Study Folder Spinomed®

Spinal orthoses for the management of osteoporosis

medi. I feel better.

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German S3 Guideline for the Prevention, Diagnostics and Therapy of Osteoporosis (DVO, 2023)

According to the S3 Guideline "Prevention, Diagnostics and Therapy of Osteoporosis in Postmenopausal Women and in Men 50 Years and Older" published by the German speaking umbrella organisation Dachverband Osteologie e. V. (DVO), **early mobilisation after minor traumatic stable vertebral fractures should be performed** to avoid complications, which might occur following immobility such as pneumonia, pulmonary embolism and functional deficits **(highest grade of recommendation A)**.

For the painless mobilisation following acute stable osteoporotic vertebral fractures, different therapy approaches are available. According to the S3 Guideline, conservative treatment with spinal orthoses such as the Spinomed® or Spinomed® active may be considered. Furthermore, spinal orthoses should be used in combination with physiotherapeutic exercises and posture training.

→ As evidence for pain reduction, enhanced posture and improved function, the S3 Guideline refers to the publication by Hettchen et al. (2022) among others.

→ In this randomised controlled trial, the efficacy of the spinal orthosis **Spinomed® active** has been proven in women with older osteoporotic vertebral fractures and hyperkyphosis (see page 17).

Reference: DVO e.V. S3-Guideline "Prophylaxe, Diagnostik und Therapie der Osteoporose bei postmenopausalen Frauen und bei Männern ab dem 50. Lebensjahr"; AWMF-register number: 183 - 001; Status: 06/09/2023. Published online at: https://www.awmf.org/leitlinien/detail/ll/183-001.html (Last access 19/02/2024).

Clinical Trials – Scientific Evidence

Spinomed® – Efficacy in women with postmenopausal osteoporosis (Pfeifer et al., 2004)

Study population

62 female patients

Inclusion criteria

Osteoporosis with at least one clinically manifested vertebral fracture	Angle of kyphosis ≥ 60 degrees (Photomorphometric assessment)	Age: > 60 years

Baseline characteristics

Number of vertebral fractures (Group A / B): Ø 2.0 / 2.1	Body height (Group A / B): Ø 156 / 156 cm	Age (Group A / B): Ø 72.8 / 72.3 years

Study design

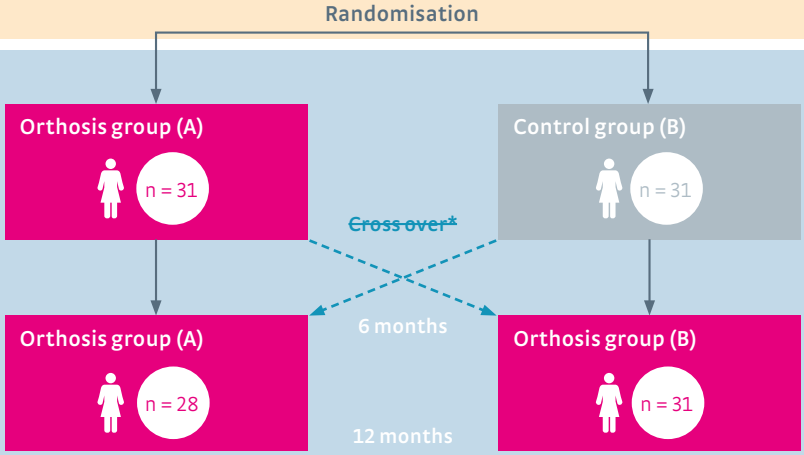
Endpoints

Primary endpoint:

- Change in isometric back extensor strength (incl. change in the degree of thoracic kyphosis)

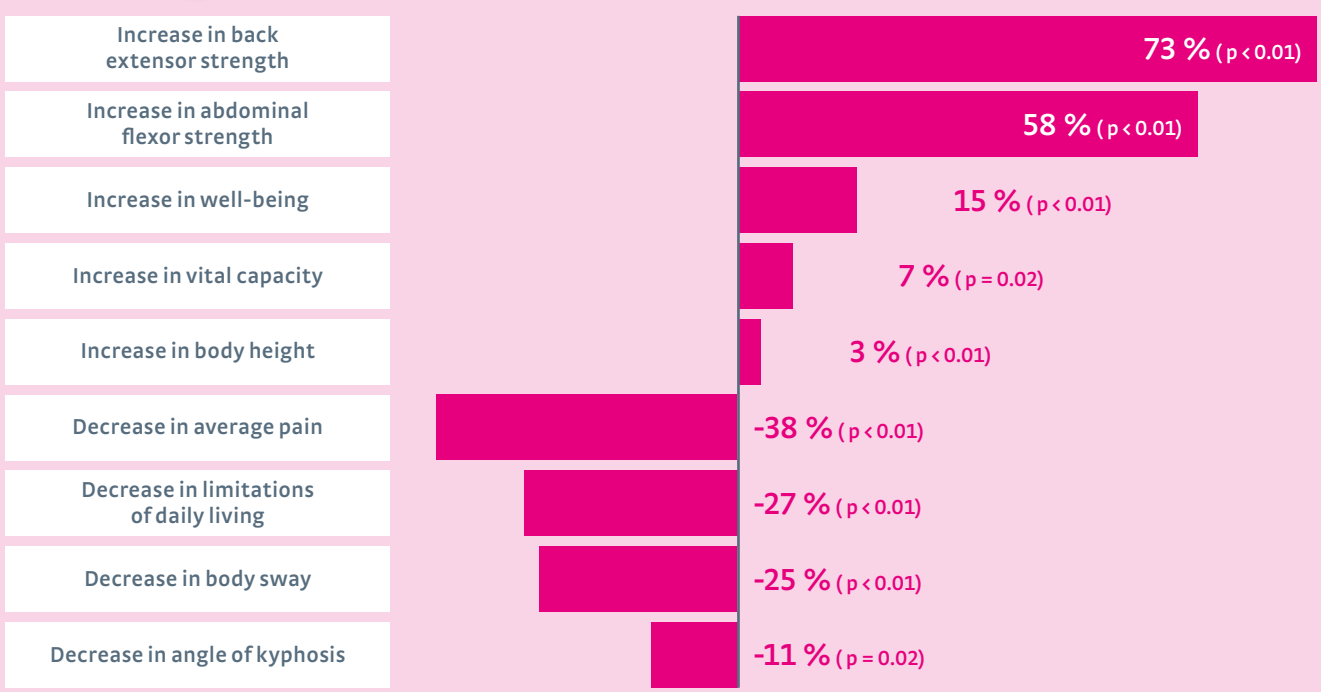
Secondary endpoints:

- Isometric abdominal flexor strength
- Body height, body sway
- Vital capacity
- Quality of life (pain, limitations of daily living, well-being)



Results

Significant improvements in all endpoints after 6 months of orthosis use



* The initially planned cross-over-design was modified due to ethical reasons. Patients in group A refused to stop wearing the orthosis after six month.

Reference: Pfeifer M et al. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2004;83(3):177-186.

In a prospective randomised controlled trial, Pfeifer et al. (2004) proved the efficacy of the Spinomed orthosis in postmenopausal women with osteoporosis.

The originally planned cross-over-design was modified after six months due to the high efficacy of the **Spinomed** orthosis:

- Patients in the orthosis-group (group A) refused to stop wearing the **Spinomed** after six months. Therefore, this group used the orthosis for a total of twelve months.
- The control group (group B) started the orthotic treatment after six months. In this group, the efficacy of the **Spinomed** was observed over a period of a total of six months.

The study results revealed that wearing the **Spinomed** orthosis led to an increase in back extensor and abdominal flexor strength, a decrease of the angle of kyphosis and a reduction of body sway. All the improvements were statistically significant. Besides the efficacy and tolerability of the spinal orthosis, improvements in well-being led to a very high patient compliance rate. All of the patients wore the **Spinomed** orthosis for at least six months. The authors rated the overall compliance with the **Spinomed** during the total study period as excellent.

Reference: Pfeifer M et al. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2004;83(3):177-186.

Spinomed® / Spinomed® active – Efficacy in postmenopausal women with osteoporosis (Pfeifer et al., 2011)

Study population

108 female patients

Inclusion criteria

At least one clinical osteoporotic vertebral fracture during the last six months	Angle of kyphosis ≥ 60 degrees (Stereo-photomorphometric assessment)	Age: > 60 years

Baseline characteristics

Number of vertebral fractures (Group A / B / C): Ø 2.0 / 1.6 / 2.1	Body height (Group A / B / C): Ø 157 / 159 / 156 cm	Age (Group A / B / C): Ø 72.8 / 72.3 / 69.7 years

study design

Endpoints

Primary endpoint:

- Change in isometric back extensor strength

Secondary endpoints:

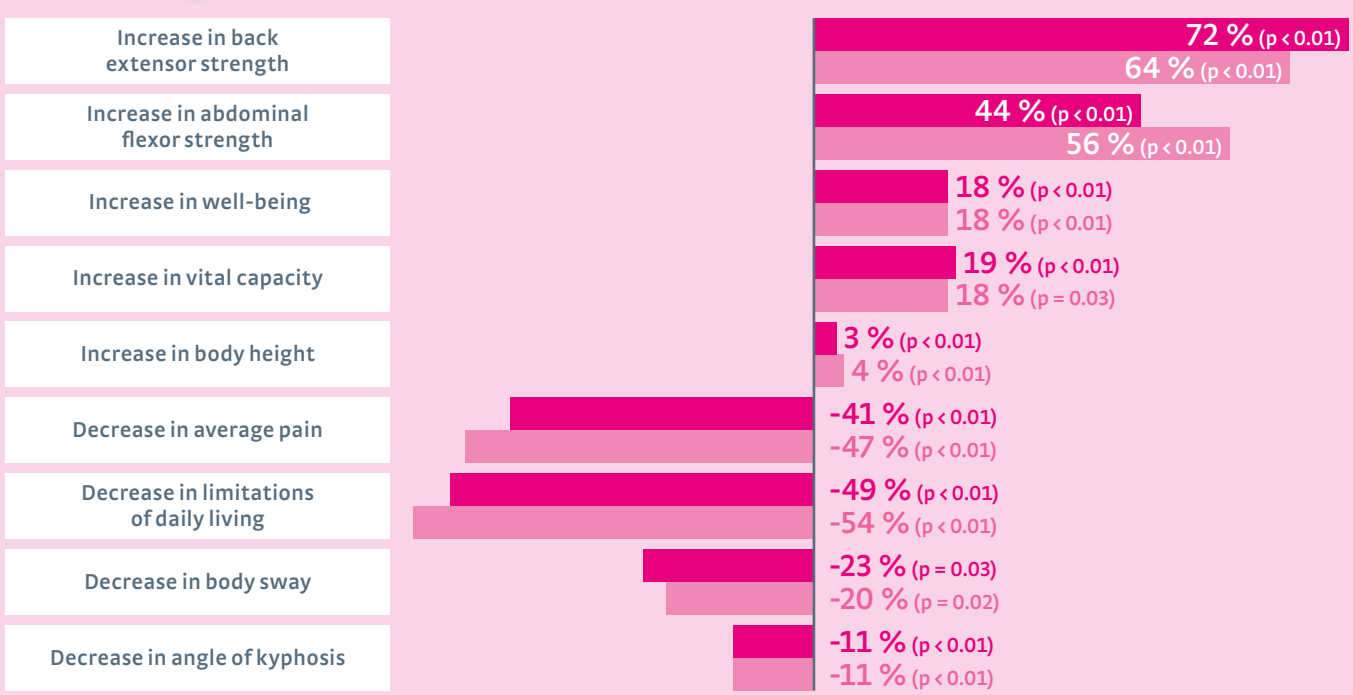
- Isometric abdominal flexor strength
- Angle of kyphosis, body height, body sway
- Vital capacity
- Quality of life (pain, limitations of daily living, well-being)

Randomisation

Orthosis group Spinomed (A)* n = 36	Orthosis group Spinomed active (B)* n = 36	Control group (C) n = 36
~~Cross over*~~ after 6 months		
Orthosis group Spinomed (A)* n = 33	Orthosis group Spinomed active (B)* n = 34	Orthosis group Spinomed (C) n = 33

Results

Significant improvements in all endpoints after six months of orthosis use



* The initially planned cross-over-design was modified due to ethical reasons. Patients in group A and B refused to stop wearing the orthosis after six month.

