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Efficacy of a Flexible Orthotic Device in Patients with Osteoporosis

Wirksamkeit einer flexiblen Rumpforthese bei Osteoporosepatienten

Abstract

Objective: The efficacy of a flexible orthotic device in osteoporosis patients was investigated. **Materials and methods:** An open observational study was performed on 50 osteoporosis patients in order to investigate the efficacy of a new osteoporosis orthotic device (Osteo-med, Thämert). The outcome parameters were pain, activities of daily living, and individual compliance. The observation period was app. 2.5 months, and the orthotic device was worn continuously during daytime. **Results:** At the end of the observation period there was a highly significant reduction in pain under stress (from 6.1 ± 1.7 to 4.5 ± 1.4 [$p < 0.00001$]), pain when driving (from 5.2 ± 2.4 to 3.8 ± 1.9 [$p < 0.00001$]), and pain at rest (from 4.1 ± 2.4 to 3.1 ± 1.9 [$p < 0.0001$]). More than 50% of the patients judged their ability to perform everyday activities as „much better“ or „better“. As well as the main outcome parameters, the aspects of „comfort“, „handling“, „fit“, „skin tolerability“ and „feeling of safety“ were rated as being better by patients who had been previously treated with other orthotic devices or bandages than by patients without previous treatment. These differences were statistically significant for the first four aspects. **Conclusion:** This Thämert Osteo-med orthotic device could be a useful addition to the medical care of osteoporosis patients and a complement to drug treatment and physiotherapy with regular exercises.

Key words

Clinical trial · orthotic device · osteoporosis treatment · physiotherapy

Zusammenfassung

Fragestellung: Es wurde die Wirksamkeit einer flexiblen Rumpforthese bei Osteoporosepatienten untersucht. **Material und Methodik:** Bei 50 Osteoporosepatienten wurde in einer offenen Anwendungsbeobachtung die Wirkung einer neuen Osteoporoseorthese (Osteo-med, Fa. Thämert) überprüft. Zielparameter waren Schmerz, Alltagsaktivität und individuelle Compliance. Der Beobachtungszeitraum betrug ca. 2,5 Monate, die Orthese wurde tagsüber durchgehend getragen. **Ergebnisse:** Am Ende der Beobachtungsphase zeigte sich bei allen 50 Patienten eine hochsignifikante Reduktion des Schmerzempfindens. Unter Belastung nahmen die Schmerzen von $6,1 \pm 1,7$ auf $4,5 \pm 1,4$ ($p < 0,00001$), beim Autofahren von $5,2 \pm 2,4$ auf $3,8 \pm 1,9$ ($p < 0,00001$) und in Ruhe von $4,1 \pm 2,4$ auf $3,1 \pm 1,9$ ($p < 0,0001$) ab. Über 50% der Patienten beurteilten die Fähigkeiten, Alltagsverrichtungen nachgehen zu können als „deutlich besser“ oder „besser“. Neben dem Hauptzielparameter Schmerz wurden in der vorliegenden Studie die Aspekte „Tragekomfort“, „Handling“, „Passform“ und „Hautverträglichkeit“ von den Patienten mit Vorbehandlung signifikant, der Aspekt „Sicherheit empfinden“ besser benotet als von den Patienten ohne Vorbehandlung mit anderen Orthesen oder Bandagen. Ein weiterer interessanter Aspekt zeigt sich im Einfluss der Physiotherapie auf das Behandlungsergebnis: Wurde die Physiotherapie mit Beginn der Orthesenbehandlung abgebrochen, war die Beschwerdebesserung signifikant geringer ausgeprägt, als bei den Patienten, bei denen die Physiotherapie fortgesetzt wurde ($p = 0,023$). **Schlussfolgerung:** Neben der medikamentösen und physikalischen Therapie mit regelmäßiger Übungsbehandlung könnte die hier untersuchte Os-

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Bibliografie

Phys Med Rehab Kuror 2005; 15: 1 – 6 © Georg Thieme Verlag KG Stuttgart · New York
ISSN 0940-6689

teoporoseorthese eine sinnvolle Ergänzung der nicht medikamentösen medizinischen Versorgung von Osteoporosepatienten darstellen. Eine bestehende Physiotherapie sollte aufgrund der hier erhobenen Daten nicht durch die Behandlung mit einer Osteoporoseorthese ersetzt werden, vielmehr scheint die gemeinsame Behandlung einen positiven additiven Behandlungseffekt zu besitzen.

