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Research Article

Effects of a New Spinal Orthosis on Posture, Trunk Strength, and Quality of Life in Women with Postmenopausal Osteoporosis
A Randomized Trial

ABSTRACT

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Objective: One fourth of women ≥50 yrs of age in the general population have one or more vertebral fractures. The orthotic treatment modality in the management of vertebral fractures caused by osteoporosis remains subjective because no objective data from clinical trials are available. The objective of this research was to evaluate the efficacy of a newly developed spinal orthosis in patients with osteoporotic vertebral fractures.

Design: We conducted a study that measured trunk muscle strength, angle of kyphosis, body height, body sway, and variables of quality of life such as pain, well-being, and limitations of daily living.

Results: Wearing the orthosis for 6-mo period was associated with a 73% increase in back extensor strength, a 58% increase in abdominal flexor strength, an 11% decrease in angle of kyphosis, a 25% decrease in body sway, a 7% increase in vital capacity, a 38% decrease in average pain, a 15% increase in well-being, and a 27% decrease in limitations of daily living. The overall tolerability of the orthosis was good, no side-effects were reported, and the drop-out rate of 3% was rather low.

Conclusions: The use of an orthosis increases trunk muscle strength and thus 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. Therefore, 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] A fourth of women ≥50 yrs of age 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 increment in vertebral fractures and the risk 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 alendronate,[8] risedronate,[9] and raloxifene,[10] which improve bone quality.[11] These therapeutics, however, only prevent approximately 50% of spinal fractures.[11] In addition, there is need to improve back muscle strength because muscle atrophy parallels the decline of bone mineral density of the spine[12] and contributes significantly to kyphotic postural changes.[13] The multi-disciplinary rehabilitation concept of spinal osteoporosis, therefore, includes back-strengthening exercises to counteract thoracic kyphosis in hyperkyphotic subjects.[12,14]

Traditionally, spinal orthoses have been used in the management of thoracolumbar injuries treated with or without surgical stabilization. The vast majority of orthoses, however, are used in patients with low back pain.[15] In the United States alone, >250,000 corsets are prescribed each year.[16] These orthoses, however, have never been tested under standardized conditions. Especially, no prospective, randomized, and controlled clinical trials are available to document efficacy according to the criteria of evidence-based medicine. This is also the case for osteoporosis, in which approximately one-fourth of women ≥50 yrs of age have one or more

vertebral fractures.[17] 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.[18] Furthermore, the use of rigid thoracolumbar braces in osteoporosis is limited by factors such as atrophy of trunk muscles and restricted respiration, leading to low compliances.[18]

Therefore, a completely new orthosis has been developed, especially taking into account the needs of patients with vertebral osteoporosis. On the basis of important articles published by Sinaki et al.,[19–21] our study was designed as a prospective, randomized, and controlled crossover study to determine the efficacy of this newly developed orthosis in patients with spinal osteoporosis.

METHODS

Study Participants. We studied ambulatory, community-dwelling women ≥60 yrs of age who were recruited through newspaper advertisements.

Figure 1: Spinomed, a back orthosis, consists of an abdominal pad and a light metal splint along the spine, which is workable as a cold material. A system of belts with Velcro allows adjustments for individual sizes by an orthopaedic technician. The orthosis weighs 450 g and is worn like a back pad.

The inclusion criteria were at least one clinical vertebral fracture caused by osteoporosis and an angle of kyphosis of ≥60 degrees as measured by stereophotomorphometry. Exclusion criteria were disorders affecting bone mineral metabolism (e.g., hyperthyroidism, primary hyperparathyroidism, hypercortisolism, and osteomalacia) and severe degenerative diseases of the spine such as osteoarthritis, scoliosis, and malignancies. All subjects received standard medical treatment for osteoporosis, including calcium and vitamin D and a newer bisphosphonate. The subjects were asked to wear the orthosis approximately 2 hrs/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.

Study Design. This study was planned as a prospective, randomized, crossover study. Initially, the design called for subjects to be randomized into two groups, with group A starting to wear the orthosis for a 6-mo period and subjects in group B serving as controls. After completion of the first 6 mos, group B was to be

provided with the orthosis, and group A was to serve as the control. The beneficial course of the first intervention phase, however, led to the fact that participants in group A refused to stop wearing the orthosis. After contacting the ethics committee responsible for this clinical trial, it was decided to modify the originally planned crossover because of ethical reasons.

