L. Vogt[1]
H.-D. Hildebrandt[2]
K. Brettmann[1]
M. Fischer[3]
W. Banzer[1]

Clinical Multidimensional Evaluation of a Multifunctional Osteoporosis-Orthosis

Klinische mehrdimensionale Evaluation einer multifunktionalen Osteoporoseorthose

ABSTRACT

Purpose: The current study determined the immediate and one year follow-up effects of a multifunctional osteoporosis orthosis, manufactured without rigid elements. **Materials and methods:** The study evaluated 54 osteoporosis patients before and after a 12 months time interval. Patients were randomly assigned to two study groups. The participants of the test group were asked to wear the orthosis throughout the one year test period. Patients of the control group carried no specific device. First and second measurements evaluated the thoracic kyphosis as well as the spinal curvature during upright standing. The study also investigated the experienced pain level and the number of falls. During the second examination the spinal posture of twelve randomized selected subjects was evaluated before and after a three hours orthosis wearing period. **Results:** The immediate effects, obtained during the first examination, demonstrated a substantial amount of spine straightening facilitated by orthosis wearing. During the orthosis condition the subjects accomplished at least 60% of their maximum active thoracic erection. Almost 80% to 90% of all participants experienced an increase in spinal erection and trunk stability. Subjects were able to maintain the straightened position over extended time periods. **Conclusions:** The results point to a direct use of the examined orthosis. Facilitating sensomotor effects are achieved without rigid elements. The effects induced by air pads improve the relief of pain by gate control mechanisms. Erect posture, pain inhibition, enhanced activity along with improved coordination and more effective physiotherapy should reduce the frequency of falls and the fracture incidence.

KEY WORDS:

• Osteoporosis • orthosis • thoracal kyphosis proprioception • air pad • compliance

[1] Abteilung Sportmedizin [Department of Sports Medicine] Johann-Wolfgang-Goethe University, Frankfurt am Main (Prof. Dr. Dr. W. Banzer)
[2] Medizinisch-Orthopädietechnisches Entwicklungs- und Beratungsbüro Ahnatal
[3] Abteilung Nuklearmedizin [Department of Nuclear Medicine], Klinikum Kassel

Address for correspondence:
Dr. Lutz Vogt Johann-Wolfgang-Goethe-Universitaet Frankfurt am Main • Abteilung Sportmedizin Ginnheimer Landstrasse 39 • 60487 Frankfurt am Main • E-Mail: L.Vogt@sport.uni-frankfurt.de

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INTRODUCTION AND STATE OF RESEARCH

Osteoporosis is a major medical and socioeconomic problem that is attracting more and more attention. It is known to lead to loss of bone density and to a change in spinal posture with added load on mechanically less resistant ventral parts of the vertebrae. According to Franck [1], the overstretching of the extensor muscles of the back with reduced circulation leads to the significant reduction of the back extensor strength. Pain results from the fractures, the malposition of the facets of the small vertebral joints, from irritation of the capsules and ligaments as well as from the situation of the extensor muscles.

According to Abendroth [2] the nociception alters the movement sequence. The proprioceptive information becomes less significant or is changed, a reduced muscular stabilization with segmental instability results, and this further increases the risk of fracture [2]. An immobilization of the patients as a result of the pain, with reduction of adequate, muscle stimulus and reduction of circulation, accelerates the pathogenetic process, and lack of coordination increases the risk of falling [3].

Measures to improve the spinal posture and, in this context, specifically for the erection of the thoracic spine are therefore clinically indicated. Consequently, the therapeutic process comprises in addition to drug treatment a suitable training of muscle strength and coordination as well as posture training. The fitting with an orthosis expands the range of treatment measures. Commercially available hard orthoses are, on the one hand, used for the immobilization of fractures during the acute pain stage, and in some cases devices equipped with rigid pads are also used as warning bandages to prevent inclination [4]. When using rigid shells, factors such as atrophy of the trunk muscles and restricted respiratory movement with resultantly decreased wearer acceptance are to be borne in mind. Available soft orthoses are designed to counteract the kyphosis development by means of passively acting elements [5,6].