Schlüsselwörter

Osteoporosebehandlung · Orthesen · Physikalische Therapie · klinische Studie

1. Introduction

Osteoporosis is regarded as being a systemic disease of the skeletal system and involves a reduction in bone mass and changes in the microstructure of bone tissue, resulting in increases in the brittleness of bones and the risk of fracture.

Osteoporosis is clinically important because of osteoporotic fractures that frequently affect the vertebral bodies, femoral neck and distal radius, leading to considerable impairment of health and quality of life.

The incidence of osteoporosis as such and osteoporotic fractures increases exponentially with age [1]. Vertebral body fractures mostly tend to occur in the central kyphotic part of the thoracic spine (Th 7–8) and the thoracolumbar transition [2].

Estimates for Germany indicate that the incidence of osteoporotic fractures of the vertebral bodies may be even higher than that of femoral neck fractures [3].

The obvious consequences of fractures to the vertebral bodies include kyphosis, back pain and a decrease in body length. New compression fractures can cause acute and intense back pain and are often triggered by normal everyday activities, such as bending forwards, lifting moderate weights, coughing or standing up.

The development of progressive kyphosis in the thoracic spine is further enhanced by the osteoporosis-induced deformation of the spinal column and additional fractures, spinal pain being but one of the consequences. Horizontal orientation of vision and general attention requires hyperextension of the cervical spine in the presence of major thoracic kyphosis which can lead to additional cervical syndromes. The reduction of thoracic volume and extensibility impairs vital capacity and physical energy. The caudal ribs can sink as low as to the iliac crest which can cause additional pain. At the same time, abdominal volume is restricted and viscera are protruded resulting in cosmetic problems for the patient.

By far the most frequent complaint of osteoporosis patients is pain upon standing or under physical stress, particularly when bending forward [4]. The patient's everyday functioning is considerably impaired not only due to pain and a poor posture, but often also to the fear of falling. This can lead to social withdrawal

Table 1 Study population data

Age	Mean 72.6 ± 7.1 years (52–90 years)				
Gender	All patients were female				
Height	Mean 160 ± 7 cm (147–172 cm)				
Weight	Mean 70.4 ± 11 kg (49–100 kg)				
BMI	Mean 27.6 ± 3.8 kg/m ² 30% normal weight, 36% slight, 32% moderate and 2% marked obesity				
Vertebral fractures	0	1	2	3	> 3
	n = 6	n = 9	n = 28	n = 4	n = 3
Waist circumference	Mean 93 ± 11 cm (71–114 cm)				
Duration of complaints	Mean 11.9 ± 11.9 years (3 months – 50 years)				
Pre-treatment:					
a) Surgery	one patient (2%)				
b) other braces/ortheses	23 patients (46%)				

– which further increases physical inactivity and thus the progression of the disease. Chronic pain and the consequent physical inactivity, in particular, often trigger increasing depressiveness and anxiousness [5, 6].

Pain reduction and an increase in individual mobility are important goals in the multidisciplinary treatment of osteoporosis patients. Many patients refuse analgesics, and physiotherapy, though desirable, is often hampered by the pain from which the patients are suffering. Rigidly constructed orthotic devices, however, are unsuitable for long-term therapy.

2. Objective

The aim of the present clinical study was to investigate the efficacy of a highly flexible orthotic device as an adjuvant therapy in the long-term treatment of patients with osteoporosis.

3. Materials and Methods

The efficacy of a new orthotic device (Osteo-med, Thämert Ltd, Großburgwedel, Germany) was investigated in an open clinical study. The outcome parameters were pain, activities of daily living, and individual compliance.

3.1 Patients

The study population includes 50 female patients who had been diagnosed as suffering from osteoporosis on the basis of clinical findings and osteodensitometry. The study population is described in Table 1.