The primary endpoint of the study was a change in isometric back extensor strength leading to a change in the degree of thoracic kyphosis. Secondary endpoints included isometric abdominal flexor strength, body height, body sway, lung function as determined by vital capacity, and variables of quality of life, such as pain, limitations of daily life, and well-being, as assessed by questionnaires.

At study entry, an assessment of the subjects' medical history, including circumstances and dates of the diagnosis, number and severity of falls within the previous 2 yrs, the first bone densitometry test, and fractures of the spine documented by radiography, was performed. In addition, concurrent and earlier medication, use of analgesics, dietary habits including alcohol consumption and nicotine use, previous diseases and immobilization phases, and family history were recorded.

Physical examination of the spine and whole body was undertaken to exclude secondary osteoporosis. Height reduction was calculated as the difference between body height at the age of 25 yrs, as documented in the subjects' passports, and the current measured height, which was determined using a stadiometer under standardized conditions between 8 and 9 in the morning.

Back Orthosis. The thoracolumbar orthosis Spinomed (Medi-Bayreuth, Bayreuth, Germany) was developed in cooperation with patients with severe back pain caused by osteoporosis with vertebral fractures. The back or-

thosis consists of a back pad, which is workable as a cold material, and a system of belts with Velcro (Fig. 1). This allows adjustments for individual sizes by an orthopedic technician. The orthosis weighs 450 g and is worn like a back pad.

Measurements. Isometric maximum strength of trunk muscles was determined on subjects sitting in a standardized position, with knee and hip joints at 90 degrees and the pelvis fixed by a seatbelt (Digi-Max, mechaTronic, Germany).[22] For assessment of back extensor strength, subjects were requested to press the upper part of their body against the fixed pad in the back of the measurement chair (isometric maximal back extensor strength). Maximal abdominal

flexor strength was determined at the same position, pressing forward against a fixed pad. Strength was then determined electronically by a pressure gauge. Three measurements each were performed, and the highest value was included in the analysis. The coefficients of variance were 2.2% for back extensor strength and 2.4% for abdominal flexor strength.[22]

Body sway was measured using a sway meter to record displacements of the body at waist level in 30-sec periods.[23] The device consists of a rod attached to the subject at waist level by a firm belt. The rod is 40 cm in length and extends behind the subject. A digitizing tableau is fixed on an adjustable-height table that is positioned behind the subject. The

TABLE 1
Baseline clinical characteristics of the 62 study subjects

	Value		
Characteristic	Group A, $n = 31$	Group B, $n = 31$	P Value
Age, yrs	72.8 ± 7.1	72.3 ± 6.7	0.76
Range, yrs	61–86	60–83	
Current height, cm	156 ± 6.7	156 ± 7.3	0.67
Loss of height, cm[a]	8.9 ± 5.0	8.8 ± 3.9	0.92
Weight, kg	64.2 ± 10.4	64.3 ± 10.0	0.86
Vertebral fractures, n[b]	2.0 ± 2.7	2.1 ± 2.8	0.87
Nonvertebral fractures, n[c]	0.9 ± 1.1	1.0 ± 1.3	0.65
Falls, n[d]	2.7 ± 1.5	2.8 ± 1.4	0.94
Physical activity, %			
Daily/weekly/monthly/sporadic	3/48/3/6	3/42/9/6	0.85
Concomitant diseases, n (%)			
Cardiovascular, mild hypertension	11 (35)	9 (29)	0.59
Pulmonary, asthma	3 (10)	1 (3)	0.31
Central nervous, neurologic	2 (6)	0 (0)	0.16
Musculoskeletal system, arthritis	4 (13)	2 (6)	0.40
Concomitant medication, n (%)			
Benzodiazepine use	1 (3)	0 (0)	0.32
Thyroidotherapy	10 (32)	6 (19)	0.25
Cardiovascular drugs	11 (35)	9 (29)	0.59
Corticoids, low dose	2 (6)	2 (6)	1.00

Values for age, height, loss of height, weight, fractures, and falls are mean ± standard deviation.
[a] Difference between body height at the age of 25 yrs and measured current height.
[b] Number of vertebral fractures as assessed by radiographs according to Food and Drug Administration guidelines.
[c] Nonvertebral fractures were verified by radiographs or medical records.
[d] Falls within the previous 2 yrs as reported by study subjects.