Findings from proprioception and sensomotor research indicate that, in addition to a distinct pain reduction due to stimulation of mechanoreceptors (gate control theory), functional back support bandages [7,8] proprioceptively induce or strengthen muscle work towards normal [9-11].

Orthopedic technology presents manifold requirements and target parameters, some of which necessitate, overlap or enhance one another, for the achievement of the greatest possible preventive or rehabilitative benefit in osteoporosis by means of the fitting of an appliance.

These include: Erection of the spine, pain reduction by improving the bone, arthrogenic and soft tissue situation, increasing activity, a normalized muscle recruitment with muscle stabilization and optimization of coordination, muscle activity as a suitable stimulus for bone adaptation, reduction of fracture risk by erection, bone adaptation and prevention of falls, and pronounced wearer comfort in order to prevent compliance problems since it is desired that the appliance be worn all day.

It was with this in mind that in the year 2001 Dr. H.-D. Hildebrandt developed an orthosis specially designed for female osteoporosis patients.

PRODUCT DESCRIPTION

The osteoporosis orthosis[1] "Osteo-med", Thämert company is a therapeutic appliance designed to resemble as far as possible the piece of clothing known as a bodysuit (**Fig. 1**). The dorsal fabric panel from the sacrum to the base of the neck and the ventral fabric panel from the crotch to below the breast are nonelastic. They are connected by means of two pairs of Velcro tabs in the lateral lumbar region to increase the lumbosacral pressure (**Fig. 1**). **Fig. 2** shows, on the outside for demonstration purposes, the aid pads - the lumbosacral air pad and the two thoracic air pads - otherwise found in the inner pockets. The air pads are filled with air only to between 2/3 and 3/4 of their maximum possible capacity and ensure a gentle massage with effects on proprioception, circulation and suppression of pain in the lumbar and thoracic segments of the spine. The patient can sit very comfortably in a leaning position.

For a more detailed description of the product please refer to Hildebrandt et al. [12,13].

PURPOSE OF THE INVESTIGATION

In view of the changes in spinal posture, particularly in the area of the thoracic spine as outlined above, and their significance for quality of life [14], a flattening of the osteoporosis-related pathological spinal curvature achieved by orthosis-related stimulation of postural muscle work was investigated using the objective measuring parameters thoracic spine kyphosis angle and spinal topography.

The purpose of the present investigation was to record immediate orthosis-related changes in the spinal posture in the sagittal plane as well as the effect of wearing the appliance for one year on the spinal posture of female patients diagnosed with postmenopausal osteoporosis. Furthermore, the sustainability of appliance-indicated postural changes was evaluated in an uninterrupted wearing test lasting several hours. The evaluation of biomechanical characteristics was accompanied during the one-year progressive investigation by means of questionnaire-based surveys on the erection, pain relief, increasing capacity for work, perception of safety and stability as well as fall development as experienced subjectively by the patient.

[1] "Osteo-med", Thämert company

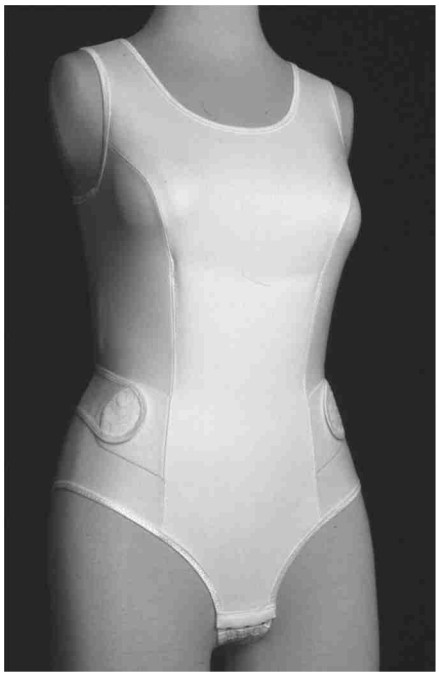


Fig. 1
Osteo-med osteoporosis orthosis (front view).

