

# Positive effects of the Spinomed® active

in women older than 65 years with osteoporotic vertebral fractures three months and older and chronic back pain<sup>1</sup>

Patient population

## Inclusion criteria (i. a.)

- Age: ≥ 65 years
- ≥ 1 low-traumatic vertebral fracture ≥ 3 months ago
- Hyperkyphosis ≥ 50°
- Chronic back pain with mean back pain intensity of ≥ 1 on the numerical rating scale (NRS)

## Exclusion criteria (i. a.)

- Medication apart from analgesics and diseases known to affect the study outcomes
- Secondary osteoporosis
- Structurally fixed kyphosis with lack of extension ability of the thoracic spine
- Kypho- or vertebroplasty
- Prior use of spinal orthoses or onset of neurological deficits during the last 6 months

**N = 80 female patients**

(Ø Age: 73.6 years; Ø Height: 162 cm; Ø 2.3 vertebral fractures)

Study design

## Randomization

**Spinal orthoses group**

n = 40

**Control group without orthosis**

n = 40

**Spinomed® active** use for 16 weeks:

- Once daily for up to 2 h during the first two weeks
- From week three, two times daily for 2-3 h

Week 0 (Baseline)

No intervention

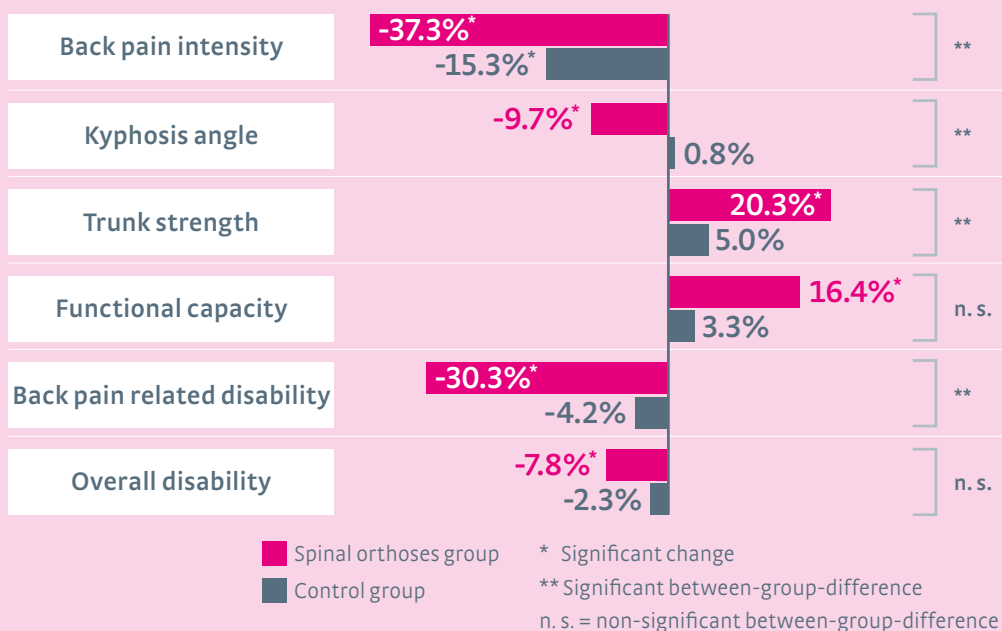
Week 16 (Follow-up)

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

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



- The improvements regarding back pain intensity, kyphosis angle, trunk strength, and back pain related disability were significantly more pronounced in the **spinal orthoses group** compared to the control group.
- Days under pain medication decreased significantly (-51 %), in the **spinal orthoses group**, whereas a non-significant increase was observed in the control group (+60 %).
- Regarding vital capacity, no significant changes were evident in both groups.

<sup>1</sup> Hettchen M, Willert S, von Stengel S, Kohl M, Kemmler W. 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. 2022;3:1038269.