height of the table is adjusted so that the rod is in a horizontal plane and the tip of a pen can draw the movements of the subject via the digitizing tableau to a computerized system. Displacements of the body in frontal and sagittal directions were recorded to measure total path length (sway distance) and to calculate mean sway velocity. Both variables have been shown to predict the risk for falls and fall-related fractures.[24] The coefficients of variance were 1.6% for sway distance and 1.8% for sway velocity.[25]

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, Jena, Germany).[5] This method has been demonstrated to be in good agreement with the Spine Deformity Index as a measure for kyphosis using radiographs.[22] Coefficients of variation were 1.7% for intraobserver variability and 1.9% for interobserver variability.[5]

Pulmonary function was estimated measuring 1-sec expiratory relaxed vital capacity and 1-sec forced expiratory volume ("microlab," Heiland, Germany).[4] Coefficients of variation were 2.3% for intraobserver variability and 2.1% for interobserver variability.[4]

Radiologic Assessment. All vertebral fractures were verified by spinal radiographs. A fracture was defined as a height reduction of a vertebra of >20% at any site or of at least 4 mm, according to Food and Drug Administration guidelines. Assessment was carried out by an experienced radiologist.[26] Differences in magnification were avoided by use of a constant film-focus distance of 115 cm.

Questionnaires. Data on various aspects affecting quality of life were collected by questionnaires. Limitations in everyday life were 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 (APPENDIX).

Perception of average pain was judged by Miltner's rating scale, which was developed within a German-speaking environment and has been proven to be reliable for osteoporosis.[5] The score is easy to apply and independent of age.[5] Patients were requested to mark their intensity of perceived pain on a scale rated from 1 to 4, in which 1 = low, 2 = moderate, 3 = severe, and 4 = very severe pain.[5]

Patients' well-being was assessed using the well-being scale devised by Hobi et al.[5] (APPENDIX). The scale was selected because it was 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. Patients were requested to select the mood they thought 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]

Statistical Analyses. The biostatistical evaluation was carried out using the statistical software package SAS for Windows, version 6.10 (SAS Institute, Cary, NC) and NCSS 6.0.21 (NCSS Statistical Software, Kaysville, UT). For determination of the sample size the software package NCSS-PASS 1.0 (NCSS Statistical Software) was used. The expected difference between both therapy groups was estimated at 40–60% of the standard deviation. To prove a difference of 50% of the standard deviation with a power of 80%, 28 subjects per group were needed. Assuming a drop-out rate of 10%, 31 subjects were included in each group. Twenty-eight subjects in group A and 31 subjects in group B completed 12 mos of the study and were included into the intention-to-treat analysis. A normal distribution could be assumed to the pre-post differences. In this case, a two-sided t test for independent samples was applied. If a significant deviation from normality was found, the Mann-Whitney U test was used.

RESULTS

Of the 89 subjects who underwent screening, 62 (70%) had an angle of kyphosis of >60 degrees due to spinal osteoporosis, with at least one vertebral fracture verified by radiography. The baseline characteristics of the 62 subjects enrolled in this trial are shown in Table 1. Both groups were comparable concerning age, height, weight, number of vertebral fractures, loss of height since the age of 25, number of nonvertebral fractures, and falls within the previous 2 yrs. In addition, concomitant diseases and concomitant medications were distributed similarly. Specifically, the use of analgesics was sporadic in both groups. Only five women in group A (16%) took analgesics two or three

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TABLE 2

Initial values of efficacy end points and changes at 6 mos in 62 study subjects according to study group (intention to treat)

