ± 6.3	−0.7 ± 6.8
Relaxed vital capacity, %		
Group A (intervention, n = 36)	82.6 ± 21.1	+6.1 ± 20.5 (RR[a] = 16.0; CI, 6.8–25.8; $P < 0.01$)
Group B (intervention, n = 36)	84.5 ± 19.2	+5.5 ± 13.1 (RR[a] = 14.3; CI, 7.3–11.4; $P = 0.03$)
Group C (observation, n = 36)	93.6 ± 17.0	−9.9 ± 16.1
FEV[b] in 1sec, %		
Group A (intervention, n = 36)	84.9 ± 22.2	+2.9 ± 13.5 (RR[a] = 6.7; CI, −0.7 to 14.1; $P = 0.04$)
Group B (intervention, n = 36)	87.3 ± 23.4	+3.1 ± 17.3 (RR[a] = 7.1; CI, −0.5 to 12.3; $P = 0.04$)
Group C (observation, n = 36)	94.4 ± 22.6	−3.8 ± 16.1
	Initial Value	**Change, Absolute Values (95%CI)**
Average pain, score-points		
Group A (intervention, n = 36)	3.9 ± 1.1	−1.5 ± 1.2 (RR[a] = −1.6; CI, −2.1 to −1.1; $P < 0.01$)
Group B (intervention, n = 36)	3.6 ± 1.2	−1.4 ± 1.1 (RR[a] = −1.7; CI, −2.2 to −1.2; $P < 0.01$)
Group C (observation, n = 36)	4.0 ± 1.0	+0.1 ± 0.9
LDL disability, score-points[c]		
Group A (intervention, n = 36)	4.7 ± 1.9	−2.1 ± 1.6 (RR[a] = −2.3; CI, −2.9 to −1.7; $P < 0.01$)
Group B (intervention; n = 36)	4.1 ± 1.7	−2.0 ± 1.5 (RR[a] = −2.2; CI, −2.8 to −1.5; $P < 0.01$)
Group C (observation, n = 36)	4.3 ± 1.6	+0.2 ± 0.8
LDL self-care, score-points[c]		
Group A (intervention, n = 36)	3.3 ± 1.1	−0.9 ± 1.1 (RR[a] = −1.1; CI, −1.5 to −0.7; $P < 0.01$)
Group B (intervention, n = 36)	3.1 ± 1.2	−1.1 ± 1.3 (RR[a] = −1.2; CI, −1.7 to −0.9; $P < 0.01$)
Group C (observation, n = 36)	2.8 ± 1.3	+0.2 ± 0.5
Well-being, score-points		
Group A (intervention, n = 36)	70.3 ± 11.2	+10.4 ± 7.9 (RR[a] = 12.7; CI, 9.7–15.7; $P < 0.01$)
Group B (intervention, n = 36)	72.2 ± 12.1	+10.7 ± 8.2 (RR[a] = 13.1; CI, 8.9–16.3; $P < 0.01$)
Group C (observation, n = 36)	71.7 ± 11.7	−2.3 ± 3.0

[a]Cox regression analyses including 95% CI.

[b]The degree of kyphosis was quantified via three-dimensional photomorphometry.

[c]Limitations of daily living assessed by scores for disability and ability of self-care.

CI, confidence interval; FEV, forced expiratory volume; LDL, low-density lipoprotein; RR, relative risk.

RESULTS

The baseline characteristics of the 108 subjects enrolled in this trial are shown in Table 1. Concomitant diseases and concomitant medications were distributed similarly. Specifically, the use of analgesics was sporadic in all groups. Only five women in group A (14%) took analgesics on a daily basis, three women in group B (8%) used analgesics, and five (14%) women in group C took medications for pain relief.

Beginning with month 0, 36 subjects started wearing the orthosis in groups A and B, whereas 36 subjects started to serve as controls in group C. The baseline measurements of endpoints were similar as shown in Table 1. According to the original cross-over study design, groups should be changed after 6 mos. Because of the orthosis' high efficacy, however, only three subjects in group A (8%) agreed to finish the intervention period, whereas the remaining 33 subjects (92%) continued wearing the orthosis and were followed for an intervention period of 12 mos, totally. This high number of subjects who completed the study was not the one that was envisioned. The main reason for stopping treatment in group A was continued pain. The corresponding numbers for group B were two (6%) subjects, who left this clinical trial mainly because of low comfort, and 34 (94%) women were observed over the whole trial period. During the observation phase, three (8%) women in group C underwent kyphoplasty and were excluded from this clinical trial.