All patients were exposed to a mixture of everyday stresses – including lifting and carrying, walking, standing and sitting (domestic and free time). Only a single patient was still at work. Only one patient previously underwent a surgical intervention (2%, tertiary prophylaxis); all other patients had been treated with drugs for the secondary prophylaxis of osteoporosis. All patients received a medical osteoporosis treatment including bisphosphonates, calcium, and vitamin d3; 14 patients took NSAID



Fig. 1 „Osteo-med“ – osteoporosis orthosis (Thämert, Großburgwedel, Germany).

of elastic material to ensure optimal pressure on the lumbar pads. When the patient moves, the air in the pads is displaced providing a continuous back massage (Figure 1).

The device is available in different sizes; an orthosis of the correct size was handed over to each study patient during a regular outpatient consultation and was then worn during the day.

3.3 Period of observation and data collection

The patients were enrolled between January and June 2003 in the context of normal medical care in a specialised outpatient ambulance for osteology. The patients' informed consent was obtained before the start of the observation. After informed consent was given, patients were supplied with the osteoporosis orthotic device. Neither additional expenditure nor any monetary benefit arose for the patients. Monitoring and data evaluation were performed by members of the Department of Physical Medicine and Rehabilitation of Hannover University Medical School (MF, CG).

Data were collected before the start of the observation period and after 10 weeks. There were slight individual differences in the length of the observation period owing to the times of the appointments; the mean duration of observation was 2.5 ± 0.7 months.

The outcome parameter „pain“ was measured with a 10-point numerical rating scale, activities of daily living with a 5-point verbal rating scale. Comfort, handling, fit, skin tolerability and feeling of safety and of warmth were rated using separate 6-point numerical scales.

3.4 Statistics

The data was analysed with the STATISTICA package (StatSoft, Inc., Tulsa, OK, USA) employing the following tests: Spearman's rank correlation test (correlation between two continuous variables), Wilcoxon test for pair differences (difference in continuous parameters between paired samples), Mann-Whitney U-test (difference in continuous parameters between unpaired samples), and χ^2 -test (difference between frequency distributions of discrete characteristics). The level of significance was consistently set at $p < 0.05$.

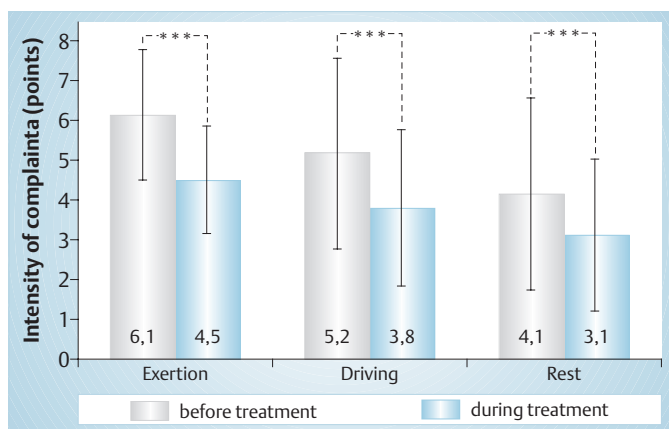


Fig. 2 Intensity of complaints before and during orthosis usage.

(ibuprofen 800 mg or diclofenac 50 mg) upon demand. The mean DXA value was -3.01 ($SD \pm 0.44$, range -4.25 – -2.48). 9 patients had had one vertebral fracture prior to treatment onset, 28 patient two, 4 patients three, and 3 patients four fractures or more; 6 patients had not suffered from a vertebral fracture so far.