Index and Study Group	Initial Value	Change	P Value
Body height, mm			
Group A (intervention, $n = 31$)	1563 ± 67	+5.3 ± 6.3	<0.01
Group B (observation, $n = 31$)	1560 ± 73	−0.4 ± 4.7	
Angle of kyphosis, degrees[a]			
Group A (intervention, $n = 31$)	74.2 ± 9.8	−7.9 ± 4.9	0.02
Group B (observation, $n = 31$)	70.8 ± 9.9	−1.6 ± 5.5	
Back extensor strength, newtons			
Group A (intervention, $n = 31$)	260 ± 130	+189 ± 152	<0.01
Group B (observation, $n = 31$)	263 ± 122	+7 ± 55	
Abdominal flexor strength, newtons			
Group A (intervention, $n = 31$)	161 ± 72	+94 ± 71	<0.01
Group B (observation, $n = 31$)	157 ± 66	+23 ± 46	
Body sway path length, mm			
Group A (intervention, $n = 31$)	84.4 ± 70.1	−20.4 ± 40.2	<0.01
Group B (observation, $n = 31$)	75.7 ± 36.7	−1.7 ± 35.6	
Body sway velocity, mm/sec			
Group A (intervention, $n = 31$)	2.8 ± 2.4	−0.7 ± 1.3	<0.01
Group B (observation, $n = 31$)	2.5 ± 1.2	−0.1 ± 1.2	
Relaxed vital capacity, %			
Group A (intervention, $n = 31$)	82.6 ± 21.1	+6.1 ± 20.5	0.02
Group B (observation, $n = 31$)	93.6 ± 17.0	−9.9 ± 16.1	
Forced expiratory volume in 1 sec, %			
Group A (intervention, $n = 31$)	84.9 ± 22.2	+2.9 ± 13.5	0.04
Group B (observation, $n = 31$)	94.4 ± 22.6	−3.8 ± 16.1	
Average pain, score-points			
Group A (intervention, $n = 31$)	3.9 ± 1.1	−1.5 ± 1.2	<0.01
Group B (observation, $n = 31$)	4.0 ± 1.0	+0.1 ± 0.9	
LDL disability, score-points[b]			
Group A (intervention, $n = 31$)	4.7 ± 1.9	−2.1 ± 1.6	<0.01
Group B (observation, $n = 31$)	4.3 ± 1.6	+0.2 ± 0.8	
LDL self care, score-points[b]			
Group A (intervention, $n = 31$)	3.3 ± 1.1	−0.9 ± 1.1	<0.01
Group B (observation, $n = 31$)	2.8 ± 1.3	+0.2 ± 0.5	
Well-being, score-points			
Group A (intervention, $n = 31$)	70.3 ± 11.2	+10.4 ± 7.9	<0.01
Group B (observation, $n = 31$)	71.7 ± 11.7	−2.3 ± 3.0	

[a] The degree of kyphosis was quantified via three-dimensional photomorphometry.
[b] LDL, limitations of daily living assessed by scores for disability and ability of self care.

TABLE 3

Values of efficacy end points and changes at 12 mos in 59 study subjects according to study group (intention to treat)

Index and Study Group	Initial Value	Change	P Value
Body height, mm			
Group A (intervention, $n = 28$)	1568 ± 66	−0.3 ± 4.6	
Group B (observation, $n = 31$)	1560 ± 72	+5.8 ± 4.3	<0.01
Angle of kyphosis, degrees[a]			
Group A (intervention, $n = 28$)	66.3 ± 9.3	−1.9 ± 4.1	
Group B (observation, $n = 31$)	69.2 ± 10.0	−4.2 ± 4.9	0.03
Back extensor strength, newtons			
Group A (intervention, $n = 28$)	449 ± 195	+109 ± 59	
Group B (observation, $n = 31$)	270 ± 115	+215 ± 98	0.02
Abdominal flexor strength, newtons			
Group A (intervention, $n = 28$)	255 ± 104	+30 ± 45	
Group B (observation, $n = 31$)	181 ± 59	+93 ± 56	<0.01
Body sway path length, mm			
Group A (intervention, $n = 28$)	64.0 ± 35.9	−3.0 ± 11.0	
Group B (observation, $n = 31$)	73.9 ± 30.9	−9.7 ± 18.6	0.03
Body sway velocity, mm/sec			
Group A (intervention, $n = 28$)	2.1 ± 1.2	+0.2 ± 0.8	
Group B (observation, $n = 31$)	2.4 ± 1.0	−0.6 ± 0.6	<0.01
Relaxed vital capacity, %			
Group A (intervention, $n = 28$)	88.7 ± 16.8	+2.3 ± 24.6	
Group B (observation, $n = 31$)	83.7 ± 20.6	+7.8 ± 15.2	<0.01
Forced expiratory volume in 1 sec, %			
Group A (intervention, $n = 28$)	87.8 ± 19.3	+0.9 ± 13.5	
Group B (observation, $n = 31$)	90.6 ± 28.1	+3.1 ± 13.8	<0.01
Average pain, score-points			
Group A (intervention, $n = 28$)	2.4 ± 0.9	−0.2 ± 0.4	
Group B (observation, $n = 31$)	4.1 ± 1.1	−1.7 ± 1.1	<0.01
LDL disability, score-points[b]			
Group A (intervention, $n = 28$)	2.7 ± 1.8	−0.4 ± 0.6	
Group B (observation, $n = 31$)	4.5 ± 1.4	−2.1 ± 1.5	<0.01
LDL self care, score-points[b]			
Group A (intervention, $n = 28$)	2.4 ± 1.0	−0.1 ± 0.5	
Group B (observation, $n = 31$)	3.0 ± 1.1	−0.8 ± 0.9	<0.01
Well-being, score-points			
Group A (intervention, $n = 28$)	80.7 ± 8.7	+3.4 ± 2.2	
Group B (observation, $n = 31$)	69.4 ± 11.7	+15.0 ± 7.9	<0.01