Six months after wearing the orthosis, we found significant increases in back extensor strength, abdominal flexor strength, body height, relaxed vital capacity, forced expiratory volume in 1 sec, and well-being in groups A and B in comparison with group C (Table 2). In addition, we observed significant decreases in the angle of kyphosis, body sway path length, body sway velocity, and for average pain and the parameters describing limitations of daily living such as disability and self-care. Concerning groups A and B, however, we did not find any difference with regard to the parameters mentioned previously, which remained unchanged (Table 2).

Six months after baseline, the participants of group C stopped the observation phase and started wearing the orthosis "Spinomed." At the end of the study, group C also demonstrated significant increases concerning back extensor strength, abdominal flexor strength, body height, relaxed vital capacity, forced expiratory volume in 1 sec, and well-being (Figs. 3–6; not all data presented). Similarly to the first 6 mos of groups A and B, we observed in group C significant decreases in the percentage of the angle of kyphosis, body sway path length, body sway velocity, average pain, and limitations of daily living (Figs. 3–6; not all data presented).

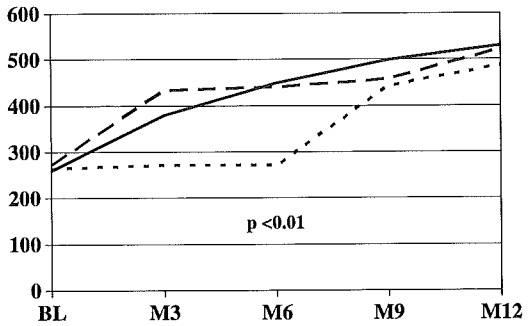

FIGURE 3 *Isometric back extensor strength in group A (solid line), with subjects (n = 33; mean age, 72.9 ± 7.1 yrs) wearing the back orthosis "Spinomed" between month 0 and month 12, and group B (dashed line) with participants (n = 34; mean age, 68.7 ± 10.9 yrs) wearing the back orthosis "Spinomed active" also between month 0 and month 12. Both groups are compared with group C (dotted line) with controls (n = 33; mean age 72.5 ± 6.7 yrs) wearing the back orthosis "Spinomed" between month 6 and month 12. All subjects had at least one vertebral fracture because of osteoporosis leading to a relatively low level of back extensor strength. Especially groups A and B increased their back extensor strength during the first 6 mos. Groups were significantly different at month 6 ($P < 0.01$), whereas no significant difference was seen at month 12.*

Concerning the 33 subjects of group A and the 34 subjects of group B, who continued wearing their orthosis for 12 mos until the end of the trial, we found no improvements in efficacy parameters such as back extensor strength and abdominal flexor strength. Similarly, we also saw no improvements for the angle of kyphosis, body sway path length, relaxed vital capacity, and average pain and limitations in daily living. These results indicate that the main treatment effects occurred within the first 6 mos and were maintained for another 6 mos (Figs. 3–6).

DISCUSSION

In this study, wearing either orthosis A or orthosis B over an intervention period of 6 mos improved posture, trunk muscle strength, and quality-of-life in women 60 yrs of age or older with postmenopausal osteoporosis with at least one clinical vertebral fracture. We observed that these effects

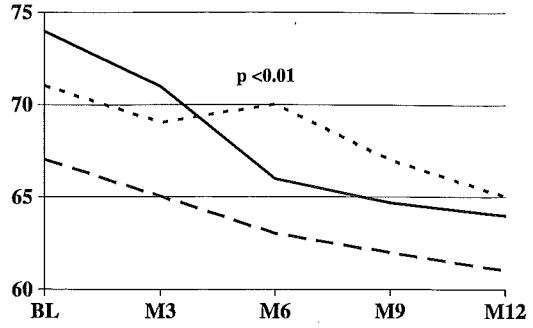

FIGURE 4 *The angle of thoracic kyphosis as measured using video-photorastermorphometry[5,6,23] in group A (solid line), with subjects (n = 33) wearing the back orthosis "Spinomed" between month 0 and month 12, and in group B (dashed line), with participants (n = 34) wearing the back orthosis "Spinomed active" also between month 0 and month 12. Both groups are compared with group C (dotted line) with controls (n = 33) wearing the orthosis "Spinomed" between month 6 and month 12. The groups were significantly different at month 6 (P < 0.01), whereas no significance existed at month 12.*

