

Scientific Summary –
Latest news from science

Osteoporotic vertebral fracture – clinical trials demonstrate the efficacy of back orthoses

Pfeifer M et al. Am J Phys Med Rehabil 2004;83(3):177-186.
Pfeifer M et al. Am J Phys Med Rehabil 2011;90(10):805-815.

#02

Spinal orthoses demonstrate a positive effect in women suffering from osteoporotic vertebral fracture

Osteoporosis is a systemic skeletal disease characterized by loss of bone mass and microarchitectural deterioration of bone tissue. This leads to an enhanced bone fragility and an increased risk of fractures.¹

An estimated 22 million women and 5.5 million men are affected by osteoporosis within the EU. 3.5 million of these patients suffer new fragility fractures, of which 520,000 are fractures of vertebral bodies.²

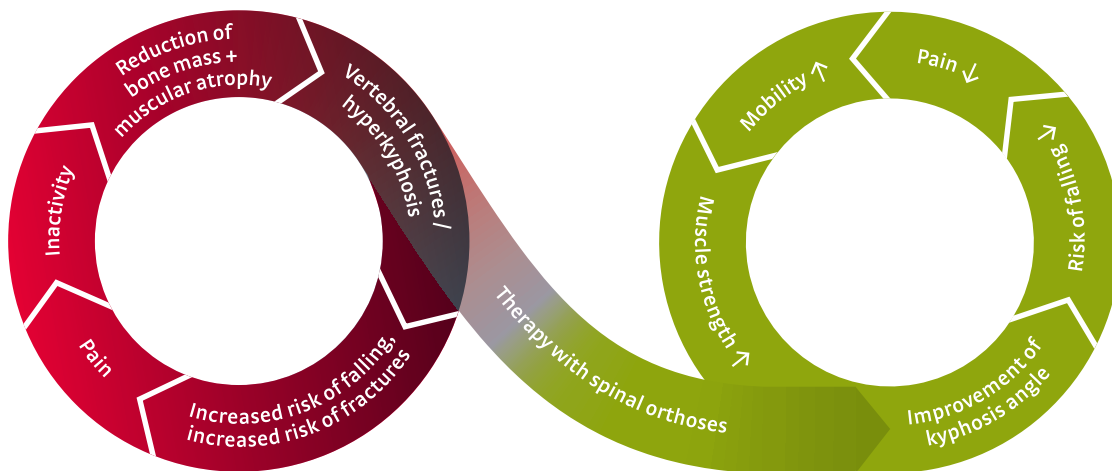
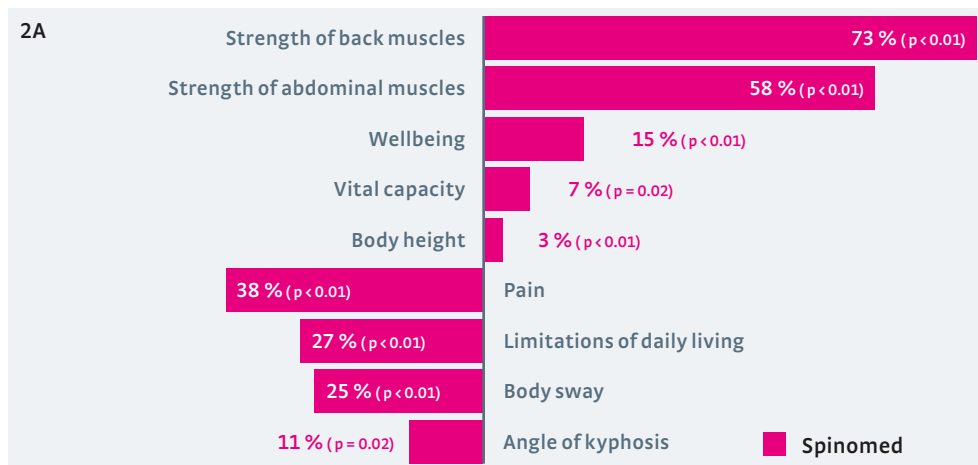