[a] The degree of kyphosis was quantified via three-dimensional photomorphometry.
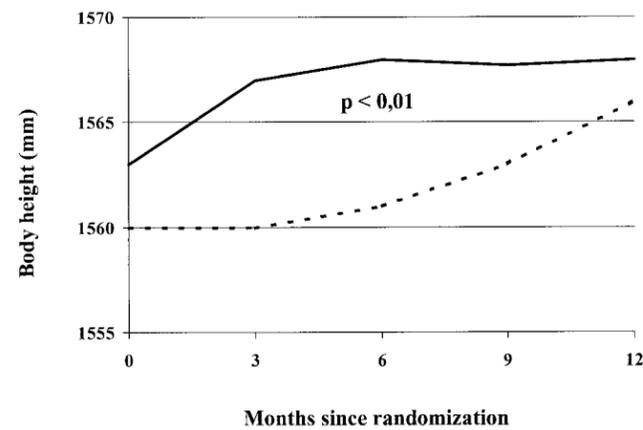[b] LDL, limitations of daily living assessed by scores for disability and ability of self care.

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Figure 2: Body height in group A (*solid line*), with subjects ($n = 28$; mean age, 72.8 ± 7.1 yrs) wearing the back orthosis between months 0 and 12, in comparison with group B (*dashed line*), with subjects ($n = 31$; mean age, 72.3 ± 6.7 yrs) wearing the back orthosis between months 6 and 12. All subjects had at least one vertebral fracture caused by osteoporosis, leading to an increased thoracic kyphosis of >60 degrees. Groups were significantly different at month 6 ($P < 0.01$), whereas no significant difference was seen at month 12.

times a week, whereas three women in group B (10%) used analgesics two or three times a week.

Beginning with month 0, 31 subjects started wearing the orthosis in group A, and 31 subjects served as controls in group B until the end of the first 6 mos. According to the original crossover study design, groups should be changed after 6 mos. Because of the orthosis' high efficacy,

however, only three subjects of group A (10%) agreed to finish the intervention period, whereas the remaining 28 subjects (90%) continued wearing the orthosis and were followed over an intervention period of 12 mos in total.

Six months after wearing the orthosis, significant increases in body height, back extensor strength, abdominal flexor strength, relaxed vital
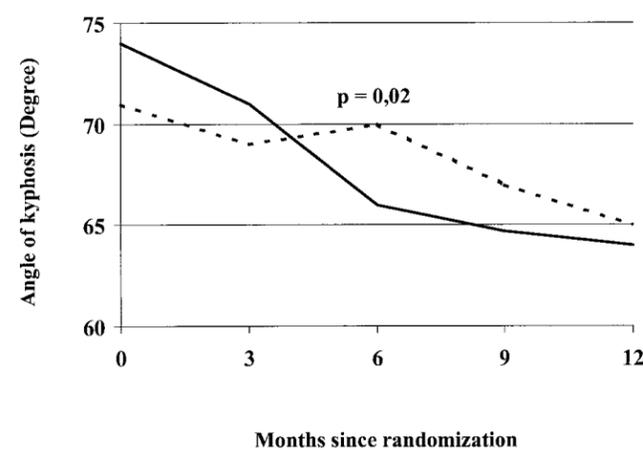