3.2 Intervention

The Osteo-med orthotic device is intended as an orthopedic adjuvant for the treatment of osteoporosis. Its external appearance resembles a body stocking. The back section of the device sports pockets for air chamber pads that are filled to a maximum of three quarters of their capacity. The pads are arranged in a simple pattern in the lumbosacral region and on both sides of the spine in the thoracic region. There are two paired Velcro tabs in the lateral lumbar region, enabling a tight fit of the lumbosacral pads to the shape of the body. The osteoporosis orthosis is made

4. Results

All 50 patients enrolled in the study appeared for the follow-up investigation, and all had worn the orthosis during daytime for the entire observation period. Treatment effects on the intensity and frequency of pain were measured under the conditions of „stress“, „car driving“ and „at rest.“ At the end of the observation period, a highly significant mean reduction in pain was found with respect to all three pain qualities: Pain under stress decreased from 6.1 ± 1.7 to 4.5 ± 1.4 points ($p < 0.00001$), pain when driving a car from 5.2 ± 2.4 to 3.8 ± 1.9 points ($p < 0.00001$), and pain at rest from 4.1 ± 2.4 to 3.1 ± 1.9 points ($p < 0.0001$), corresponding to a mean reduction in pain of about 25% for each pain quality (Figure 2).

The patients were asked to decide whether their ability to perform everyday activities (as far as sports, car driving, hobbies

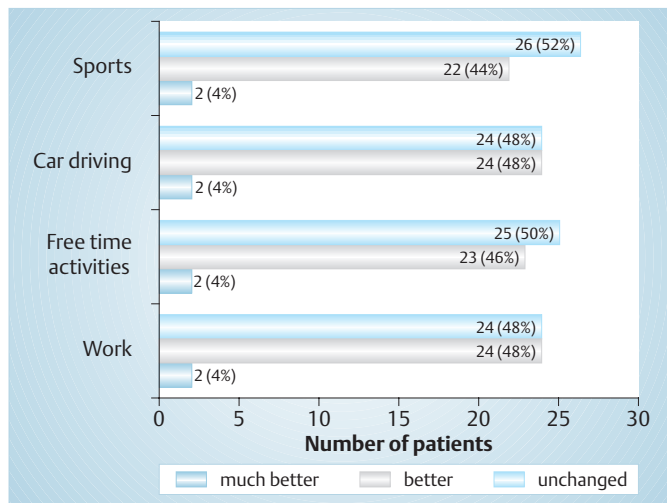


Fig. 3 Everyday activities during orthosis usage.

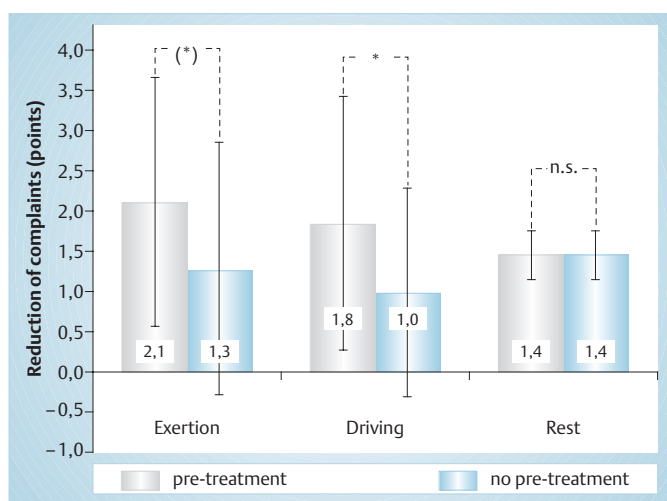


Fig. 4 Complaint reduction in patients with and without pre-treatment.

and domestic work were concerned) was „much better“ or „better“ then before treatment, which was answered positively by more than 50% (Figure 3).

As 23 of the patients had been treated with another orthotic device previously, it was possible to carry out a subgroup analysis

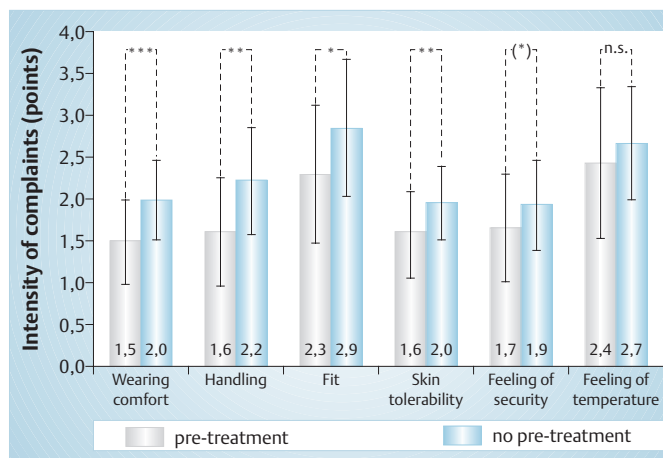


Fig. 5 Subjective rating in patients with and without pre-treatment.

of the parameters for patients with or without previous treatment. Parameters such as age, body measurements, everyday activities, duration of osteoporosis, compliance and duration of observation were similar in the two groups so that such a comparison was feasible.