Reference: Pfeifer M et al. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2011;90(10):805-815.

In 2011, the positive outcomes of the Spinomed orthosis (Pfeifer et al., 2004) were confirmed and the efficacy of the Spinomed active was proven.

Besides the **Spinomed** orthosis, the efficacy of the **Spinomed active** – a body variant with the same mode of action as the **Spinomed** – was examined. The study population consisted of postmenopausal women with osteoporosis and at least one osteoporotic vertebral fracture during the last six months.

The prospective randomised controlled clinical trial demonstrated that the use of the spinal orthoses of the **Spinomed** product familiy led to a significant increase in trunk muscle strength as well as an improved posture.
Furthermore, using the orthoses led to pain relief, which in turn increased the amount of activities of daily living and therefore enhanced well-being and quality of life.

Reference: Pfeifer M et al. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil 2011;90(10):805-815.

Spinomed® – Increase in isometric muscle strength and high patient compliance (Dionyssiotis et al., 2015)

Study population

Subgroup analysis

10 female patients

Inclusion criteria

Age: ≥ 60 years	Osteoporosis (at least one vertebral fracture in the thoracic or lumbar spine)	Reduction in vertebral height of at least 20 %	Angle of kyphosis > 55°

Exclusion criteria

Disorders affecting bone mineral metabolism	Severe degenerative diseases	Secondary osteoporosis

Study design

Endpoints

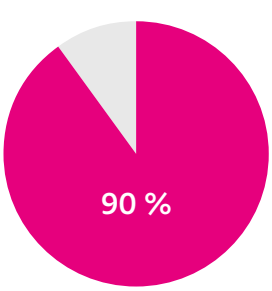
- Compliance after 6 months
- Change in isometric strength
- Change in back pain

n = 10

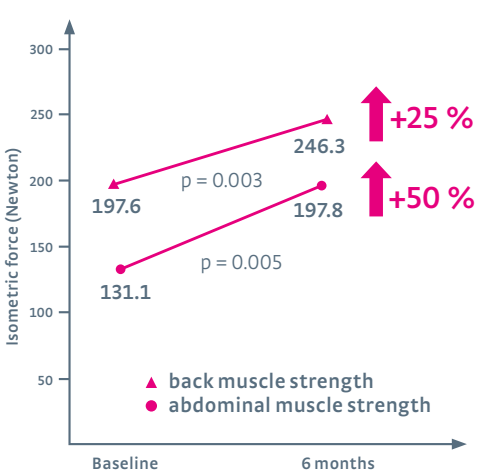
Application of the spinal orthosis
Spinomed

Results

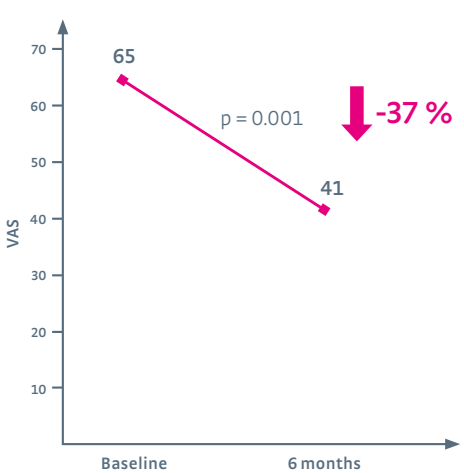
Compliance after 6 months



Increase in isometric strength after 6 months



Decrease in back pain after 6 months



Wearing the Spinomed orthosis significantly increased trunk muscle strength and decreased pain. The good efficacy is accompanied by a high patient compliance rate.

Reference: Dionyssiotis Y et al. Prospective study of spinal orthoses in women. Prosthet Orthot Int 2015;39(6):487-495.

Wearing the Spinomed orthosis for six months leads to increased muscle strength and pain relief with good patient compliance at the same time.

In 2015, Dionyssiotis et al. conducted a subgroup analysis to examine the efficacy of the **Spinomed** orthosis regarding the change in isometric muscle strength (abdominal and back muscles) and pain after six months.
An additional study focus was on the patients' compliance.

The study demonstrated that wearing the **Spinomed** orthosis for six months led to an increase in abdominal muscle strength by 50 percent and back muscle strength by 25 percent. In addition, pain was alleviated by 37 percent. Furthermore, analyses regarding the patients' compliance delivered positive results: the compliance rate of patients wearing the **Spinomed** over a duration of six months was 90 percent.

Reference: Dionyssiotis Y et al. Prospective study of spinal orthoses in women. Prosthet Orthot Int 2015;39(6):487-495.

Spinomed® – Pain relief and improved quality of life (Meccariello et al., 2017)

Study population

140 patients

Inclusion criteria

Age: ≥ 60 years	Acute back pain caused by single-level osteoporotic vertebral fracture from T6 to L3, which was due to minor trauma or strain, and without neurological symptoms

Exclusion criteria (i. a.)