Figure 3: Angle of thoracic kyphosis as measured by video-photorastermorphometry[5] in group A (*solid line*), with subjects ($n = 28$) wearing the back orthosis between months 0 and 12, in comparison with group B (*dashed line*), with subjects ($n = 31$) wearing the orthosis between months 6 and 12. Groups were significantly different at month 6 ($P = 0.02$), whereas no significance existed at month 12.

capacity, 1-sec forced expiratory volume, and well-being were found in group A (Table 2). In addition, significant decreases were observed for angle of kyphosis, body sway path length, body sway velocity, average pain, and the variables describing limitations of daily living such as disability and self care. In contrast to these findings, group B, which served as a control, remained unchanged (Table 2).

Six months after baseline, group B stopped the observation phase and started wearing the orthosis for another period of 6 mos (Table 3). At the end of the study, group B also demonstrated significant increases concerning body height, back extensor strength, abdominal flexor strength, relaxed vital capacity, 1-sec forced expiratory volume, and well-being (Table 3). Similar to the first 6 mos of group A, significant decreases for angle of kyphosis, body sway path length, body sway velocity, average pain, and limitations of daily living were observed in group B (Table 3).

Concerning the 28 subjects of group A who continued wearing the orthosis for 12 mos until the end of the trial, the efficacy variables back extensor strength and abdominal flexor strength showed an additional and significant improvement ($P < 0.01$). In addition, smaller improvements were found for angle of kyphosis, body sway path length, relaxed vital capacity, average pain, and limitations in daily living. These changes, however, did not reach the level of statistical significance. These results indicate that the main treatment effects occurred within the first 6 mos and are maintained for another 6 mos (Figs. 2–9).

DISCUSSION

In this study, wearing a thoracolumbar orthosis over an intervention period of 6 mos improved posture, trunk muscle strength, and quality of life in women ≥60 yrs of age with
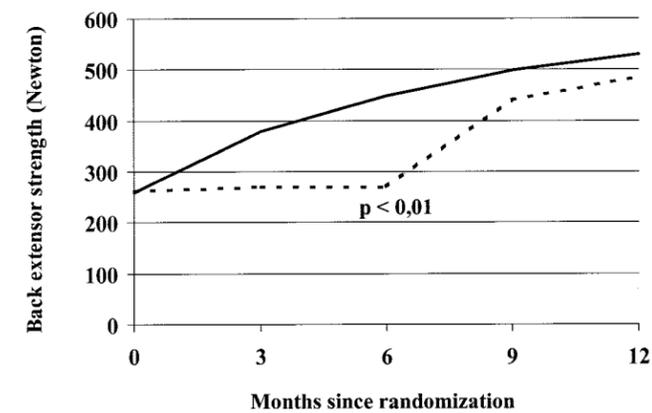

Figure 4: Back extensor strength as measured by isometric maximum strength[20] in group A (*solid line*), with participants ($n = 28$) wearing the orthosis between months 0 and 12, in comparison with group B (*dashed line*), with subjects ($n = 31$) wearing the orthosis between months 6 and 12. Groups were significantly different at month 6 ($P < 0.01$), whereas no statistically significant difference was documented at month 12.

postmenopausal osteoporosis with clinical vertebral fractures. These effects were observed to be maintained over an additional period of 6 mos. So far, there is only little evidence from the literature concerning the effectiveness of back braces.

Norton and Brown[27] were among the first to describe the efficacy of a spinal orthosis in a retrospective analysis. They concluded that all spinal devices employ three-point pressure over bony prominences to cause enough discomfort to remind the patient wear-

ing the orthosis to change or maintain posture in the orthotic device.[28] On the other hand, Morris et al.[29] found 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 intra-abdominal pressure thereby created a semi-rigid cylinder surrounding the spinal column capable of relieving some of
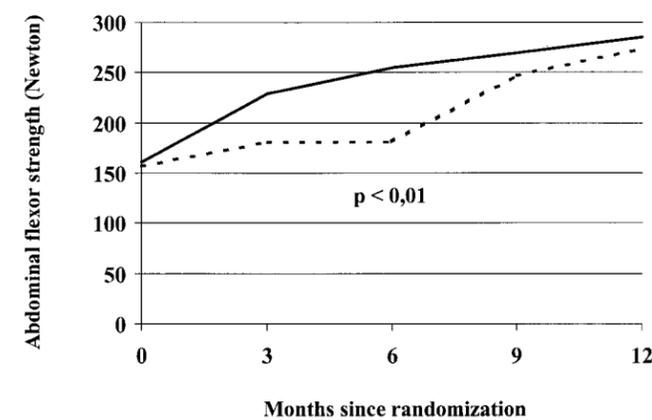