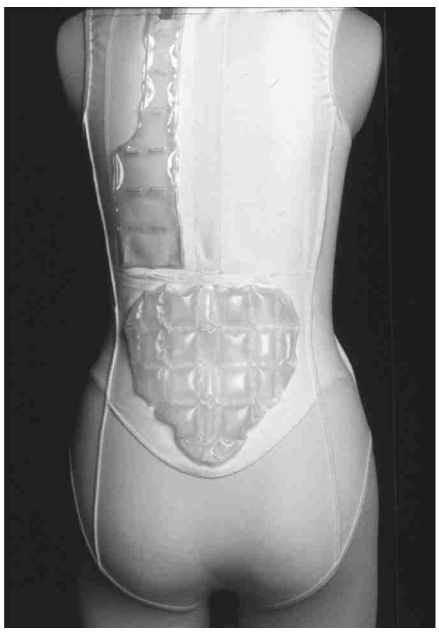


Fig. 2
Dorsal view (only one thoracic air pad shown outside for demonstration purposes).

Tab. 1 Inclusion and exclusion criteria

Inclusion criteria
- women at least 2 years after menopause
- osteoporosis-related fracture with distinctly lowered values measured in the lumbar spine and/or neck of the femur (< - 2.5 SD - deviations in the t-score) in the DXA measurement
- reduced bone mineral content in the lumbar spine and/or neck of the femur (total) (< - 2.5 SD - deviations in the t-score) in the DXA measurement, but without fracture
- active erection of spine possible
Exclusion criteria
- vertebral fractures fitted surgically with metal implants
- pronounced degenerative spinal alterations and obesity
- allergic or other skin diseases
- carcinoma disease with possible intraosseous metastasis
- ongoing osteoporosis-specific drug treatment

METHOD

For the a priori calculation of the optimal random sample size an α-level of 1 % and an error probability of $\beta = 0.1$ was set (BiAS for Windows 7.0). The variance δ^2 (21.16) and the minimum medically relevant difference (2.5 - 1/3 of the average actively achieved erection of the spine) was estimated and justified on the basis of the results of an initial preliminary examination (n = 6). Accordingly, 54 female patients were included in the kinemetric analysis of the immediate effects of the appliance.

TOTAL RANDOM SAMPLE (INITIAL MEASUREMENT)

The selection of the random sample of patients was carried out on the basis of defined inclusion and exclusion criteria (**Tab. 1**). In order to keep the medicinal effect constant, an identical standard treatment was commenced in the test group and in the control group at the start of the study. At the first medical examination 54 out of the 64 patients (age: 63 $\pm$ 8.6 years; height: 161.1 $\pm$ 6.5 cm; weight: 67.8 $\pm$ 10.4 kg) were able to actively erect the thoracic spine to a therapeutically relevant extent (clinical inspection). All 54 patients were given an antiosteoporotic agent (bisphosphonate, Actonel) during the study.

Changes in the osteodensitometry values will be analyzed within the framework of a 2-year follow-up survey.

ANALYSIS OF IMMEDIATE EFFECTS

A PC-assisted 3D real time ultrasound topometry system (Zebris® CMS 70) described as sufficiently precise and reliable was used for recording the data [15-17]. The determination of the thoracic spine kyphosis in degrees, which formed the core of the investigation, was based on the recording of the angle enclosed between C7 and Th12 in the sagittal plane [18] (**Fig. 3**). For the estimation of the change in posture induced by the Osteo-med osteoporosis orthosis the kyphosis angle was recorded under three different experimental conditions and expressed with reference to the habitual posture:
- habitual (spontaneous) posture
- deliberate max. active spinal erection without orthosis
- spontaneous posture when wearing the Thämert Osteo-med.

The additional measurement of the spinal curvature with and without orthosis ensures the retrospective inspection of the entire spinal topography and permits the direct comparison of the visualized course of the curvature (**Fig. 4**). The topometry also allows a comparison of the habitual spontaneous posture during the course of the one-year observation period and serves for the evaluation of the effect of the appliance subject to the influences of possible disease-related changes in posture in the test group and in the control group. The inclusion of data is based on topometry using the ultrasound pen and was carried out after the manner of Dalichau [19].

