

# EVALUATION OF FIELD OF APPLICATION, EFFECT, AND THERAPEUTIC SAFETY OF THE LumboLoc® Forte BACK ORTHOSIS

## INTRODUCTION

A common indication with regard to back pain is osteoarthritis of the spine. This is a degenerative condition of the small vertebral joints (facet joints), which is also known as facet syndrome, osteoarthritis of the vertebral joints, or osteoarthritis of the facet joints. The pathology is characterized by degenerating progression, resulting in structural changes to the articular surfaces which can cause clinically relevant pain and restriction in movement based on increasing degradation.

Facet joint conditions often lead to chronic pain in the lower back. Prevalence is between 15 percent (in younger patients) and 41 percent (in patients aged 60 and above).<sup>1</sup>

The objective of this non-interventional study was to evaluate the medical benefits of the back orthosis systematically. As part of data collection, we also recorded during which activities the orthosis was worn, how wearing comfort was rated, and to what extent patients were able to perform day-to-day tasks.

Patients suffering from osteoarthritis of the spine and various concomitant indications were given a stabilizing back orthosis. Treatment was largely conservative, with one patient being treated post-operatively.

## METHOD

Across Germany, 49 patients (31 women, 18 men) aged between 37 and 89 (average 68.3 years) were treated in 9 physician's practices using the LumboLoc Forte orthosis based on their indication of osteoarthritis of the spine.

46 patients suffered from concomitant indications: osteochondrosis (n = 26), intervertebral disk herniation (n = 11), foraminal stenosis (n = 11), spondylolysis (n = 11), spinal canal stenosis (n = 4), fractures (n = 3), and scoliosis (n = 2). In 18 cases, patients suffered from several concomitant indications at the same time.

Before taking part in the study, 15 patients took analgesics and 8 patients took anti-inflammatory drugs. In addition to treatment with drugs, massages (n = 5), thermotherapy (n = 7), manual therapy (n = 8), and/or treatment using stimulating electrical current (n = 7) were prescribed; 3 patients were given orthopedic foot orthoses. In total, 32 patients were sent to physiotherapy, sometimes in combination with the treatment types mentioned. Of these 49 test subjects, 47 fully completed the study.

## RESULTS

When data was collected, the treating physicians asked patients about their individual treatment goals. The most common goal for the treatment of osteoarthritis of the spine was pain reduction. This was named in all 47 completed cases (Fig. 1).

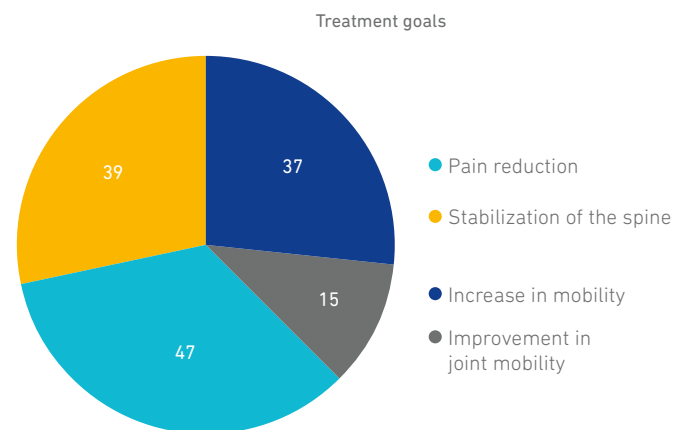


Fig. 1: Goals specified by physicians treating osteoarthritis of the spine; several answers possible in each case

During the patients' follow-up appointment, physicians were asked how effective they thought treatment using the back orthosis was, on a scale of 1 = excellent to 5 = not at all.

Pain reduction achieved was rated at 2.5 on average. Achievement of other goals was rated at 2.5 to 2.7 by the physicians; see Fig. 2.

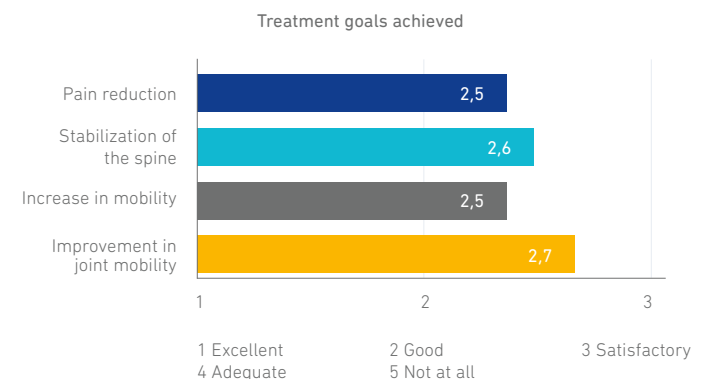


Fig. 2: Treatment goals achieved using LumboLoc Forte, evaluation provided by the treating physicians

<sup>1</sup> Source: <https://sportaerztezeitung.com/rubriken/therapie/1643/facettensyndrom>



## RESULTS

The treatment duration varied between 2 and 18 weeks. On average, patients were questioned again around 9 weeks after being given the orthosis.

