

Osteoporosis

Bettina Begerow, Michael Pfeifer and Helmut W. Minne

Orthoses and Osteoporosis

MEDWISS BAD PYRMONT and “DER FÜRSTENHOF” Clinic, Bad Pyrmont

The present study was conducted to demonstrate the effectiveness of the Spinomed® thoracolumbar brace when used by patients with osteoporosis and osteoporotic kyphosis.

The patients were alternately randomised into treatment and observation groups in a cross-over study design. In this way it is possible to gain controlled data without withholding the anticipated benefits of the orthosis from one of the groups. The initial results after wearing the braces for six months show a marked improvement in trunk muscle strength, body sway, peak kyphotic angle, and quality of life endpoints (pain and limitations in everyday routine). Thus, in the sense of evidence-based medicine, the study proved the effectiveness of wearing the Spinomed® orthosis over a period of six months for patients with osteoporosis. In the future, proof of the effectiveness of medical aids will be required by health insurers, prescribing doctors and their patients.

The orthosis Spinomed® improves posture, trunk muscle strength, and quality of life in postmenopausal women with vertebral fractures due to osteoporosis.

Summary

Thoracolumbar braces are widely used in the care of patients with vertebral fractures due to osteoporosis. Their usefulness, however, has never been tested under standardized conditions. In this cross-over study patients had been randomized into two groups: group A started with an intervention period of six months, while group B served as controls. After six months of treatment with the orthosis Spinomed®, patients in group A showed a significant improvement of trunk muscle strength, body sway, angle of kyphosis, pain, and limitations in everyday life in comparison to patients in group B. These results indicate that Spinomed® improves posture, trunk muscle strength, body sway, and quality of life in postmenopausal women with osteoporosis. The efficacy of thoracolumbar braces needs to be investigated in prospective, randomized and controlled clinical trials prior to their introduction in patients' care.

Clinical picture

Osteoporosis of the spine is marked by diminished trunk muscle strength and reduced bone mass. Both factors increase the risk of vertebral fractures. Vertebral fractures result in a loss of body height, more pronounced dorsal kyphosis with restricted pulmonary function and, in extreme cases, contact between the ribs and pelvic rim (iliocostal friction). The resulting postural guarding to prevent pain provokes further muscle atrophy with a feeling of insecurity, progressive limitations in everyday life, and a higher risk of fractures caused by falling. More intense pain and a diminished feeling of wellbeing reduce the quality of life.

The use of orthoses or any other form of support the patient wants which does not promote immobility should be considered to prevent kyphotic posture. In such cases it is necessary to avoid additional pressure points and ensure that the orthosis is comfortable to wear. Therefore, the opinions and suggestions of affected patients were taken into account during the development process, thus laying the foundations for high patient compliance.

The basic surmise was that suitable orthoses strengthen the trunk muscles and can prevent progressive kyphosis. Countering the tendency for the centre of gravity to shift anteriorly reduces body sway. This could reduce the risk of falling and sustaining bone fractures. In addition, the patients would be able to care for themselves more and enjoy a better quality of life.

Thus orthoses could play an important role in rehabilitation of the musculoskeletal system in patients with spinal osteoporosis.

Methods and study design

To test this hypothesis we conducted a clinical cross-over study in which the participating patients were randomised into two groups, A and B. Group A wore the orthosis for six months, group B served as a control. After six months the groups are then swapped over. This study design ensures that both groups can profit from wearing the thoracolumbar brace, while still providing controlled, randomised data. The primary endpoint was the kyphotic angle as measured by stereo scanning photography of the back as well as the patients' trunk sizes measure by a standardised procedure. Secondary endpoints included measurements of the maximum isometric power of the trunk extensors using a Digimax machine, and the scale that Leidig-Bruckner published in 1997 for quantifying limitations in everyday routine.



The Spinomed orthosis, based on the 'back-pack' principle, holds the spine in an erect posture following osteoporotic vertebral fractures. It consists of a cold malleable back pad which can be adjusted individually to the shape of the back using a series of straps secured with Velcro strips.

Material: thoracolumbar brace Spinomed®

The thoracolumbar brace Spinomed® is worn like a 'back-pack' and weighs 450 grams. It consists of a cold malleable back pad which is moulded to suit the patient's back, and a system of straps with Velcro fasteners which is also adapted to the patients' individual body size (see Figure).