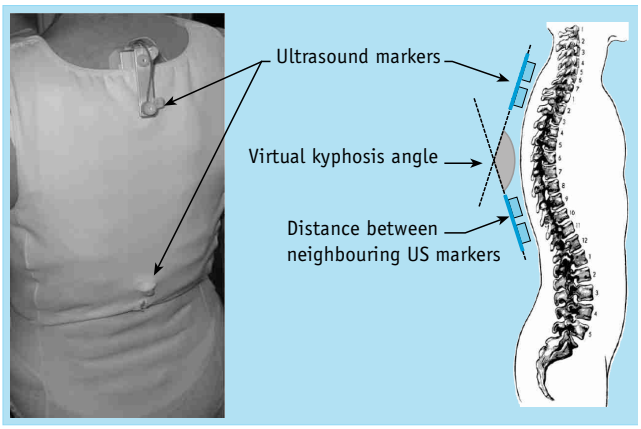
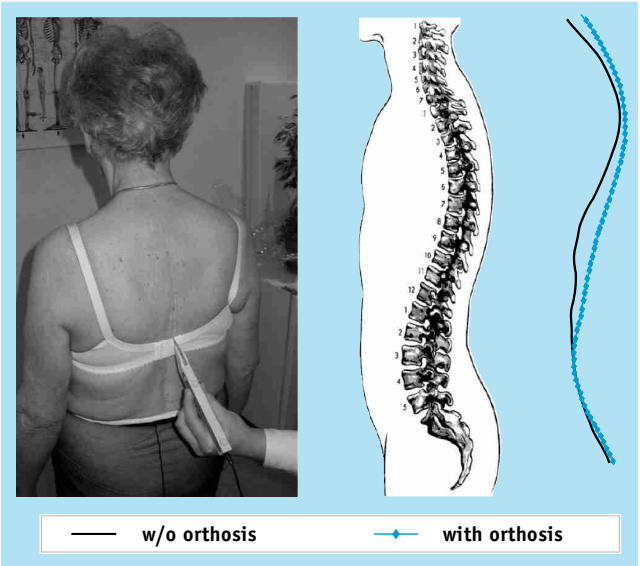


Fig. 3 Marker positioning and determination by ultrasound topometry of the "virtual" kyphosis angle of the thoracic spine.

Fig. 4 Measuring with ultrasound pen to compare the spinal topography.



INVESTIGATION OF MEDIUM TERM EFFECTS

In order to investigate the effects on spinal posture of wearing the appliance for approx. one year the patients were randomized following the first examination stage and assigned to a test group or to a control group.

PARTIAL RANDOM SAMPLE (SECOND MEASUREMENT)

At the time of the first examination an active erectibility of the spine was recognizable in all 54 patients. For 5 of these 54 patients the orthosis-related erection displayed an uncertainty of measurement The area referred to as the measurement uncertainty interval is defined after the manner of the procedure tests by Dalichau [19]. The determination of the individual changeability of the spinal shape in the case of repeat measurements is described with a measuring error of 1.18 - 1.44. (< 1.5) for which reason they were excluded from any further examinations. The assignment to the test group or to the control group was carried out by randomization on the basis of the year of birth. This resulted in 23 participants for the test group and 26 for the control group.

Seven participants in the test group and twelve in the control group had to be excluded from further participation in the study and data analysis due to various reasons (comorbidity, intolerance of and/or refusal to take medication, uncontactability, lack of time, patient's earnest wish to be assigned to the test group).

Consequently, the random sample comprised 16 test group patients (age: 63.9 ± 7.1 years; height: 158.9 ± 6.6 cm; weight: 65.4 ± 8.8 kg) and 14 control group patients (age: 62.6 ± 11.2 years; height: 161.2 ± 4.2 cm; weight: 64.6 ± 9.2 kg). The mean intervals between the first and the second measurement were 13.9 ± 2.7 (TG) and 11.9 ± 2.2 months (CG).

Fig. 5 provides an overview of the formation of the groups as a function of the study stages.

