

# IMPACT OF THE Spinova Stabi Classic LUMBAR ORTHOSIS ON THE CONSERVATIVE TREATMENT OF BACK PAIN

## INTRODUCTION

Back pain is the most common type of acute and chronic pain related to the locomotor system. It can radiate into all parts of the body.

Usually, the main cause of back pain is acute, local pain in the lower back. Other causes include vertebral displacement, intervertebral disk prolapse, and lumbago. The latter will generally occur during an everyday movement, such as lifting, turning, or bending, and result in extreme pain in the lumbar spine. The back muscles will then harden and any movement will be absolute torture.

This non-interventional study has been designed to examine whether, using this orthosis, pain can be reduced, the spine can be stabilized as well as relieved, and mobility can be improved. Data collection also included the situations in which the orthosis was worn, what patients thought about wearing comfort, and how easily everyday activities could be performed.

## METHOD

From August 2022 to March 2023, 70 patients (40 women/ 30 men) with back pain were conservatively treated using the Spinova Stabi Classic orthosis.

45 patients were diagnosed with osteoarthritis of the facet joint or facet syndrome, and 17 with osteoarthritis of the lumbar spine. Other indications included moderately severe lumbar sciatica, L4 root irritation, L3/L4 prolapse, fracture of the first lumbar vertebral body, low back pain, and low back strain.

In addition to the orthosis, the following treatment options were implemented, sometimes several at the same time: 22 patients underwent physiotherapy, 17 thermotherapy, 14 manual therapy, 8 therapeutic exercise, and 17 acupuncture.

Patients were between 16 and 91 years old, with 50 percent between 47.5 and 77.3 (see Fig. 1).

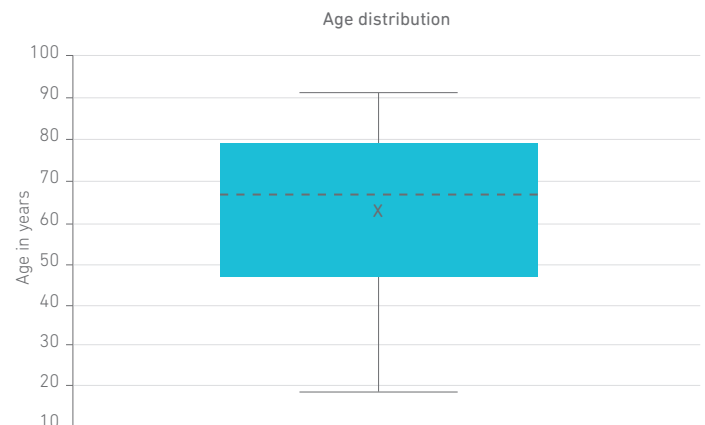


Fig. 1: Age distribution

Pain reduction, improvement in mobility, and stabilization of the spine were the most common treatment goals. (Fig. 2)

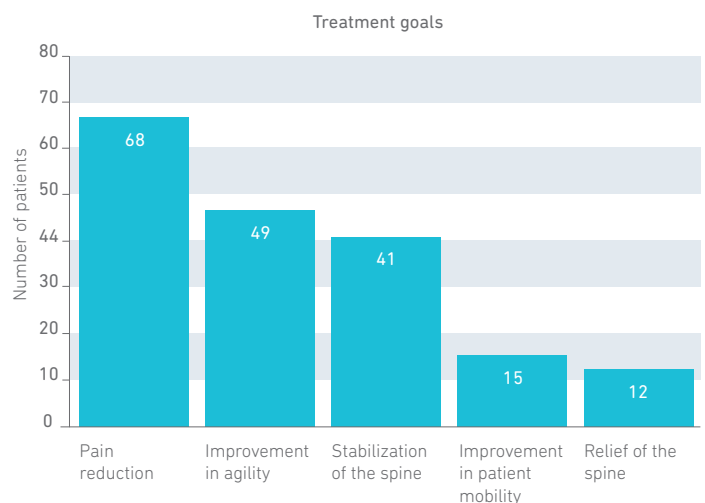


Fig. 2: Treatment goals, treating physicians' specification, several answers possible

## RESULTS

The extent to which the treatment goals were achieved, and therefore the benefits experienced by patients, was rated at 7.3 on average (on a scale of 1 to 10, with 1 being no benefit, and 10 being maximum benefit) by the treating physicians. (No graphic).

Most patients reported wearing the orthosis for 3 to 4 hours per day (52.9 percent) or 5 to 8 hours (34.3 percent). 9 patients (12.8 percent) wore it for 1 to 2 hours per day.

The investigation period for each patient using the orthosis was 1 to 2 weeks on average, thus focusing on the acute effect of the orthosis.