No significant differences between groups were found with respect to the absolute values before and under orthosis treatment. There was a trend towards a greater treatment-related improvement in pain under stress for the patients with previous treatment; the corresponding difference for pain when driving a car was statistically significant (Table 2). Figure 4 shows the differences in pain reduction for those patients who had been pre-treated with another orthotic device.

Apart from the main outcome parameter of pain, the parameters „comfort“, „handling“, „fit“, „skin tolerability“ and „feeling of safety“ tended to be rated better by the patients with previous treatment. Except for the „feeling of safety“, these differences were statistically significant. On the other hand, the rating of „feeling of warmth“ was similar in the two groups (Table 3 and Figure 5). These group differences could also be detected in the χ^2 -test of the frequencies with which the single ratings had been awarded (comfort: $p=0.0036$, handling: $p=0.010$, fit: $p=0.038$, skin tolerability: $p=0.020$, feeling of safety: $p=0.157$, feeling of warmth: $p=0.240$).

Table 2 Comparison of patients with and without pre-treatment (U-Test)

		No pre-treatment with braces or bandages			Pre-treatment with braces or bandages			Significance level
		n	Mean	SD	n	Mean	SD	p
1. Before treatment	Exertion	27	5.96	1.87	23	6.35	1.37	0.492
	Driving	27	5.04	2.56	23	5.30	2.22	0.630
	Rest	27	4.19	2.60	23	4.09	2.23	0.913
2. During treatment	Exertion	27	4.70	1.49	23	4.26	1.21	0.206
	Driving	27	4.07	2.13	23	3.48	1.68	0.384
	Rest	27	3.22	2.06	23	3.00	1.76	0.864
Difference [§]	Exertion	27	1.26	1.58	23	2.09	1.56	0.063
	Driving	27	0.96	1.29	23	1.83	1.59	0.031*
	Rest	27	0.96	1.37	23	1.09	1.41	0.694

[§]A positive difference is equivalent to an improvement under orthosis therapy; * $p < 0.05$; U-test

Table 3 Rating of subjective parameters (U-Test)

	No pre-treatment with braces or bandages			Pre-treatment with braces or bandages			Significance level p
	n	Mean	SD	n	Mean	SD	
Wearing comfort	27	2.00	0.48	23	1.48	0.51	0.00089*
Handling	27	2.22	0.64	23	1.61	0.66	0.0018*
Fit	27	2.85	0.82	23	2.30	0.82	0.043*
Skin tolerability	27	1.96	0.44	23	1.57	0.51	0.0057*
Feeling of security	27	1.93	0.55	23	1.65	0.65	0.093
Feeling of temperature	27	2.67	0.68	23	2.43	0.90	0.313

* p < 0.05; U-test

Furthermore, possible influences on the regression of symptoms during treatment with the orthotic device were investigated. Pain under stress showed a significant correlation with the duration of symptoms ($p = 0.0062$): the longer the duration, the more markedly the pain under stress regressed during treatment with the orthosis. The same correlation was found for the improvement in pain when driving a car ($p = 0.0011$) and at rest ($p = 0.0083$).

Side-effects: No side-effects of any sort, such as poor tolerability of the material, were observed or reported by a patient at any time during the observation period.

