

Scientific Summary – Latest news from science

Spinomed® active – Numerous positive effects in women older than 65 years with osteoporotic vertebral fractures three months and older and chronic back pain

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.

#11

The use of a spinal orthosis is effective in women older than 65 years with osteoporotic vertebral fractures three months and older

Osteoporosis is a common condition affecting millions of people worldwide. Recent data report the global prevalence of osteoporosis to be 18.3 %.¹ Patients suffering from osteoporosis are at high risk for fragility fractures due to the decreased bone stability. In Europe, an estimated 660.000 fragility fractures affected the vertebral bodies in 2019.² A current systematic review concluded that spinal orthoses are recommended in the conservative treatment of acute osteoporotic vertebral fractures in neurologically intact patients.³ Recently, a randomized controlled trial evaluated whether the spinal orthosis **Spinomed® active** is effective in women 65 years and older with osteoporotic vertebral fractures (≥ 3 months) and chronic back pain.⁴

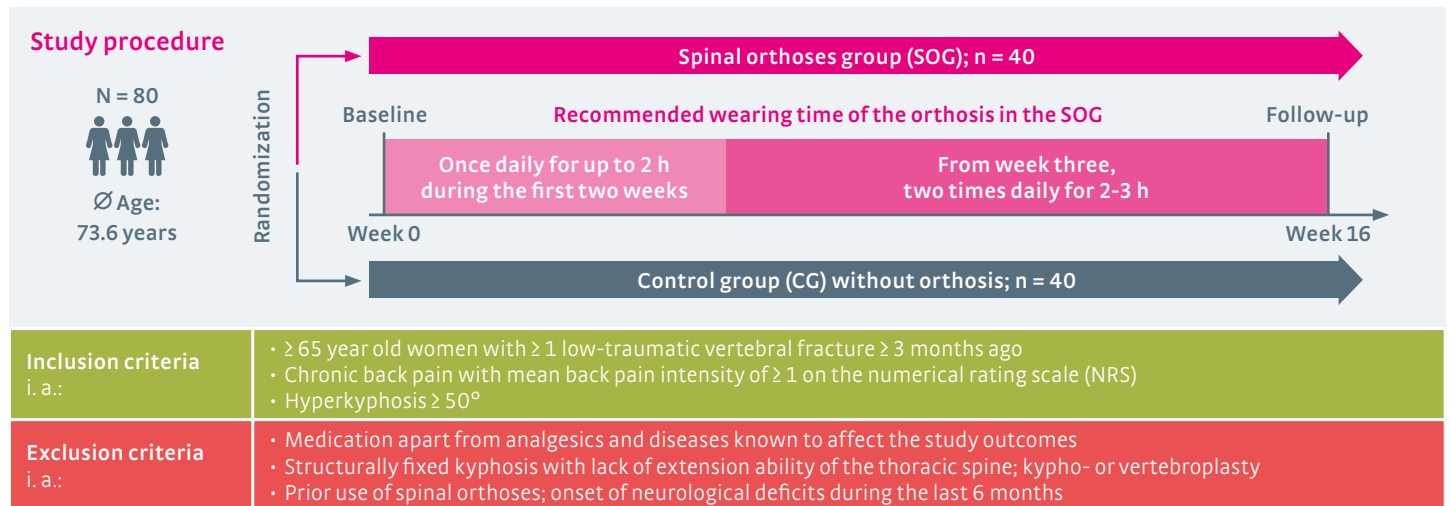


Fig. 1: Study procedure, recommendations regarding the wearing time of the orthosis and selected inclusion and exclusion criteria.