When asked in which situations patients donned the orthosis (several answers were possible), 45.7 percent stated at work, 25.7 percent wore it the entire day, 22.8 percent during leisure activities, and 7.1 percent in other situations. (Fig. 3)

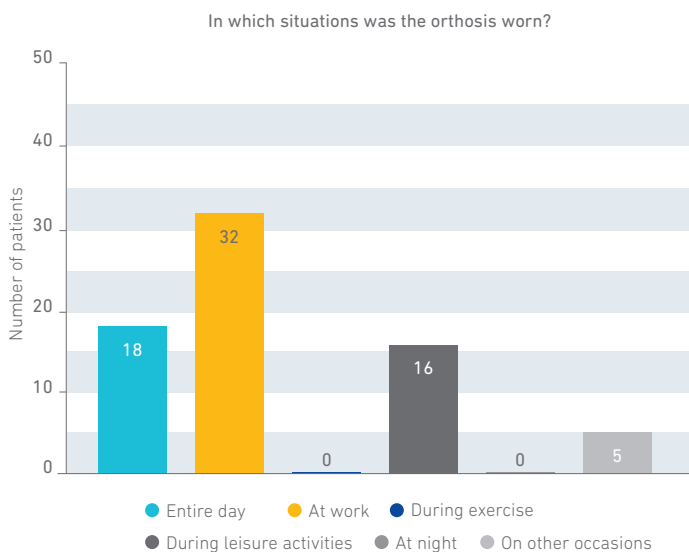


Fig. 3: The diagram shows in which situations the orthosis was worn. (Patients n total = 70, several answers were possible)

Pain perception was recorded using a 10-point VAS scale. Pain reduced by an average of 1.6 points, from 5.7 to 4.1. This represents a pain reduction by 28.1 percent. (Fig. 4)

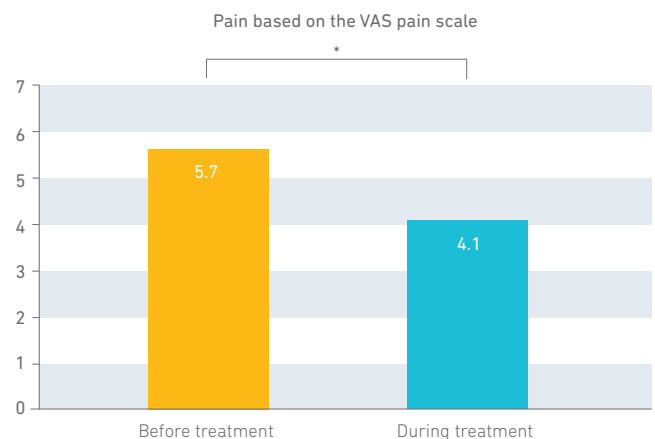


Fig. 4: Pain perception rated on a 10-point VAS scale; (0 = no pain/10 = severe pain) Significance: Wilcoxon Signed Rank Test,  $P < 0.001$

39 patients regularly took pain medication. 69 percent of these were able to reduce the amount of pain medication during treatment, thanks to the orthosis, 31 percent stayed with the same amount.

51 patients (about 73 percent) answered the question whether the donned orthosis stabilizes the spine and provides a feeling of protection with good to very good. 18 patients (about 26 percent) found the effect satisfactory, and only 1 patient merely adequate. Nobody stated that the orthosis provided very little or no stabilization.

## RESULTS

The following assessments were made on a 10-point VAS scale: The feeling of stability when standing and when taking the stairs improved by one point on the scale on average when the orthosis was worn. The feeling of stability when walking on even, firm ground or on loose ground improved by an average of 1.1 points (see Fig. 5).

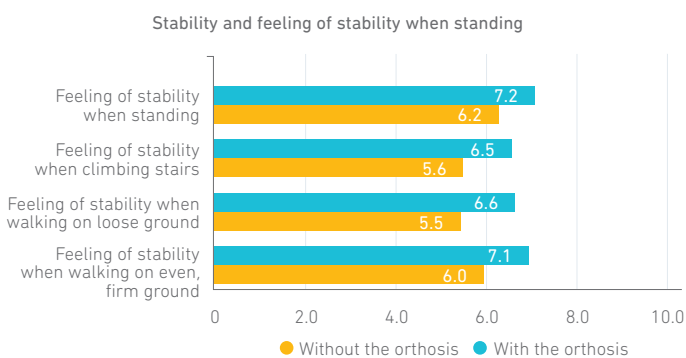


Fig. 5: Stability and the feeling of stability when standing rated using a 10-point VAS scale (0 = non-existent/10 = very good)  
\*Significance: Wilcoxon Signed Rank Test, P = < 0.001

When asked about the estimated maximum walking distance without pain, the following statements were made: The walking distance without pain was rated at 5.4 on a 10-point VAS scale without the orthosis (0 = short/10 = long), with the orthosis, the average was 6.5.

Therefore, wearing the orthosis increased the pain-free walking distance by 20.4 percent (no graphic).

When asked how good mobility was during treatment, patients stated an average of 5.4 without the orthosis and 6.6 with the orthosis on a 10-point VAS scale. This represents an improvement in mobility of 22.2 percent (see Fig. 6).