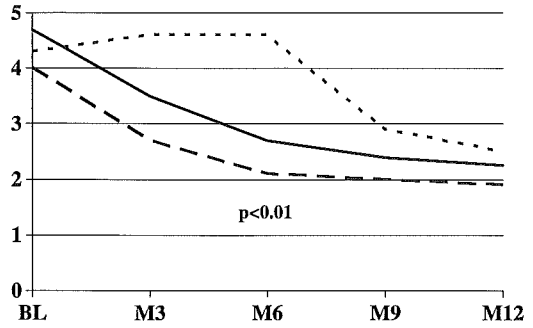

FIGURE 6 *Limitations of daily living determined according to Leidig-Bruckner et al.[6] in 33 subjects of group A (solid line) wearing the orthosis "Spinomed" between month 0 and month 12 as well as 34 subjects of group B (dashed line) wearing the orthosis "Spinomed active" also between month 0 and month 12. Both groups are in comparison with group C (dotted line) with controls (n = 33) wearing the orthosis between month 6 and month 12. The groups were significantly different at month 6 (P < 0.01), whereas no statistically significant difference was seen at month 12.*

were maintained for an additional period of 6 mos, and we found no significant difference between orthosis A and orthosis B. So far, there is only little evidence from the literature concerning the effectiveness of back braces in the management of vertebral fractures caused by osteoporosis and other spinal diseases.

Norton and Brown[30] were among the first who described the efficacy of a spinal orthosis in a retrospective analysis. They concluded that all spinal devices use a three-point pressure over bony prominences to cause enough discomfort to remind the patient wearing the orthosis to change or maintain posture while using the orthotic device.[31] On the other hand, Morris et al.[32] wrote that increased abdominal pressure decreases the net force applied to the spine when attempting to lift a weight from the floor. They believed that one of the major functions of a lumbar support, including corsets and rigid braces, was abdominal compression. The resultant increased intraabdominal pressure, thereby creating a semirigid cylinder surrounding the spinal column that is capable of relieving some of the imposed stresses on the vertebral column itself.[33] In contrast, Nachemson et al.[34] noted that no lumbosacral orthosis raised intragastric pressure significantly. Intraabdominal pressure will increase only with closure of the glottis during muscular activity. The lumbosacral support, when tightened within patient tolerance, decreases the intradiskal pressure at the lumbar spine by approximately 30%.[35]

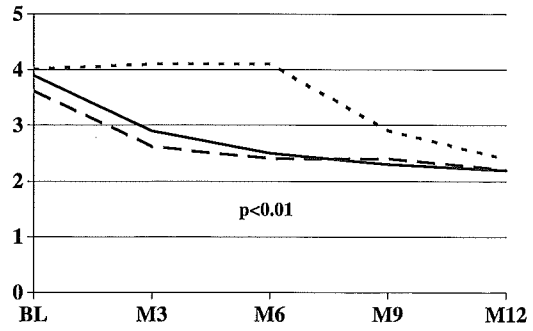

FIGURE 5 *Average pain as measured by Miltner's rating scale[5,6,23] in 33 subjects of group A (solid line) wearing the orthosis "Spinomed" between month 0 and month 12 and in 34 subjects of group B (dashed line) wearing the orthosis "Spinomed active" also between month 0 and month 12. Both groups are compared with 36 controls of group C (dotted line) wearing the orthosis "Spinomed" between month 6 and month 12. The groups are significantly different at month 6 (P < 0.01), whereas no statistical difference was seen at month 12.*

To our knowledge, these various hypotheses concerning efficacy have never been tested in a prospective randomized controlled manner. Clinical experiences indicate that the pressure over bony prominences and the abdominal compression forces especially are responsible for increased pain, muscle atrophy, reduced pulmonary function, and overall severe discomfort, which altogether limit

the compliance of patients and result in the nonusage of orthoses. Because of the fact that placebo-controlled clinical trials for technical devices are not possible, we conducted a prospective randomized cross-over study to achieve conclusions on a high level of evidence.