When asked in which situations patients donned the orthosis (several answers were possible), 42.6 percent stated during leisure activities, 34 percent wore it the entire day, 36.2 percent at work, 25.5 percent on other occasions, 10.6 percent during exercise, and 2.1 percent at night. Nobody wore it during the day and at night; see Fig. 3.

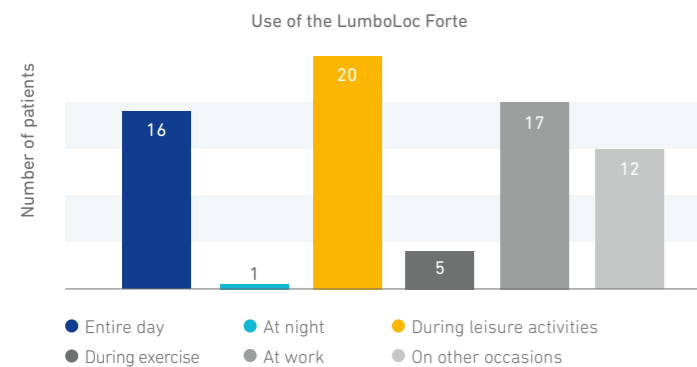


Fig. 3: Use of the LumboLoc Forte, patients (n total = 47, several answers were possible)

Pain perception was recorded using a 10-point VAS scale. Pain reduced significantly by an average of 3.2 points, from 7.1 to 3.9. This represents a pain reduction by 45.1 percent. (Fig. 4)

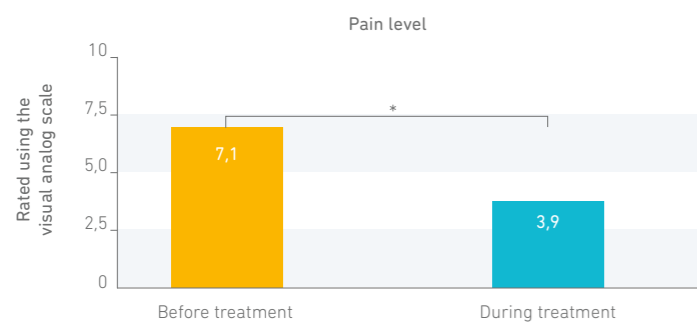


Fig. 4: Pain perception rated on a 10-point VAS; 0 = no pain to 10 = extremely serious pain

34 patients regularly took pain medication. 19 of these were able to reduce the amount of pain medication during treatment, 15 stayed with the same amount.

When asked how the orthosis provided support during treatment, a total of 55.3 percent of patients stated that the orthosis provided good to excellent support and increased confidence during treatment. 19.1 percent of patients rated the treatment support provided by the orthosis as satisfactory, while 14.9 percent found it adequate. 8.5 percent of patients reported that they felt hardly or not at all supported by the orthosis (see Fig. 5).

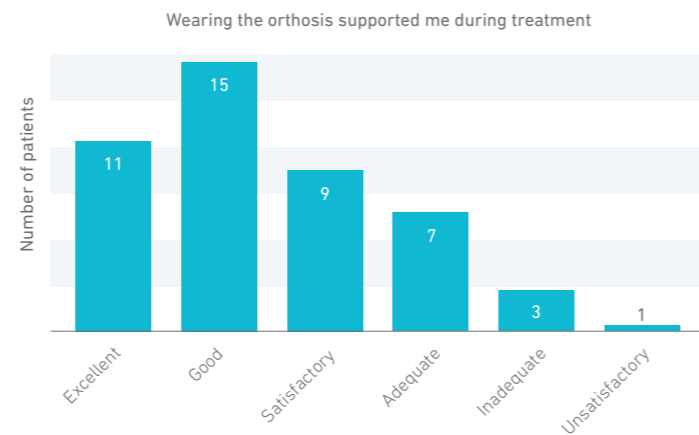


Fig. 5: Support provided by the LumboLoc Forte. (Rating: excellent to unsatisfactory)

Data concerning stability during walking, stability when taking the stairs, feeling of stability when standing, and mobility was collected based on a visual analog scale (VAS, 0 to 10). Wearing the orthosis resulted in significant improvement in all parameters. The subjective feeling of stability when walking and taking the stairs increased by an average of 3.1 points on the scale. The feeling of stability when standing increased by an average of 2.7 points. Furthermore, perceived mobility increased by 3.3 points on average (see Fig. 6).