Multiple or previous vertebral fractures	Disorders which affect bone metabolism	Severe lung diseases

Study design

Endpoints
6 months after vertebral fracture

Primary outcome:
Functional recovery in terms of
- pain (VAS-Scale)
- respiratory function (FEV1)
- quality of life (OLBPDQ)

Secondary endpoints:
Radiological outcome in terms of
- preserveration of vertebral height
- sagittal alignment
- spine stability
- union rate

n = 140

- n = 72 – Wearing a 3-point-orthosis
- n = 68 – Wearing the spinal orthosis **Spinomed**

Study visits

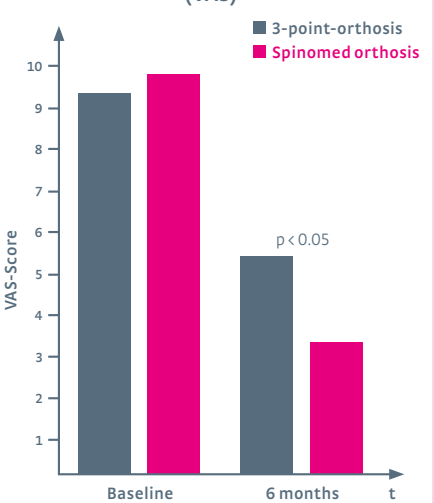
Baseline – 1 month – 2 months – 3 months – 6 months – t

Wearing the orthosis for two and half months while sitting or standing*

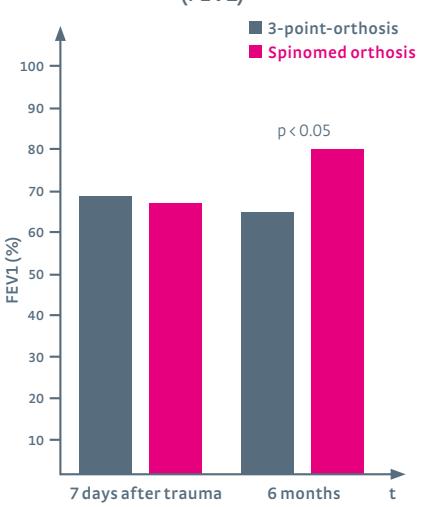
Weaning from the orthosis
+
Exercises to strengthen paravertebral, abdominal, and gluteal muscles*

Results

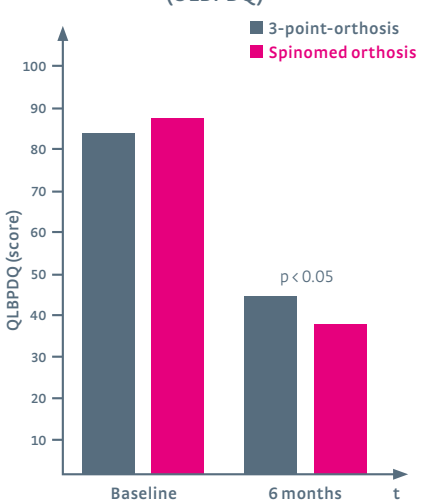
Pain relief (VAS)



Improvements in respiratory function (FEV1)



Reduction in restrictions (OLBPDQ)



Significantly lower complication rate in the Spinomed group.

Radiological results revealed that both orthoses are effective in stabilizing the fractured osteoporotic spine.

* Additionally, all patientes were given medical treatment for osteoporosis with vitamin D and bisphosonates.
OLBPDQ = Owestry Low Back Pain Disability Questionnaire; lower values indicate a higher quality of life

Reference: Meccariello L et al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study. Aging Clin Exp Res 2017;29(3):443-449.

Wearing the spinal orthosis Spinomed leads to a significant pain relief and a significant improvement in respiratory function compared to a 3-point-orthosis.

In a prospective controlled clinical trial, Meccariello et al. examined the influence of a 3-point-orthosis compared to the spinal orthosis **Spinomed** on pain, respiratory function and back pain related restrictions in patients with osteoporotic vertebral fractures.
Patients were divided into two groups and wore either a rigid 3-point-orthosis or the spinal orthosis **Spinomed** for the duration of two and half months. Afterwards, patients began weaning from the orthoses and started exercising regularly to strengthen paravertebral, abdominal, and gluteal muscles. The last follow-up assessment took place six months after trauma.

In the **Spinomed** group, a significant reduction in pain was shown after three and six months compared to the 3-point-orthosis. In addition, significant improvements in respiratory function between the third and sixth month were detected in the **Spinomed** group. Furthermore, authors observed a significantly lower complication rate in the **Spinomed** group. Radiological results regarding the stabilisation of the fractured osteoporotic spine were comparable in both groups.

Reference: Meccariello L et al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study. Aging Clin Exp Res 2017;29(3):443-449.

Spinomed® – Wearing a spinal orthosis as an alternative training method (Kaijser Alin et al., 2019)

Study population

113 female patients

Inclusion criteria

- Age: ≥ 60 years
- Osteoporosis (with or without vertebral fractures)
- Back pain

Exclusion criteria

- Spinal stenosis
- Severe scoliosis

Randomisation

Study design

Endpoints

Primary endpoint:

- Back pain (based on VAS / Borg CR-10)

Secondary endpoints:

- Back muscle extensor strength
- Kyphotic index

Spinomed orthosis group – n = 38

- Adjustment of the orthosis by an orthopedic technician
- Instruction in using the orthosis
- Duration of orthotic use: 2 h per day

Equipment training group – n = 38

- 1 h of exercise at a gym led by a physiotherapist once a week for 6 months
- Home exercise program at least 4 times a week

(i. a. back extensor and leg strength training, posture, balance)

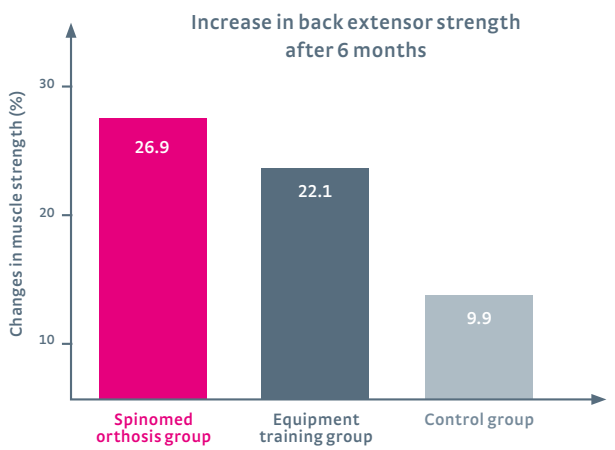
Control group – n = 37

- No Intervention

Study visits

Baseline – 1 month (for intervention groups only) – 3 months – 6 months – t

Results



Wearing an activating spinal orthosis represents an alternative training method in elderly patients.