The straps have a stabilising effect in the lumbar spine and counter possible hyperlordosis. The system also pulls the shoulders back. This stretches the chest muscles and strengthens the dorsal extensors. The concept is based on the principle of "biofeedback". This means that, although the orthosis cannot hold the wearer in the desired erect posture, it does encourage such a posture. The wearer him/herself must adopt and maintain this posture.

This explains why the muscles are activated and strengthened. Due to this muscle stimulation the orthosis should only be worn for a few hours at a time, and the wearing time should be increased gradually.

Results

The randomised, controlled study has already shown the scientifically demonstrable effects of wearing the Spinomed® thoracolumbar brace.

Both groups consisted of 30 female patients with a mean age of 73 years, a mean height of 157 cm, and an average body weight of 64 kg. The patients in both groups had lost 9 cm in height, and all the volunteers had suffered an average of 2 vertebral fractures.

The study endpoints were also the same in the two groups at the start of the study. These were the maximum isometric power of the dorsal extensors, body sway over 30 seconds, the maximum dorsal kyphotic angle measured by 3D photography, vital capacity, and quality of life parameters recorded by a questionnaire.

Wearing the Spinomed® thoracolumbar brace for at least 2 hours daily over a period of 6 months led to the following changes:

The treatment group showed a demonstrable reduction in the maximum dorsal kyphotic angle compared with the control group. The maximum isometric power of the dorsal extensors in the treatment group increased by over 30%. Body sway was significantly improved in comparison with the control group. Although the vital capacity remained virtually unchanged over the six month wearing period, it deteriorated in the control group.

Both parameters for the quality of life (pain and limitation in everyday routine) improved in the treatment group, while they tended to remain unchanged in the control group.

Discussion and interpretation of the results

The data presented above are the results of an interim analysis because the study has not yet been completed. The results are from the first study phase which covered the first six months. This so-called "pre-post comparison" shows differences between the two groups in terms of a marked strengthening of the dorsal musculature and reduced body sway. The results, however, are already most encouraging because they are associated with less pain and improved functioning in everyday activities. It must be mentioned here that analgesic consumption in both groups was generally low, and that only about 10% of the volunteers took pain-killers.

Another successful aspect of therapy was the reduction in the maximum kyphotic angle which was accompanied by a parallel slight increase in body height. Overall this must be interpreted as an improvement in posture. This was also confirmed by the patients who wore the orthoses. The users reported that they found the Spinomed® brace most helpful when doing light household work and on longer walks. Altogether the volunteers felt more resilient and needed fewer rests during the day.

To our knowledge this is the first evidence-based study conducted to prove the effectiveness of a thoracolumbar brace. Treatment of osteoporosis patients with supporting corsets and corselets to date has been based entirely on the clinical experience of the prescribing doctors, and thus does not satisfy the stringent quality demands of evidence-based medicine. These quality criteria, which can only be satisfied by controlled, randomised clinical studies, do not only apply to drugs, but also equally to medical aids, and in future will not only be required by health insurers, but also by the patients themselves.

References

1. Kunz R, Ollenschläger G, Raspe H, Jonitz G, Kolkmann FW: *Lehrbuch Evidenzbasierte Medizin in Klinik und Praxis. Deutscher Ärzte-Verlag Köln 2000.*

2. *Leidig-Bruckner G, Minne HW, Schlaich C et al.: Clinical grading of spinal osteoporosis: quality of life components and spinal deformity in women with vertebral osteoporosis. J Bone Miner Res 1997; 12: 663-75.*
3. *Minne HW et al. Osteoporose 2001: Gesellschaftliche Bedeutung - Diagnostik - Therapeutische Maßnahmen. Springer Verlag Berlin-Heidelberg 2001.*
4. *Pfeifer M, Begerow B, Minne HW: The orthosis Spinomed® improves posture, lung function, trunk muscle strength, and quality of life in postmenopausal women with spinal osteoporosis: results of a prospective, randomized, and controlled, cross-over study. J Bone Miner Res 2001; 16(Suppl. 1): abstract SA 373.*

Address for correspondence:
Dr. sportwiss. Bettina Begerow
Dr. med. Michael Pfeifer
Prof. Dr. med. Helmut W. Minne
MEDWISS BAD PYRMONT
Am Hylligen Born 7
31812 Bad Pyrmont
Tel.: +49-5281-151414
FAX: +49-5281-151100
Mail: iko_pyrmont@t-online.de

Published in:
Orthopädie Technik 2/02
Pages 86 - 89