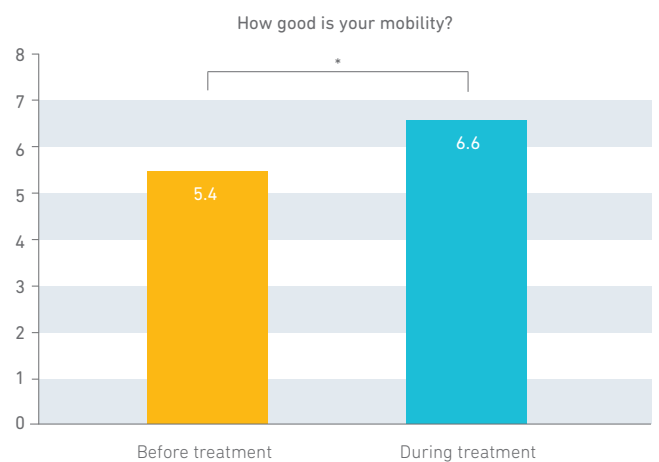


Fig. 6: Mobility rated using a 10-point VAS scale (0 = very bad/10 = very good)  
Significance: Wilcoxon Signed Rank Test, P = < 0.001

When using the orthosis, 97 percent of patients were able to perform everyday activities, such as gentle work in the kitchen or garden, as well as shopping, etc. without restrictions or with minor restrictions only (see Fig. 7).

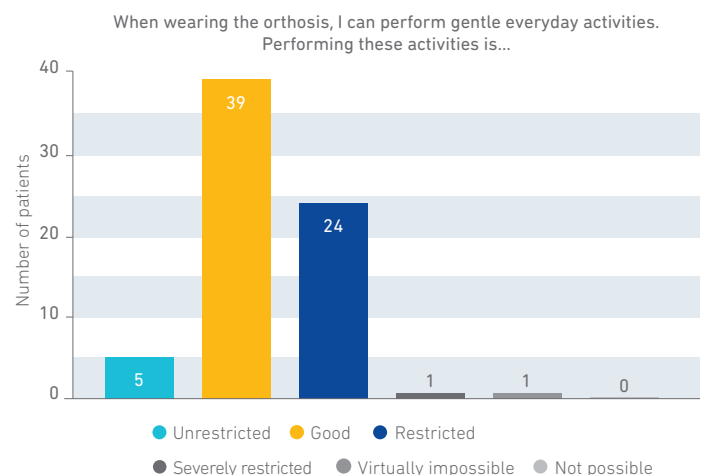


Fig. 7: Question whether everyday activities can be performed when using the orthosis e.g. gentle work in the kitchen or garden, as well as shopping, etc.

## RESULTS

Handling/donning of the orthosis was perceived as easy to very easy by 52.9 percent, without problems by 24.3 percent, strenuous by 15.7 percent, and problematic to very difficult by 7.1 percent. 70 percent of patients rated the fit as good to excellent, 27.1 percent as satisfactory, and 2.9 percent as poor. Nobody rated it as adequate or inadequate. Patients rated the wearing comfort with regard to breathability as 2.4 on average, skin friendliness as 2.3, and weight of the orthosis as 2.3. (Fig. 8)

## CONCLUSION:

- Pain reduction by an average of 28.1 percent
- Improvement in patient mobility by 22.2 percent
- Improves feeling of stability
- Offers a high degree of wearing comfort

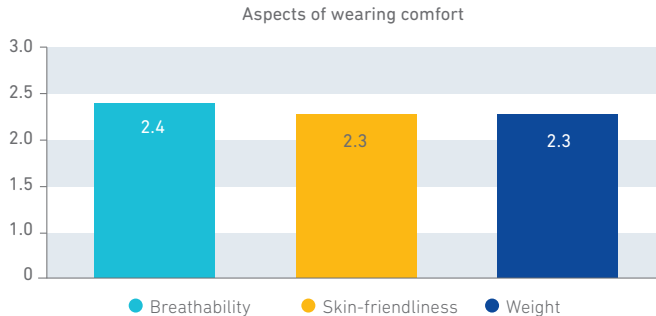


Fig. 8: Assessment of wearing comfort on a scale of 1 to 6 (1 = excellent to 6 = inadequate)

## ADVERSE REACTIONS, ADVERSE EVENTS:

None of the 70 patients suffered any adverse effects caused by the orthosis for the wearing duration.

## CONCLUDING OBSERVATION

The Spinova Stabi Classic orthosis has been proven to be effective when it comes to pain reduction and improvement in stability as well as mobility in patients suffering from back pain. Furthermore, the orthosis offers a high degree of wearing comfort and allows patients to perform everyday activities, largely without restrictions. Based on the positive results and lack of serious side effects, the Spinova Stabi Classic can be recommended as a safe and effective treatment option in the case of back pain. Further data acquisition is desirable to confirm the existing findings.