Reference: Kaijser Alin C et al. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Arch Osteoporos 2019;14(1):5.

Wearing the Spinomed orthosis for six months leads to similar effects regarding the increase in back muscle strength compared to physiotherapeutic exercise intervention and therefore represents an alternative training method.

In a prospective randomised controlled clinical trial, Kaijser Alin et al. (2019) examined the effects of a spinal orthotic therapy in patients with osteoporosis.
For the study, patients were divided into three groups. One group wore the **Spinomed** orthosis for a period of six months, while a second group received an exercise training program once a week guided by a physiotherapist, which was supplemented by a home exercise program four times a week. Patients in the third group did not receive any intervention (control group).

In the **Spinomed** orthosis group a noticeable improvement in back extensor muscle strength was observed. The increase in back muscle strength in the orthosis group was even higher than in patients completing the physiotherapeutic exercise program.
Therefore, using a spinal orthosis represents an alternative training method that is integrable in daily living – especially in older patients.

Reference: Kaijser Alin C et al. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Arch Osteoporos 2019;14(1):5.

Spinomed® active – Positive effects on strength-based and functional outcomes in men with osteoporosis (Genest et al., 2021)

Study population

47 male patients ≥ 65 years

Main inclusion criteria

Indicators for relevant osteoporosis

- T-Score ≤ -2.5 or
- Previous osteoporosis diagnosis or
- Ongoing osteoporosis treatment or
- 10-year fracture risk probability ≥ 20 %

Randomisation

Study design

Outcomes

Primary endpoint:

Maximum isometric strength of trunk extensors and flexors

Secondary endpoints (i. a.):

- Chair-Rise-Test (CRT)
- Usual Gait Speed (UGS)

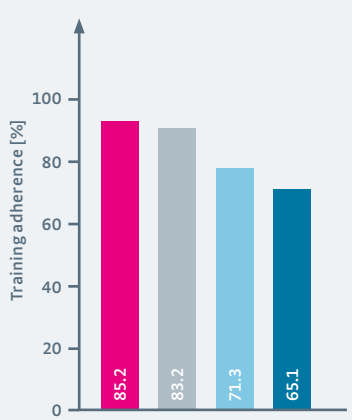
Spinomed® active-group	Vibration training-group	Resistance training-group	Qi Gong-group
n = 13	n = 13	n = 11	n = 10
• Individual fitting of the orthosis at the beginning of the trial • Prescribed wearing time: min. 3h/day	• Whole body vibration training on a vibration platform • 2 x 20 minutes per week	• Individual, supervised resistance training with focus on trunk strength • 8 exercises • 2 x 30 minutes per week	• Instructed group sessions • Content: Body-posture, breathing and meditation • 2 x 45 minutes per week

Study visits

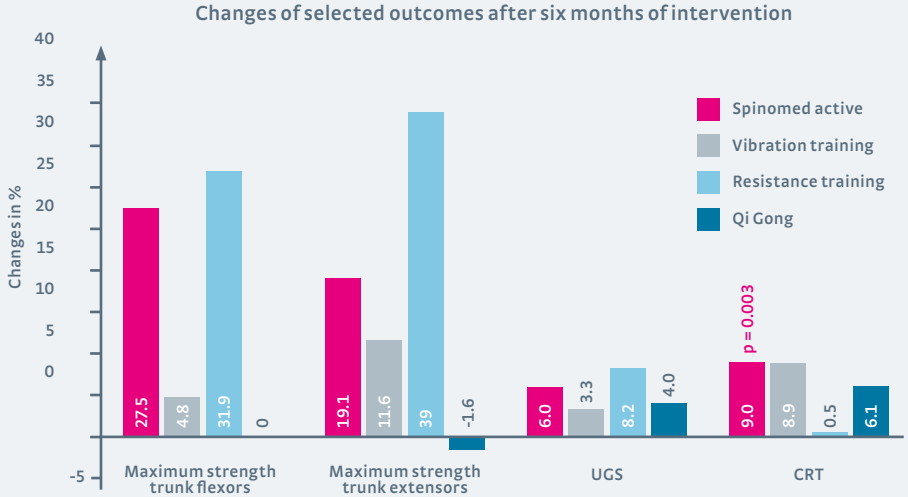
Baseline — Month 3 — Month 6 — t

Results

Training adherence



Changes of selected outcomes after six months of intervention



Reference: Genest F et al. Feasibility of simple exercise interventions for men with osteoporosis - A prospective randomized controlled pilot study. Bone Rep. 2021;15:101099.

Men with osteoporosis benefit from using the Spinomed active by means of an improved trunk and leg strength (Genest et al., 2021)

For a prospective, randomised, controlled pilot study by Genest et al. (2021), 47 men with indicators of a relevant osteoporosis were randomised in one of four different interventions: supervised resistance training, Qi Gong, vibration training or the use of the spinal orthosis **Spinomed® active**. The intervention period was six months. The aim of study was to examine the efficacy, feasibility and safety of different therapies in men with osteoporosis.

After six months, remarkable improvements of the trunk strength were observed in the **Spinomed® active**-group (flexion: + 27.5 percent; extension + 19.1 percent). Only the gold standard of professionally supervised resistance training led to even greater improvements regarding the trunk strength. Furthermore, using the **Spinomed® active** led to a statistically significant increase in the Chair-Rise-Test performance, which is an indicator for the leg strength. With regard to the training adherence, the **Spinomed® active**-group had the highest value among all groups (85.2 percent).