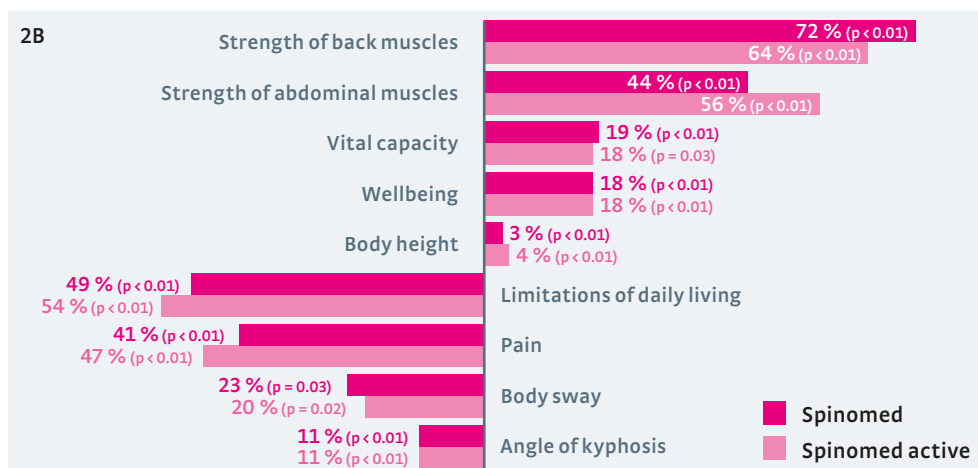
Abb. 1: Circulus vitiosus "Pathophysiological process of osteoporosis" and possible therapy measures (simplified diagram)

Two clinical studies prove the efficacy of the back orthoses Spinomed and Spinomed active in female patients suffering from postmenopausal osteoporosis

In two clinical trials, Pfeifer et al. demonstrated positive effects on osteoporosis-related symptoms by using spinal orthoses.^{3,4} Due to the positive results both studies were implemented in the German S3 guideline referring osteoporosis.⁵



The first study confirmed that wearing a back orthosis (Spinomed) leads amongst other things to a significant increase of back and abdominal muscle strength as well as vital capacity and a decrease of the kyphosis angle and the body sway after six months compared to the control group. In addition, the female patients profit from an increased quality of life, especially due to the reduction of pain.³



In a second study the back orthoses Spinomed and Spinomed active were tested against a control group. After six months of using the orthoses, the results of the first study could be verified, since a significant improvement of the symptoms and an increase of wellbeing could be clearly demonstrated.⁴

Fig. 2 A/B: Change of the osteoporosis-related symptoms after six-months by using the (A) back orthosis Spinomed and (B) Spinomed as well as Spinomed active

Conclusion:

Guideline-compliant therapy of osteoporotic vertebral fractures using spinal orthoses

The positive study results (Pfeifer et al. in 2004 and 2011) **demonstrated the efficacy of the back orthoses Spinomed or Spinomed active** in postmenopausal women suffering from osteoporosis.^{3,4} Therefore, these two studies were included in the current German S3 guideline “Prophylaxis, diagnostic and therapy of osteoporosis” due to their high relevance. **The guideline recommendations were assessed with the high recommendation grade “recommended” and with the highest to high evidence grade according the SIGN* criteria (1++ and 2++) as well as the highest strength of consensus.**⁵

Therefore, by using these **spinal orthoses** pain and functional impairments can be effectively **treated according to the guidelines.**

*SIGN: Scottish Intercollegiate Guidelines Network

Expert's statement (Dr. M. Pfeifer):

*“Considering the current scientific study situation of evidence based medicine **only orthoses should be used** and prescribed whose **efficacy was clearly proven in several clinical trials.** From this point of view, **the use of so called “imitator bandages” should be avoided.** Since a potential patient's risk cannot be excluded, it can only be warned against the use of alternative orthosis and / or bandages.”⁶*

¹ Consensus Development Conference. Diagnosis, prophylaxis and treatment of osteoporosis. Am J Med 94,1993:646–650.

² Svedbom A et al. Osteoporosis in the European Union: a compendium of country-specific reports. Arch Osteoporos 2013;8:137.

³ 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.

⁴ 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.

⁵ German S3 guideline referring prophylaxis, diagnostic and therapy of osteoporosis in postmenopausal women and in men. AWMF-registry-No.: 183/001; version: 2017. Online available at: https://www.awmf.org/uploads/tx_szleitlinien/183-001_S3_Osteoporose-Prophylaxe-Diagnostik-Therapie_2019-02.pdf (Last access: 2020; Apr 20th)

⁶ Pfeifer M. The role of back orthoses in the treatment of vertebral fractures due to osteoporosis. Osteologie 2015;24:11-16.