The most intriguing finding of this study is the significant increase in trunk muscle strength, which is, most likely related to an increased muscular activity while wearing one of these two orthoses. This is consistent with the findings by Lantz and Schultz,[36] who described an increased electrical activity of back muscles when a lumbosacral orthosis is worn.[36] This observation supports the notion that the so-called biofeedback may be an underlying principle of efficacy. Stronger back muscles may be the reason for the decreased angle of kyphosis and the increased body height. This again is a precondition for a better posture and a correction of the center of gravity, which then results in lower values of body sway. As body sway is a well-documented risk factor for falls and fall-related fractures;[21–23] this improvement of balance may be accompanied by a lower rate of falls and nonvertebral fractures.[37] The decrease of the angle of kyphosis seen in this study may allow better inspiration and expiration, which has been verified by an increased vital capacity and a better forced expiratory volume in 1 sec, which may decrease the risk for pneumonia and overall mortality in these patients. Therefore, the orthosis Spinomed active used in this study is invisible, weightless, and performs its desired function. Therefore, Spinomed (orthosis A) has already been described as a good opportunity in the management of back pain in osteoporotic vertebral fractures.[38]

The overall compliance of the study participants was excellent: 105 study subjects completed at least 6 mos of intervention each, and another 100 subjects continued over a 12-mo period. This may be explained in part by our results, which showed that wearing the orthosis was accompanied with improved quality-of-life as measured by decreased pain and limitations of daily living as well as increased well-being. The main reasons for dropouts in group A was continued pain (three women), low comfort in group B (two women) and kyphoplasty in group C (three women).

CONCLUSIONS

Thoracolumbar orthoses need to find a balance between the often conflicting requirements of function, cosmetics, and acceptability.[37] We conclude that the orthoses used in this study increases trunk muscle strength and thus improves posture and body height in patients with vertebral fractures caused by osteoporosis. In addition, a better quality-of-life is achieved using pain reduction, decreased limitations of daily living, and augmented well-being.

Given the widespread use of orthoses in various diseases, there is an urgent need for controlled clinical trials to further elucidate the functions and applications of these technical devices.

ACKNOWLEDGMENTS

We thank Dr. H.A. Griesser, editor-in-chief of our local newspaper ("DEWEZET," Hameln) for his help in recruiting the participants of this study. Furthermore, we thank, for the excellent cooperation, the orthopeadic technicians Florian Korte and Martin Steinke (Brandscheidt Co., Syke, Germany), who made the orthoses to fit for all study subjects. We thank Dorin Lazarescu, MPH, (Lazarescu Statistics, Bad Pyrmont, Germany) for his statistical advice. Finally, we thank our patients with osteoporosis who not only participated in this clinical trial but also helped us develop the orthoses tested. Audits have been performed routinely by the German Ministry for the approval of investigational products ("Bundesamt für Arzneimittel und Medizinprodukte").

The orthoses used in this study were developed by medi Inc, Bayreuth, Germany, in strong cooperation with patients with vertebral fractures caused by osteoporosis to meet the special needs and requirements of this group of patients. medi Inc provided funding for this study and markets orthoses worldwide. However, medi Inc had no control over the study design as well as over the decision to approve or submit the manuscript for publication.

APPENDIX

Limitations in Everyday Life

These are based on Leidig-Bruckner et al.[6]

Motion In General

Six abilities of everyday life—walking, bending, climbing stairs, getting up from a lying position, dressing, and carrying bags—were related from 0 to 2 (easily possible, possible with difficulties, possible only with extra help). Finally, a sum score is calculated ranging from 0 to 12.

Self-Care in General

The assessment could be answered as follows: 1, possible without extra help; 2, overall possible, dependent on help in some cases (cleaning windows,

drawing curtains, and carrying heavy bags); 3, possible but with difficulties and increased time, dependent on help in some cases; 4, possible but with difficulties and increased time, dependent on help even in routine cases (shopping, ironing, and cleaning floor); 5, dependent on extra help for everyday routine functions (cleaning, cooking); 6, nursing care needed.