The authors conclude that less demanding interventions such as the use of the **Spinomed® active** are safe, feasible and effective with regard to strength-based outcomes. Therefore, the safety and efficacy of the **Spinomed® active** has been proven in men with osteoporosis.

Reference: Genest F et al. Feasibility of simple exercise interventions for men with osteoporosis - A prospective randomized controlled pilot study. Bone Rep. 2021;15:101099

Spinomed® active – Positive effects in women with older osteoporotic vertebral fractures (Hettchen et al., 2022)

Study population

Inclusion criteria (i. a.)

≥ 1 low-traumatic vertebral fracture ≥ 3 months ago	Hyperkyphosis ≥ 50°	Chronic back pain with mean pain intensity of ≥ 1 on the numerical rating scale [NRS]

80 female patients ≥ 65 years

Study design

Randomisation

Spinal orthosis group	Control group without orthosis
n = 40	n = 40
Spinomed® active use for 16 weeks: • 1 x daily for up to 2 h in the first two weeks • 2 x daily for 2–3 h from the third week	No intervention

Week 0 (Baseline)

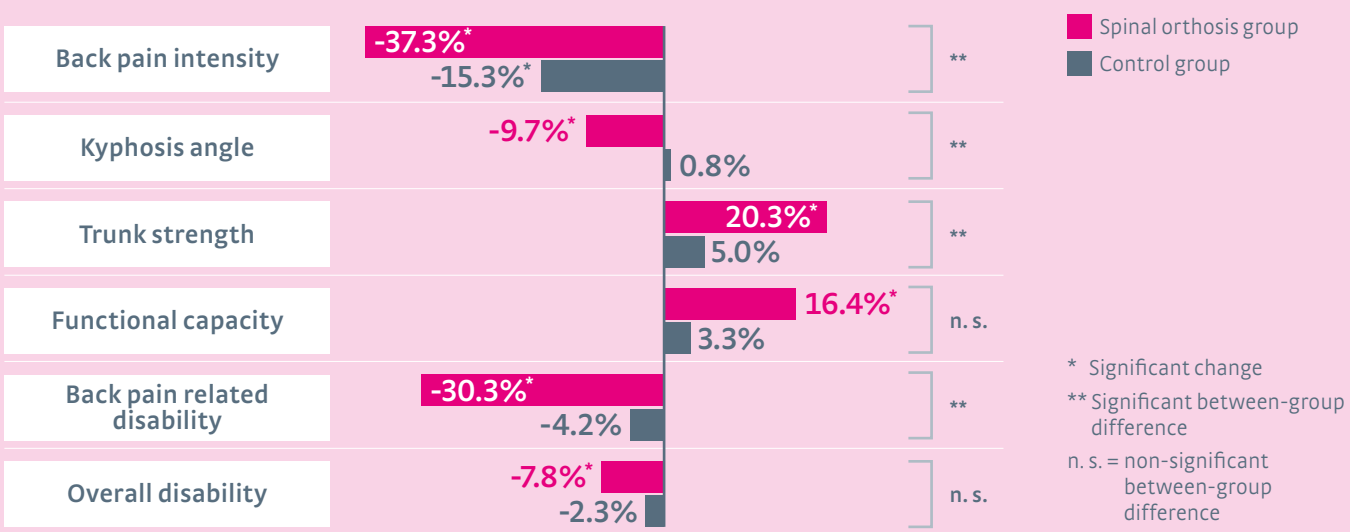
Week 16 (Follow-up)

Outcomes

- **Changes in average back pain intensity [NRS]**
- Changes in thoracic kyphosis angle [Kyphometer]
- Changes in isometric trunk strength [Back-Check® 607, Dr. Wolff]
- Changes in functional capacity [30 seconds Chair-Rise-Test]
- Changes in back pain related disability [Roland and Morris Disability Questionnaire]
- Changes in overall function and disability [Late Life Function and Disability Index]
- Changes in vital capacity [Forced expiratory vital capacity (FVC); forced expiratory 1 s volume (FEV1)]

Results

Wearing the **Spinomed® active** led to significant effects regarding the following outcomes:



Reference: Hettchen M et al. Effects of the „Spinomed active" orthosis on chronic back pain in kyphotic women with osteoporotic vertebral fractures three months and older: A randomized controlled study. Front Pain Res (Lausanne). 2022;3:1038269.

Women with osteoporotic vertebral fractures three months and older benefit from using the Spinomed® active (Hettchen et al., 2022)

In a randomised controlled trial, Hettchen et al. (2022) examined the effects of the spinal orthosis **Spinomed® active** in women (≥ 65 years) with older (≥ 3 months) osteoporotic vertebral fractures, chronic back pain and thoracic hyperkyphosis. In total, 80 patients were randomised equally into an intervention group and a control group. The intervention period was 16 weeks.

At the end of the intervention period, a significant pain reduction was apparent in both groups, however the pain reduction was significantly more pronounced in the **Spinomed® active** group. Regarding the kyphosis angle, trunk strength, functional capacity and back pain related as well as overall disability, improvements were statistically significant in the **Spinomed® active** group. In the control group, no significant changes were observed. Furthermore, the days under pain medication significantly decreased in the **Spinomed® active** group and increased non-significantly in the control group. The vital capacity remained almost unchanged in both groups.

Based on the confirmed positive effects of the **Spinomed® active**, the authors suggest to expand the recommendation for using the **Spinomed® active** to kyphotic women with osteoporotic vertebral fractures and chronic back pain independently of the age of the fracture.

Reference: Hettchen M et al. Effects of the "Spinomed active" orthosis on chronic back pain in kyphotic women with osteoporotic vertebral fractures three months and older: A randomized controlled study. Front Pain Res (Lausanne). 2022;3:1038269.