Study results

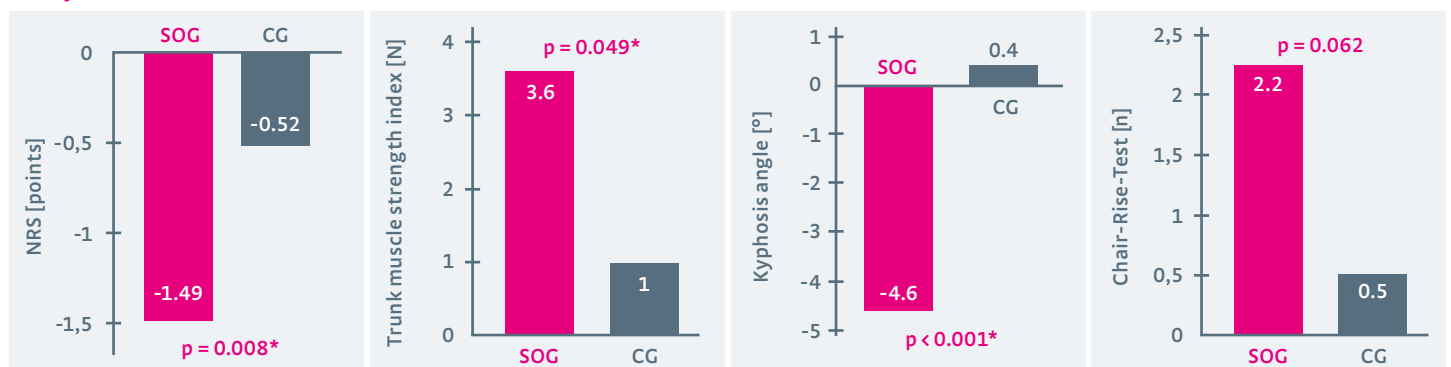


Fig. 2: Changes in the SOG and CG following the intervention period of 16 weeks regarding the study outcomes pain (NRS = numerical rating scale; 0-10), trunk muscle strength, kyphosis angle, and functional capacity (Chair-Rise-Test). p-values represent between-group-differences regarding the changes.

* statistically significant difference

- **Significant pain reduction** in the **SOG** (p < 0.001) and CG (p = 0.025). Pain reduction was **significantly more pronounced** in the **SOG** (p = 0.008). Additionally, **days under pain medication decreased significantly** in the **SOG** (p = 0.010) and increased non-significantly in the CG (p = 0.205). Between-group-difference: p = 0.056.
- In the **SOG**, a **significant increase of trunk muscle strength** was observed (p < 0.001), whereas no significant change was evident in the CG (p = 0.2). The **increase in trunk muscle strength was significantly higher** in the **SOG** (p = 0.049).
- While the **kyphosis angle** remained almost unchanged in the CG (p = 0.61), it **decreased significantly** in the **SOG** (p < 0.001). The **difference** between the **SOG** and CG regarding the changes **was significant** (p < 0.001).
- There were **significant improvements in the Chair-Rise-Test** in the **SOG** (p = 0.001) and no significant changes in the CG (p = 0.43). Improvements in the **SOG** compared to the CG did not reach significance (p = 0.062).
- **Back pain related disability** decreased** in the **SOG** (p < 0.001) and remained almost constant in the CG (p = 0.46) leading to a **significant between-group-difference** (p < 0.001).
- Regarding overall subjective function and disability*** as well as vital capacity, no significant differences between **SOG** and CG were observed (p = 0.057 and 0.432, respectively).

** determined by the Roland and Morris Disability Questionnaire
*** determined by the Late Life Function and Disability Index

Embedding the study results into the current state of research regarding Spinomed® active

The efficacy of the **Spinomed® active** was already verified in ≥ 65 year old men with signs of relevant osteoporosis. Accordingly, daily wearing of the orthosis (recommendation: 3 h/day) for 6 months led to an increase in trunk muscle strength of 19.1 % (extension) and 27.5 % (flexion), respectively, as well as a significant improvement in the Chair-Rise-Test. Adherence was reported to be 85.2 %.^{5*}

Authors' conclusions

- *“The present study clearly confirms the positive effects of the **“Spinomed active”** orthosis on average back pain intensity in hyperkyphotic women ≥ 65 years with older (≥ 3 months) low-traumatic (osteoporotic) vertebral fractures.”*
- *“In the present study we observed a large positive effect of the spinal orthosis on the kyphosis angle as determined in a straightened upright position. This finding indicates the uprighting effect of the **“Spinomed active”** orthosis generated by activation and strengthening of the back extensor muscles and a better posture which might be provided by the biofeedback of the orthosis.”*
- *“Besides effectiveness, attractiveness and usability are core components of successful interventions. In summary, wearing protocols and telephone interviews indicate quite high participant compliance ($> 80\%$) with the present intervention.”*
- *“Based on our results, we suggest expanding the recommendation for an application of the **“Spinomed active”** orthosis to kyphotic women with osteoporotic vertebral fractures and chronic back pain independently of the age of the fracture.”*

* Detailed information regarding the study methodology and results can be found in the Scientific Summary #09 or in the original article from Genest et al. (2021).⁵

References

- ¹ Salari N et al. The global prevalence of osteoporosis in the world: a comprehensive systematic review and meta-analysis. J Orthop Surg Res. 2021;16(1):609.
- ² Kanis JA et al. SCOPE 2021: a new scorecard for osteoporosis in Europe. Arch Osteoporos. 2021;16(1):82.
- ³ Kweh BTS et al. The Role of Spinal Orthoses in Osteoporotic Vertebral Fractures of the Elderly Population (Age 60 Years or Older): Systematic Review. Global Spine J. 2021;11(6):975-987.
- ⁴ 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.
- ⁵ Genest F et al. Feasibility of simple exercise interventions for men with osteoporosis - A prospective randomized controlled pilot study. Bone Rep. 2021;15:101099.