Figure 5: Abdominal flexor strength as measured by isometric maximum strength[20] in group A (*solid line*), with subjects ($n = 28$) wearing the orthosis between months 0 and 12, in comparison with group B (*dashed line*), with subjects ($n = 31$) wearing the orthosis between months 6 and 12. Groups were significantly different at month 6 ($P < 0.01$), whereas no difference was seen at month 12.

the imposed stresses on the vertebral column itself.[30] In contrast, Nachemson et al.[31] noted that no lumbosacral orthosis raised intragastric pressure significantly. Intra-abdominal pressure will increase with closure of the glottis during muscular activity. The lumbosacral support, when tightened within patient tolerance, decreases the intradiscal pressure at the lumbar spine by approximately 30%.[32]

These various hypotheses of efficacy cited above, however, have never been tested in a prospective, randomized and controlled matter. Clinical experiences indicate that especially the pressure over bony prominences and the abdominal compression forces are responsible for increased pain, muscle atrophy, reduced pulmonary function, and overall severe discomfort, which altogether limit the compliance of patients and result in nonusage of orthoses. Because of the fact that placebo-controlled clinical trials for technical devices are not possible, we conducted a prospective, randomized, crossover 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 the orthosis. This is consistent with the findings by Lantz and Schultz,[33] who described an increased electrical activity of back muscles when a lumbosacral orthosis is worn. 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,[23–25] this improvement of balance may be accompanied by a lower

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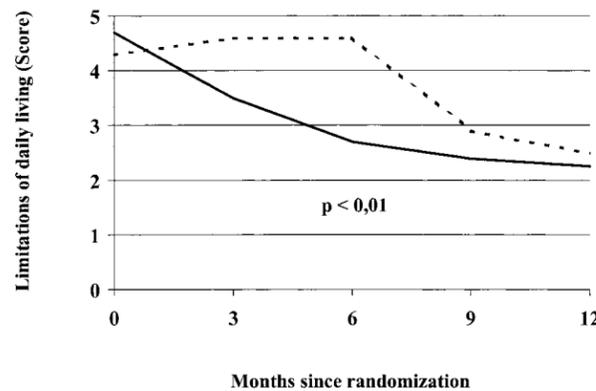March 2004   Effects of a Spinal Orthosis in Osteoporosis   **183**

Figure 6: Average pain as measured by Miltner's rating scale[5] in 28 subjects of group A (*solid line*), wearing the orthosis between months 0 and 12, compared with 31 subjects of group B (*dashed line*), wearing the orthosis between months 6 and 12. Groups are significantly different at month 6 (*P* < 0.01), whereas no statistical difference was seen at month 12.
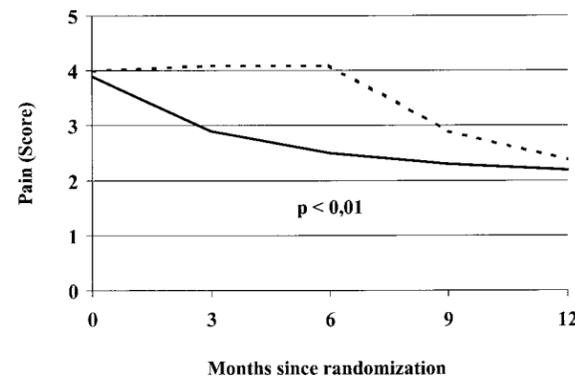