Spinomed® – Use of a spinal orthosis following kyphoplasty (Schupfner et al., 2020)

In a prospective clinical comparative study, Schupfner et al. examined the effects of a surgical, conservative or combined treatment in patients with osteoporotic vertebral fractures. In total, 90 patients were included in the study, receiving one of the following interventions:

→ conservative treatment with the spinal orthosis **Spinomed** (n = 30)
→ surgical treatment with balloon kyphoplasty (BKP) (n = 30)
→ combined therapy with balloon kyphoplasty and post-operative use of the **Spinomed** (n = 30)

Results

- Patients receiving a BKP perceived an acute pain relief which was significantly more pronounced compared to the conservative treatment
- After six months, no differences were observed between the intervention groups regarding pain or quality of life
- Pain reduction after six months was highest in the conservative treatment group receiving the **Spinomed** – though results were not statistically significant
- The use of the **Spinomed** did not lead to an additional height reduction of the vertebral body in the time course

→ In order to benefit from the positive acute (BKP) and long-term (**Spinomed**) effects of the single treatment options, the authors conclude: "*When used in combination with an activating orthosis, the therapy [kyphoplasty] has a positive effect on long-term vertebral straightening and thus also the sagittal plane of the spine.*"

Reference: Schupfner R et al. Prospective Comparison of Osteoporotic Vertebral Fracture Treatment. Ortho & Rheum Open Access J 2020;16(2):555932.

Further expert opinions regarding kyphoplasty

Prof. Dr. Christopher Niedhardt

In general, a recently fractured patient suffers from an increased refracturing risk. In order to improve the patient's safety, especially regarding the risk of falls, the use of a spinal orthosis is reasonable.

In this way, the patient receives a spinal straightening and therefore more stability.

"A patient with painful vertebral fractures requires an orthosis, no matter whether he had a surgery or not."

Dr. Gerd Ivanic

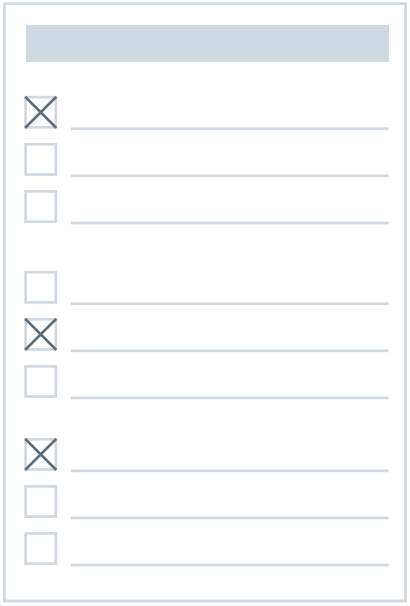
Spinal orthoses represent an alternative to a surgical intervention.

Based on the spinal straightening, the orthosis leads to a strengthening of the back muscles; in addition, improvements in the muscle corset result from the spinal straightening.

Following a surgery like a kyphoplasty or vertebroplasty, the patient should necessarily be kept in an upright position and therefore the use of an orthosis is reasonable.

"[...] because after a fracture is before a fracture."

Patient Surveys – Real-Life-Setting



Spinomed® – Spinal orthosis supports activities of daily living (Kaijser Alin et al., 2020)

Study population

18 female patients

Baseline characteristics

Age: ∅ 78 years	Indication: Osteoporosis	Moderate back pain (VAS: at least 30 mm, Borg CR-10: 2.5 – 3)

Conduction of five qualitative focus group interviews

Results

Impacts on daily life

Selection of responses of Spinomed users

- Improved posture
- Improved breathing
- Increased awareness of posture even when the orthosis had been removed
- Increased walking distance and amount of activities
- Improved feeling of stability and security
- Decrease of back pain
- Improved sleep quality
- Easier performance of day-to-day-activities
- Less fatigue

Individual adjustments

- **The individual and correct fitting of the orthosis is important.**
- **Importance of getting detailed information about how the spinal orthosis should be fitted and handled.**
- **Regular adjustment and fitting of the orthosis are necessary.**

"An activating spinal orthosis could be perceived as being a 'close friend' and a support in their everday lives."

Reference: Kaijser Alin C et al. Experiences of using an activating spinal orthosis in women with osteoporosis and back pain in primary care. Arch Osteoporos 2020;15(1):171.

Qualitative focus group interviews show that the patient expectations regarding the efficacy of the spinal orthosis Spinomed are met. Furthermore, the orthosis serves as support in daily life.

Following the clinical trial in 2019, Kaijser Alin et al. (2020) additionally conducted qualitative focus group interviews within the same study population.
During the interviews, three main categories were addressed in particular: impact on daily life, individual adaptation and personal relationship.
Besides pain relief, **Spinomed** users reported improved breathing due to enhanced posture as well as increased feelings of stability and safety. On the basis of an increased walking distance, patients had an increased scope of activities.

Regarding the use of the **Spinomed** orthosis, it was shown that individual adjustment in connection with detailed information on handling and regular fitting are of great importance.

The patients' answers lead the authors to the conclusion that the expectations of the **Spinomed** users regarding the orthosis are met. Therefore, using a spinal orthosis might be a reasonable support in daily life.

Reference: Kaijser Alin C et al. Experiences of using an activating spinal orthosis in women with osteoporosis and back pain in primary care. Arch Osteoporos 2020;15(1):171.

Spinomed® – Representative patient survey confirms the efficacy of spinal orthoses in real-life-setting (medi GmbH & Co. KG, 2020)

Study population

311 patients with osteoporosis

Orthoses treatment

Spinomed	Spinomed active	Spinomed active men

Patient characteristics

♂ n = 275 / n = 36 ♀

Age group distribution

- < 50 years: 1 %
- 50 – 60 years: 6 %
- 60 – 70 years: 15 %
- 70 – 80 years: 30 %
- > 80 years: 48 %

Study design

Questions on

- Subjective use
- Handling
- Fitting
- Comfort
- Frequency / duration of use
- Recommendation rate

Voluntary patient survey

of patients who received one of the spine straightening orthoses from their physician

- Period: april 2019 – may 2020
- Patient education about the survey
- Multiple choice partially possible
- Responses online or postal

Results

Subjective use

- ✔ **65 %** of the patients reported that Spinomed supported them **much** to **very much during their therapy**.
- ✔ **64 %** confirmed that the orthosis led to a **much** to **very much improved mobility in daily life**.
- ✔ **68 %** of the patients had an enhanced feeling of **safety** while wearing the orthosis.
- ✔ **56 %** reported a **clear** or **very clear pain relief**.
- ✔ **64 %** confirmed that Spinomed **enhanced the quality of life much** to **very much**.