Well-Being

The questionnaire (from Begerow et al.[5]) consists of four subscales each containing four bipolar pairs of adjectives to be checked off in seven graduations.

Vitality

tired 1 2 3 4 5 6 7 fresh,
strong 1 2 3 4 5 6 7 weak,
feeble 1 2 3 4 5 6 7 energetic,
healthy 1 2 3 4 5 6 7 sick.

Intrapsychologic Balance

calm 1 2 3 4 5 6 7 nervous,
unbalanced 1 2 3 4 5 6 7 well-balanced,
confident 1 2 3 4 5 6 7 insecure,
anxious 1 2 3 4 5 6 7 fearless.

Social Extroversion

talkative 1 2 3 4 5 6 7 discreet,
reserved 1 2 3 4 5 6 7 communicative,
sociable 1 2 3 4 5 6 7 shy,
secluded 1 2 3 4 5 6 7 gregarious.

Vigility

attentive 1 2 3 4 5 6 7 inattentive,
alert 1 2 3 4 5 6 7 absent-minded,
concentrated 1 2 3 4 5 6 7 nonconcentrated,
focused 1 2 3 4 5 6 7 divertible.

REFERENCES

1. Cooper C, Atkinson EJ, O'Fallon WM, et al: Incidence of clinically diagnosed vertebral fractures: A population-based study in Rochester, Minnesota. *J Bone Miner Res* 1992;7:221–7
2. Ettinger B, Black DM, Nevitt MC, et al: The Study of Osteoporotic Fractures Research Group. Contribution of vertebral deformities to chronic back pain and disability. *J Bone Miner Res* 1992;7:449–56
3. Sinaki M: Musculoskeletal challenges of osteoporosis. *Aging* 1998;10:249–62
4. Schlaich C, Minne HW, Bruckner T, et al: Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int* 1998;8:261–7
5. Begerow B, Pfeifer M, Pospeschill M, et al: Time since vertebral fracture: An important variable concerning quality of life in patients with postmenopausal osteoporosis. *Osteoporos Int* 1999;10:26–33
6. Leidig-Bruckner G, Minne HW, Schlaich C, et al: Quality of life components and spinal deformity in women with chronic low back pain and women with vertebral osteoporosis. *J Bone Miner Res* 1997;12: 663–75
7. Lyles KW, Gold DT, Shipp KM, et al: Association of osteoporotic vertebral compression fractures with impaired functional status. *Am J Med* 1993;94: 595–601
8. Liberman UA, Weiss SR, Bröll J, et al: Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal women. *N Engl J Med* 1995;333:1437–43
9. Reginster JY, Minne HW, Sorensen OH, et al, for the Vertebral Efficacy with Risedronate Therapy (VERT) Study Group: Randomised trial of the effects of risedronate on vertebral fractures in women with established postmenopausal osteoporosis. *Osteoporos Int* 2000;11:83–91
10. Chesnut CH III, Skag A, Christiansen C, et al, for the Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe: Effects of oral ibandronate administered daily or intermittently on fracture risk in postmenopausal osteoporosis. *J Bone Miner Res* 2004;19:1241–9
11. Black DM, Delmas PD, Eastell R, et al, for the HORIZON pivotal fracture trial: Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *N Engl J Med* 2007:356:1809–22
12. Ettinger B, Black DM, Mitlak BH, et al, for the Multiple Outcomes of Raloxifen Evaluation (MORE) Investigators: Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: Results from a 3-year randomised clinical trial. *JAMA* 1999;282:637–45
13. Neer RM, Arnaud CD, Zanchetta JR, et al: Effect of parathyroid hormone (1–34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *N Engl J Med* 2001;344:1434–41
14. Chesnut CH III, Rosen CJ, for The Bone Quality Discussion Group: Reconsidering the effects of antiresorptive therapies in reducing osteoporotic fracture. *J Bone Miner Res* 2001;16:2163–72
15. Sinaki M, McPhee MC, Hodgson SF, et al: Relationship between bone mineral density of spine and strength of back extensors in healthy postmenopausal women. *Mayo Clin Proc* 1986;61:116–22
16. Sinaki M, Khosla S, Limburg PJ, et al: Muscle strength in osteoporotic versus normal women. *Osteoporos Int* 1993;3:8–12
17. Itoi E, Sinaki M: Effect of back-strengthening exercise on posture in healthy women 49 to 65 years of age. *Mayo Clin Proc* 1994;69:1054–9
18. Perry J: The use of external support in the treatment of low back pain. *J Bone Joint Surg Am* 1970;52: 1440–2