KINEMETRIC MEASUREMENT

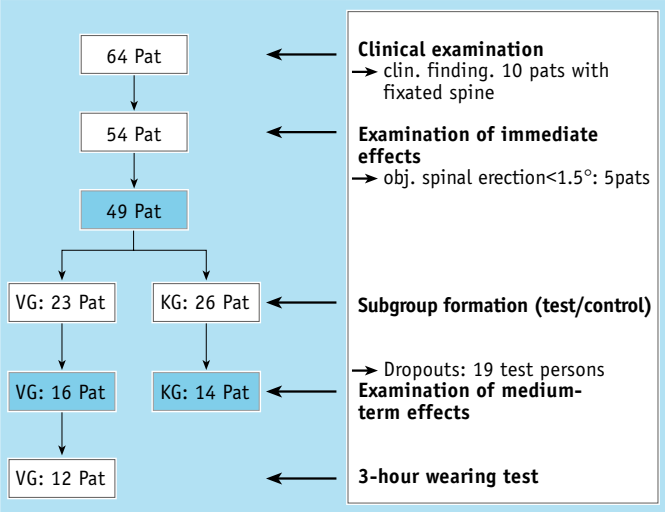
During the follow-up examination the kyphosis angle and the spinal curvature were recorded again under the effects of the orthosis and in relation to the posture without the orthosis as well as to the actively possible erectibility of the spine.

3-HOUR WEARING TEST

In order to determine the effects on spinal posture of wearing the orthosis for several hours, the kyphosis angle was measured again during the follow-up examination in twelve randomly selected patients (age: 61.9 ± 9 years; height: 160.7 ± 7.1 cm; weight: 71.6 ± 12.3 kg) within a time interval of three hours.

During this time the orthosis was worn without interruption and the test persons pursued their normal day-to-day activities. The surveys evaluate a possible diminishing of the effect in the case of uninterrupted wearing.

[2] The area referred to as the measurement uncertainty interval is defined after the manner of the procedure tests by Dalichau [19]. The determination of the individual changeability of the spinal shape in the case of repeat measurements is described with a measuring error of 1.18 - 1.44.



VG = test group; KG = control group
Fig. 5 Total patient group and formation of subgroups

Tab. 2 Assessment instruments

Proof of osteoporosis using DXA
Determination of kyphosis angle by ultrasound topometry
Measurement of spinal topography by ultrasound topometry
Subjective self-rating using pain scale
Scaled assessment of wearer comfort
Verbal descr. of subjective perception of posture and stability
Info on physical activity, fall tendency and wearing frequency

Tab. 3 Change in mean kyphosis angle (± standard deviation) using Osteo-med orthosis in relation to deliberate maximum possible active erection of spine

Change in posture with Osteo-med orthosis	Deliberate active erection of spine	Osteo-med orthosis	Percentage erection achieved
≥1,5° (n= 49)	6.5 ± 3,91°	3.4 ± 1.9°	59.9 ± 22.9 %

Tab. 4 Number of test persons with appliance-induced erection of the spine of less than 1/3; 1/3 - 2/3 and more than 2/3 of the possible active erection

n = 49	Number	%
< 1/3	8	16.3
1/3 – 2/3	22	44.9
> 2/3	19	38.8

QUESTIONS TO PATIENTS

Subjectively perceived pain intensity, wearer comfort, wearing frequency, postural perception, stability perception, day-to-day activity and tendency to fall were recorded retrospectively during the follow-up examination.

Using a numeric scale (range of values 1-10, 1 = no pain, 10 = max. imaginable pain) the subjectively perceived pain intensity was recorded with and without the orthosis. In addition, the orthosis-related effect on pain occurring with various types of load (standing, walking, house- and garden work, sitting) was inquired about.

The evaluation of the wearer comfort was also carried out on the basis of a numeric scale (range of values 1-10, 1 = very comfortable, 10 = very uncomfortable).

The wearing frequency was expressed per week and per day. The assessment of the subjective perception of posture and stability was carried out by means of defined verbal descriptions. Furthermore, effects on physical activity in prescribed areas (household, sports) were inquired about. Orthosis-related effects on the tendency to fall were also recorded.

Tab. 2 provides an overview of all the assessment instruments used during the study.