Figure 7: Limitations of daily living determined according to Leidig-Bruckner et al.[6] in 28 subjects of group A (*solid line*), with subjects wearing the orthosis between months 0 and 12, in comparison with group B (*dashed line*), with subjects (*n* = 31) wearing the orthosis between months 6 and 12. Groups were significantly different at month 6 (*P* < 0.01), whereas no statistically significant difference was seen at month 12.
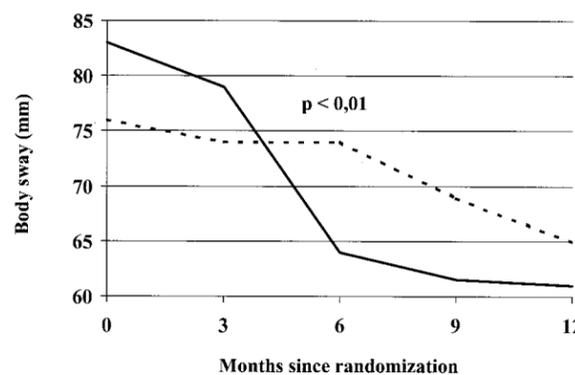

Figure 8: Body sway as measured according to Lord et al.[23] in 28 subjects of group A (*solid line*), wearing the orthosis between months 0 and 12, compared with 31 subjects of group B (*dashed line*), wearing the orthosis between months 6 and 12. Significant group differences were observed at month 6 (*P* < 0.01), whereas differences at month 12 were not significant.

rate of falls and nonvertebral fractures.[34] This is consistent with the findings by Sinaki and Lynn,[35] who described a reduction of fall risk through proprioceptive dynamic posture training in osteoporotic women with kyphotic posturing. The decrease of the angle of kyphosis seen in this study may allow better inspiration and expiration, which has been verified by an increased 1-sec vital capacity and a better 1-sec forced expiratory volume, which may decrease the risk for pneumonia and overall mortality in these patients.

The overall compliance of the study participants was excellent: all 62 study subjects completed at least 6 mos of intervention each, and another 28 subjects continued for a 12-mo period. This may be explained in part by our results that wearing the orthosis was accompanied with improved quality of life as measured by decreased pain and limitations of daily living and with increased well-being.

Thoracolumbar orthoses need to find a balance between often conflicting requirements of function, cosmetics, and acceptability.[34] We conclude that the orthosis used in this study increases trunk muscle strength and thus improves posture and body height in patients with vertebral fractures due to osteoporosis. In addition, a better quality of life is achieved by pain reduction, decreased limitations of daily living, and augmented well-being. Thus, the orthosis used in this study comes very close to an ideal, which is invisible, weightless, and performs its desired function. Given the widespread use of orthoses in various diseases, there is an urgent need for controlled clinical trials to further elucidate functions and applications of these technical devices.

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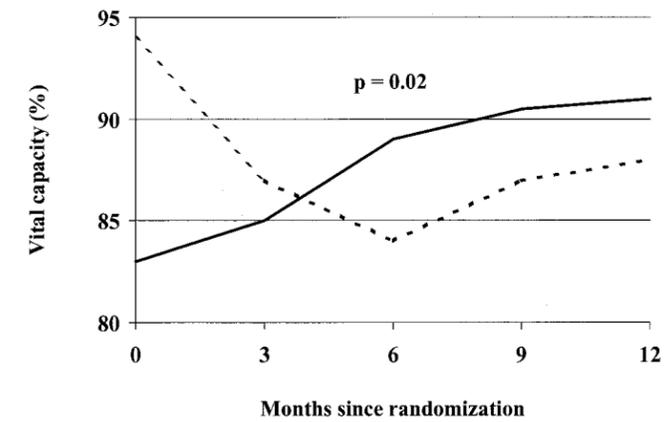

Figure 9: Vital capacity as a marker for pulmonary function[4] in 28 subjects of group A (*solid line*), wearing the orthosis between months 0 and 12, in comparison with 31 subjects of group B (*dashed line*), wearing the orthosis between months 6 and 12. Groups were significantly different at month 6 (*P* = 0.02), whereas no significant difference was seen at month 12.

pants of this study and the orthopedic technicians Florian Korte and Martin Steinke (Brandscheidt Co., Syke) for their excellent cooperation and their fitting of the orthoses for all study subjects.

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APPENDIX

Limitations in Everyday Life

Motion in General. Six abilities of everyday life, which are 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.[6]

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, 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, cleaning floor); 5 = dependent on extra help for everyday routine functions (cleaning, cooking); and 6 = nursing care needed.

Well-being

The questionnaire consists of four subscales, each containing four bipolar pairs of adjectives to be checked off in seven graduations.[5]

APPENDIX

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
Intra-psychological 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
Vigilance								
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	Unconcentrated
Focused	1	2	3	4	5	6	7	Divertable