19. Deyo RA, Tsui-Wu YJ: Descriptive epidemiology of low-back pain and its related medical care in the United States. *Spine* 1987;12:264–8

20. Melton LJ III, Lane AW, Cooper C, et al: Prevalence and incidence of vertebral deformities. *Osteoporos Int* 1993;3:113–9

21. Patwardhan AG, Li SP, Gavin T, et al: Orthotic stabilization of thoracolumbar injuries. A biomechanical analysis of the Jewett hyperextension orthosis. *Spine* 1990;15:654–61

22. Sinaki M: A new back support in rehabilitation of osteoporosis program-exercise: Posture training support, in Christiansen C, Overgaard K (eds): *Osteoporosis 1990*. Copenhagen, Denmark, Osteopress, 1990, pp 1355–7

23. Pfeifer M, Begerow B, Minne HW: Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis. *Am J Phys Med Rehabil* 2004;63:177–86

24. Pfeifer M, Begerow B, Minne HW, et al: Vitamin D status, trunk muscle strength, body sway, falls, and fractures among 237 postmenopausal women with osteoporosis. *Exp Clin Endocrinol Diabetes* 2001;109: 87–92

25. Lord SR, Clark RD, Webster IW: Postural stability and associated physiological factors in a population of aged persons. *J Gerontol* 1991;46:M69–76

26. Nguyen T, Sambrook P, Kelly P, et al: Prediction of osteoporotic fractures by postural instability and bone density. *BMJ* 1993;307:1111–5

27. Pfeifer M, Begerow B, Minne HW, et al: Effects of a short-term vitamin D and calcium supplementation on body sway and secondary hyperparathyroidism. *J Bone Miner Res* 2000;15:1113–8

28. Genant HK, Jergas M, Palermo L, et al: Comparison of semiquantitative visual and quantitative morphometric assessment of prevalent and incident vertebral fractures in osteoporosis. The Study of Osteoporotic Fractures Research Group. *J Bone Miner Res* 1996;11:984–96

29. Sauer P, Leidig G, Minne HW, et al: Spine deformity index (SDI) versus other objective procedures of vertebral fracture identification in patients with osteoporosis: A comparative study. *J Bone Miner Res* 1991;6:227–38

30. Norton PL, Brown T: The immobilization efficiency of back braces, their effect on the posture and motion of the lumbosacral spine. *J Bone Joint Surg Am* 1957; 39:111–39

31. Lumsden RM, Morris JM: An in vivo study of axial rotation and immobilization at the lumbosacral joint. *J Bone Joint Surg Am* 1968;50:1591–1602

32. Morris JM, Lucas DB, Bresler B: Role of the trunk in stability of the spine. *J Bone Joint Surg Am* 1968;50: 327–51

33. Morris JM: Low back bracing. *Clin Orthop* 1974;102: 126–32

34. Nachemson A, Schultz A, Andersson G: Mechanical effectiveness studies of lumbar spine orthoses. *Scand J Rehabil Med* 1983;9:139–49

35. Nachemson A, Morris JM: In vivo measurements of intradiscal pressure: Discometry, a method for the determination of pressure in the lower lumbar discs. *J Bone Joint Surg Am* 1964;46:1077–92

36. Lantz SA, Schultz AB: Lumbar spine orthoses wearing. Effect on trunk muscle myoelectric activity. *Spine* 1986;11:838–42

37. Platts RGS: Orthotics. In: Harris NH, Birch R, eds. *Clinical Orthopeadics*. London, England: Blackwell Science; 1995:1165–90

38. Francis RM, Aspray TJ, Hide G, et al: Management of back pain in osteoporotic vertebral fractures. *Osteoporos Int* 2008;19:187–94