RESULTS

Immediate effects

Kinemetric measurements

The 49 patients who displayed an active reduction or elimination of thoracic kyphosis achieved an orthosis-induced mean erection of 3.4 ± 1.9°. Therefore, by wearing the orthosis, the patients achieved a mean percentage erection of approx. 60% with reference to the possible active erection (**Tab. 3**). The "orthosis-induced relative erection" displays a highly significant deviation ($p < 0.001$) from the specified constant 0% (= erection during habitual "normal" posture). The post hoc power calculation was carried out using the software package BiAS for Windows 7.0 on the basis of the algorithms of the one-sample t-test. The post hoc analysis yields a power of $\varepsilon = 0.9604$.

If an appliance-induced possible active erection of at least 1/3 is defined as a criterion for the proof of efficacy of the orthosis, this hypothetically required minimum effect of the appliance can be proven in more than 80% of all test persons examined (**Tab.4**).

The extent of the appliance-induced modifications of posture for the spine as a whole is shown by way of example in **Fig.4**. The spinal profiles determined also confirm that the clinically relevant orthosis-related erection is not limited to the thoracic spine.

Medium-term effects and 3-hour wearing test

The percentage erection achieved in the test group and the control group displayed no significant differences in the means at the beginning of the approx. one-year intervention test.

Kinemetric measurements

The results of the follow-up examination reveal for the test group an almost comparable effect on the erection

Tab. 5 Means and 95% confidence intervals of immediate modification of the kyphosis angle while wearing the Osteo-med orthosis at the first examination and after a one-year wearing phase (test group; n = 16) in comparison with the control group (n = 14)

Osteo-med orthosis		Mean ± SD	95% CI
Test group (n = 16)	1st examination	2.9 ± 1.3°	2.2 - 3.7°
	2nd examination	2.9 ± 0.7°	2.5 - 3.3°
Control group (n = 14)	1st examination	3.1 ± 1.0°	2.3 - 3.7°
	2nd examination	2.5 ± 0.8°	2.1 - 3.0°

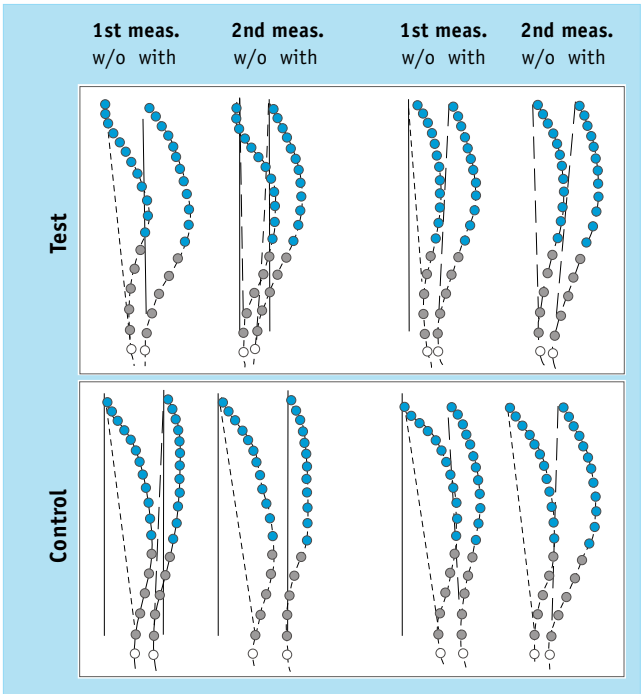


Fig.6 Overview by way of example of comparative spinal curvatures of two test persons in each case from the test group and from the control group with and without Osteo-med at 1st and 2nd examination.

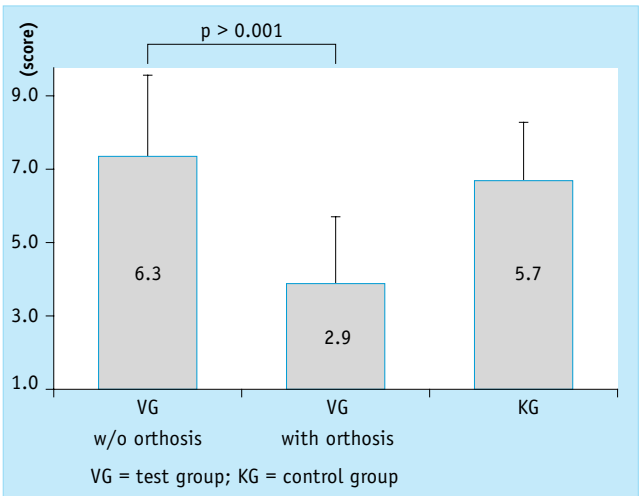


Fig.7 Representation of the mean subjective pain perception of the test group with and without orthosis and of the control group (range of values of the numeric scale 1-10, 1 = no pain, 10 = maximum imaginable pain).