Further parameters

(Handling and comfort, frequency and duration of use, recommendation rate)

- ✔ **61 %** rated the **donning and doffing** as **easy** to **very easy**
- ✔ **74 %** perceived the comfort of **the orthosis** as **good** to **very good**.
- ✔ **72 % wore** the **orthosis daily** or **almost daily**
- ✔ **67 % wore** the **orthosis 5 – 8 h** or **more than 8 h** daily

94 % recommendation rate

Reference: medi GmbH & Co. KG, 2020

A patient survey regarding the application of the Spinomed, Spinomed active or Spinomed active men shows the patients' subjective satisfaction with the products concerning improved mobility, pain relief, enhanced feeling of safety and increased quality of life.

In a representative survey of more than 300 patients with osteoporosis, the subjective benefit and usage of spine straightening orthoses were examined.
Patients wearing the spinal orthoses **Spinomed**, **Spinomed active** or **Spinomed active men**, respectively were asked to answer a questionnaire concerning the use, duration of application and comfort of the products.

Two thirds of the patients reported that their orthosis helped them much or very much during the therapy and that the device led to an improved mobility and an increased feeling of safety. More than 50 percent of the participants confirmed that they experienced (very) clear pain relief by wearing the orthosis, which led to an increase in quality of life.
Handling, fitting and comfort were mainly rated as good to very good, reflecting in a high adherence rate.

The mainly good to very good product ratings resulted in a very high recommendation rate of 94 percent.

Reference: medi GmbH & Co. KG, 2020

Representative patient survey regarding the use of spinal orthoses as medical device (eurocom e. V., 2019)

Study population

1.295 user (≥ 16 years)
of medical devices

of which

463 use soft supports/orthoses
(applied to wrist, ellbow, shoulder, **spine**, knee and foot)

Study design

Questions about

Medical devices:
- Distribution and field of use
- Satisfaction and effects

Two-stage patient survey

Representative population survey
(Omnibus-survey)

Face-to-Face-survey of medical device users

Results

Spinal soft support and orthosis users report on ...

Positive effects
- ✔ **89 %** increased quality of life
- ✔ **84 %** less pain
- ✔ **72 %** more mobility
- ✔ **66 %** faster resumption of employment

Reduced consumption of analgesics
- ✔ **65 %** less analgesics
- ✔ **14 %** complete renunciation from analgesics

Less surgeries
- ✔ **32 %** renunciation from a surgery
- ✔ **18 %** delay of a surgery

81 % of spinal soft support and orthoses users reported that their medical device has a **great** to **very great benefit** for them.

References:
eurocom e. V.: Rückenbandagen und Rückenorthesen: Weniger Schmerzen, mehr Mobilität. Ergebnisse der repräsentativen Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e.V. Published online: https://www.eurocom-info.de/wp-content/uploads/2021/03/eurocom_Broschuere-Ruecken_Allensbach_web.pdf (Last access 19/02/2024).
eurocom e. V. Nutzen und Wirksamkeit medizinischer Hilfsmittel: Steigende Lebensqualitat durch weniger Schmerz und mehr Mobilitat. Reprasentative Umfrage des Instituts fur Demoskopie Allensbach im Auftrag von eurocom e. V. Published online: https://www.eurocom-info.de/wp-content/uploads/2019/08/Allensbach-Brosch%C3%BCre_Webversion.pdf (Last access 19/02/2024).

A survey on behalf of eurocom e. V. confirms the increased demand for medical devices and the great effects of spinal soft supports and orthoses.

In 2019, the Allensbach Institute was commissioned by eurocom e. V. in order to conduct a representative patient survey on the use and subjective efficacy of medical devices (soft supports/orthoses, medical compression stockings and foot orthoses). The survey confirms the results of a first, identical survey conducted in 2014, underlining an increased demand for medical devices. For example, 7.8 million people in Germany use soft supports or orthoses of which 15 percent are wearing a spinal soft support/ orthosis.

A particular subgroup analysis showed that 54 percent of patients who rely on the assistance of spinal soft supports/orthoses are wearing them due to chronic back pain. 81 percent of the users confirmed a high to very high benefit.

Survey participants reported that wearing spinal soft supports and orthoses led to an improved quality of life and increased mobility. In addition, the application contributed to pain relief which led to a reduced consumption of analgesics in more than two thirds of the users. Furthermore, 32 percent of the spinal soft support/orthosis users stated that they could avoid a surgery due to the medical device use.

References:
eurocom e. V.: Rückenbandagen und Rückenorthesen: Weniger Schmerzen, mehr Mobilität. Ergebnisse der repräsentativen Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e.V. Published online: https://www.eurocom-info.de/wp-content/uploads/2021/03/eurocom_Broschuere-Ruecken_Allensbach_web.pdf (Last access 19/02/2024).
eurocom e. V. Nutzen und Wirksamkeit medizinischer Hilfsmittel: Steigende Lebensqualitat durch weniger Schmerz und mehr Mobilitat. Reprasentative Umfrage des Instituts für Demoskopie Allensbach im Auftrag von eurocom e. V. Published online: https://www.eurocom-info.de/wp-content/uploads/2019/08/Allensbach-Brosch%C3%BCre_Webversion.pdf (Last access 19/02/2024).
Intended purpose: Spinomed /Spinomed active/Spinomed active men are braces designed to actively relieve load and correct the lumbar spine / thoracic spine in the sagittal plane.

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