5. Discussion

Orthotic devices and bandages are generally recommended as a possible adjuvant in conservative therapy of manifest osteoporosis [7 – 10]. The main indication for the use of such devices on the trunk is secondary prevention – i.e., to avoid or treat the acute phase after vertebral body fractures [11 – 14]. Most orthotic devices employed are stable frame constructions or semi-rigid trunk orthoses. The aim of this adjuvant therapy is to stabilise the trunk mechanically – and thus relax it – in order to alleviate pain and/or to help fractures to heal. Stable orthotic devices provide an additional psychological effect which is especially important after vertebral body fractures as it makes the patients feel safe(r) when they resume their daily activities thus helping to avoid, or at least reduce, the post-acute phase of immobilisation or even bed rest. As these orthotic devices are only used for a short-time, they will not reduce muscular strength or stamina [15].

Vertebral body fractures and extensor muscle strength reduction result in a kyphotic change of posture which is by far the most important physical and psychological problem in osteoporosis [16]. The extensors of the back musculature are weakened resulting in an impairment of muscular balance that increases the tendency to kyphotic changes in posture and the risk of further ventral vertebral body fractures.

The kyphotic changes in posture not only accelerate the development of chronic postural back pain, but also impair the function of the back musculature, resulting in increased stiffness and trunk ataxia as well as a lack of stability when standing or walk-

ing [17]. Lynn et al. have performed a controlled clinical study using a postural graphic method of measurement and were able to demonstrate that the risk of falls was greater for female patients with both osteoporosis and kyphotic malposture as compared to patients with osteoporosis without malposture or with healthy controls, respectively [18].

Once proprioception and back extensor muscle strength have improved, the ability of patients to maintain an erect posture increases [19]. In addition, improved strength and coordination of the back musculature tend to reduce chronic back pain from osteoporosis [20]. Rigid orthotic devices have repeatedly been recommended to support an erect posture, even though currently available rigid devices have been reported to have substantial disadvantages. In particular, rigid braces are uncomfortable to wear, greatly restrict movement and look unattractive resulting in a generally poor compliance. In addition, they are expensive, and there are medical contraindications, especially hiatus and abdominal hernias [18]. Moreover, stable orthotic devices should only be used for a limited period of time. Kaplan et al. pointed out that orthotic devices impose a risk of reduction in muscular strength. Their controlled pilot study with a 4-week observation period demonstrated that the strength of the back extensors was reduced to below the initial value in 40% of female patients who were wearing a stable orthotic device [21]. This effect is particularly undesirable in osteoporosis patients as discussed above.

The availability of pre-emptive treatment modalities supporting an erect posture without the described disadvantages would be beneficial for many osteoporosis patients. An earlier study has shown that the orthotic device used in the current investigation can partially correct kyphotic malposture [22]. The points that remained unclear were the effects of this osteoporosis orthotic device on the development of pain during long-term wear and the subjective evaluation by the patients of handling and comfort.

In the present study, the device was worn for 2.5 months and, during this period, there was a statistically significant and clinically relevant reduction in chronic back pain by app. 25% in this group of female patients with osteoporosis. The patients also rated the comfort and handling of the orthosis as „good“ or „very good“. More than half of the patients could perform everyday activities „better“ or „much better“. The analysis of subgroups also yielded interesting results: The improvement of

symptoms was significantly greater in patients who had previously been treated with another orthotic device than in patients without this pre-treatment, suggesting that the alleviation of pain was greater than with other orthotic devices. The handling and comfort were consistently rated as being worse by patients without pre-treatment than by patients with pre-treatment. This warrants the conclusion that the pre-treated patients were comparing the present orthotic device with the one used previously, resulting in a more favourable appraisal than of patients without previous orthosis treatment.

As the patients were instructed to wear the orthotic device throughout the day for the whole observation period of 2.5 months, side effects (e. g. skin intolerance or hygienic problems) should have been conceivable if present, but were not reported by any patient. In addition, the follow-up investigations found no signs of skin irritation in possible stress zones (groin or arm pit). Although part of the study was performed during summer (and a very hot summer, for that), temperatures did not reduce wearing comfort in any of the patients.

6. Conclusion

The osteoporosis orthotic device examined in this study seems to improve posture and reduce pain, thus being a potentially effective complement to drug treatment and regular physiotherapy. Before this modality can be generally recommended, it would be desirable to perform controlled crossover studies and to investigate possible effects on the strength and coordination of the trunk musculature.

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