Tab. 6 Extent of active erection of the spine and induced change in the kyphosis angle before and after wearing the Osteo-med orthosis for three hours (n = 12)

3 hour wearing test n=12	Active erection of spine	Osteo-med orthosis	Percentage erection achieved
Measurement I	4.7 ± 1.-3°	3.0 ± 1.0°	66%
Measurement II	4.3 ± 1.1°	2.8 ± 0.9°	67%

of the spine expressed in degrees in comparison with the first examination (**Tab.5**). In relation to the deliberate maximum possible active straightening an additional improved erection of the spine (67 vs. 57%) is achieved with the orthosis in the test group. For the control group the orthosis-related erection is 53% of the possible active erection.

The ultrasound topometry of the surface relief in the comparison of the spinal posture with and without orthosis illustrates the straightening effect of the Osteo-med osteoporosis orthosis. An overview of comparative spinal curvatures of the test group and the control group is shown in **Fig.6**.

3-hour wearing test

The results of the 3-hour wearing test displayed in the comparison of the two measuring times an orthosis-related active erection of the spine of 66 and 67%, respectively, in relation to the maximum possible deliberate active erection (**Tab.6**).

Questions to patients

The mean pain score of the control group was given as 5.7 ± 1.6. Nine out of 16 patients in the test group (56.3%) reported osteoporosis-related pain (score 6.3 ± 2.2). The mean pain score during the wearing period confirms with 2.9 ± 1.8 a significant (p > 0.001) orthosis-related pain reduction (**Fig.7**).

Seven out of nine patients who reported a pain-induced limitation of load duration in various day-to-day activities confirmed a load capacity unlimited in terms of time or a distinct increase in the load duration when wearing the orthosis. Only two patients confirmed no orthosis-related increase in the load duration.

All the patients described the appliance as comfortable to wear. The information concerning the wearer comfort recorded by means of a numeric scale (range of values 1 - 10, 1 = very comfortable, 10 = very uncomfortable) were in the area of 1 for six patients, five patients reported a value of 2 and another five a value of 3.
According to the reports by persons in the test group the Osteo-med osteoporosis orthosis was worn for an average of 13.3 ± 2.1 hours/day on 6.3 ± 0.8 days per week during the mean wearing period of almost 14 months.

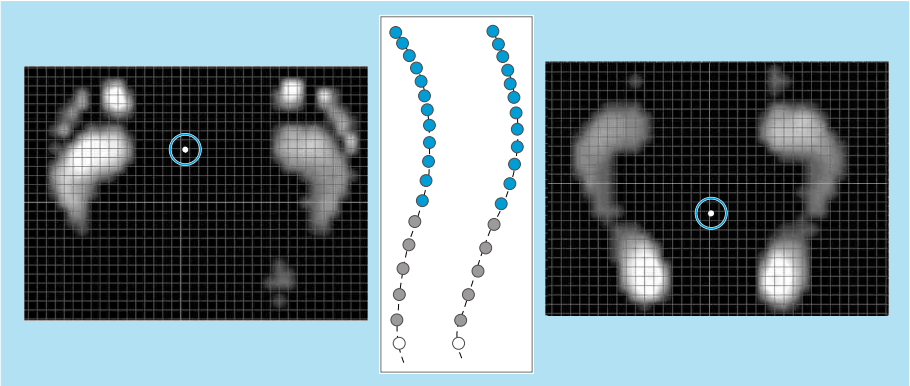


Fig.8 Projected center of gravity of body (circle mark) while standing with anterior and posterior tilting of trunk

While wearing the osteoporosis orthosis 13 (81.3%) of the patients questioned perceived their posture as more upright and 15 (93.6%) patients reported a feeling of greater stability in the trunk segment. According to their own statements 5 (31.3%) of the patients questioned felt more protected, 4 (25%) felt their posture to be safer.

Five patients reported an orthosis-related increase in their physical activity when coping with day-to-day demands. Seven of the patients questioned reported that they were more active in terms of sports. In the control group two patients confirmed an increase in day-to-day activities while six reported an increase in sporting activity.

Six patients in the test group and three patients in the control group reported that they had had several falls before the start of the study. During the follow-up period no falls occurred in the test group, while four patients in the control group reported having fallen during the follow-up period.

DISCUSSION

According to the results obtained, the wearing of the orthosis brings about a spontaneously active erection of the spine of 60% on average of the deliberate maximum possible active erection. The wearing of the orthosis leads therefore to a clinically significant erection of the trunk signifying an improvement of posture and statics and to major statistical effects.

These results obtained locally for defined segments of the spine are verified impressively by means of the ultrasound topometry of the entire sagittal surface relief of the lumbar and thoracic spine performed in parallel (cf. 6.2.1??). In a large portion of the study population they also illustrate, in combination with the reduction of the lumbar lordosis and thoracic kyphosis, the dorsal guidance of the trunk (including the shoulder and head section) by means of the stretching of the hips and upright pelvic posture. This shift of the body's center of gravity in the posterior direction is accompanied by a centering of the projected center of mass in the area of the bipedal supporting surface (**Fig.8**). This shift of the involved sections of the body (trunk, head, upper extremities) with consequences for the overall statics results in an improvement of the stance and gait stability and explains the reduction in fear and incidence of falling proven in the present progressive study and in other appliance surveys [20]. The effects are nevertheless associated with a subjectively increased feeling of safety with an increase in day-to-day physical activity, participation in working, social and cultural life and therefore in the perceived quality of life.

The second part of the study focussed on the question of the sustainability or the possible reduction in the spontaneous effect with increased wearing time. At the time of the follow-up examination a 53% erection is still achieved in the control group. In the test group even a 67% spontaneous erection of the spine is achieved after a one-year wearing phase immediately after putting on the orthosis. It can be concluded that even when the orthosis is worn permanently the proprioceptively facilitating function of the appliance does not diminish. These conclusions are also substantiated by the results of the 3-hour wearing test.

The results of the 3-hour wearing test confirm that even after wearing the orthosis for approx. three hours no decrease in effect is observed. Therefore a 66% erection resulting from wearing the orthosis proven in the 3-hour time interval in addition to the extent of the orthosis-related erection of the spine after a one-year wearing period (67% of the active erection) counts as further evidence of the sustainability of this specific appliance. The results demonstrate all in all the function and the potential of the reaction and adaptation mechanisms on which this is based as well as the correctness of the selected design and manufacturing principles of the orthosis.

Although no validated questionnaires were used in the investigation the results of the pain score confirm that subjectively perceived osteoporosis-related pain is distinctly reduced or ceases completely during the wearing periods. The results can therefore document the erection-related pain reduction and the pain reduction due to gate control effects resulting from the orthosis. These mechanisms can also be regarded as essential for the frequently increased

pain-free load duration in the coping with the various demands of day-to-day life. Improvements of the feel for the body and greater safety reduce not least of all the incidence of falls. The increased physical activity in day-to-day activities and during leisure time causes one to expect positive consequences for social participation and independence.

On the basis of the objectively measured and subjectively perceived erection with reduction of the load on the particularly vulnerable ventral portions of the thoracic vertebrae, the reduction in falls due to improved coordination and the subjective increase in stability it can be presumed that the orthosis can contribute quite significantly to the prevention of fractures right from the beginning. In the long term an additional positive effect on bone density is to be expected due to pain reduction and increased activity with use of the muscles. Particularly the wearer comfort and the subjectively perceived positive effects yield a good compliance with great willingness to wear the appliance and effect intensity.

CONCLUSION

The complete effect in the form of an active spontaneous erection is achieved without rigid elements or stabilization aids. The appliance tested stimulates the use of the body's own neurophysiological resources to improve posture and function. The mere wearing of the orthosis ensures essential elements of an effective osteoporosis treatment.

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