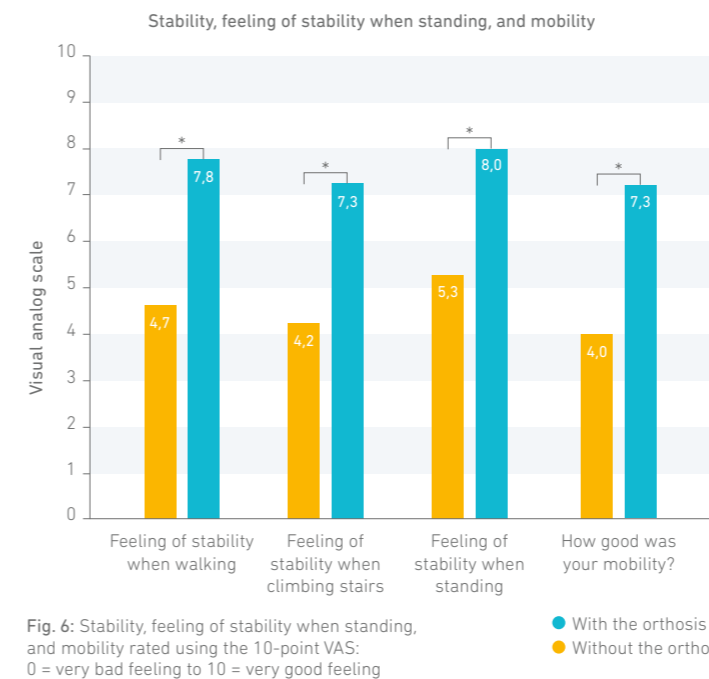


Fig. 6: Stability, feeling of stability when standing, and mobility rated using the 10-point VAS: 0 = very bad feeling to 10 = very good feeling

Data collection concerning the maximum pain-free walking distance estimated by the patients themselves resulted in a significant improvement during treatment with the LumboLoc Forte. Before treatment started, the average evaluation of the pain-free walking distance was 3.9 on the 10-point VAS (0 = very short, 10 = very long). During treatment with the LumboLoc Forte, the average value went up to 6.6 points, which represents a relative increase of 69.3 percent. Overall, this indicates that wearing the orthosis results in a significant increase in the subjectively perceived pain-free walking distance (top figure).

When asked "Can you perform everyday activities with the orthosis, such as easy tasks in the kitchen, garden, or going shopping?", 63.8 percent of patients answered that they were able to carry out these activities with no restrictions or very well. Another 29.8 percent mentioned that they were restricted when carrying out these tasks. Only 6.4 percent of those asked reported that they were seriously restricted or were hardly able to perform the activities. Nobody was completely unable to carry out the everyday activities (see Fig. 7).

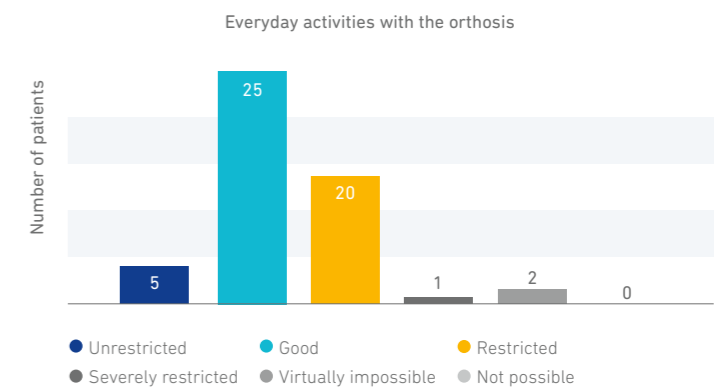


Fig. 7: Everyday activities with the LumboLoc Forte

Considering all "Pros" and "Cons", how satisfied are you with the orthosis overall? 39 patients answered this question by saying they were mostly satisfied to very satisfied with the orthosis. Eight patients questioned expressed partial to low satisfaction. None of the patients asked said that they were not satisfied with the orthosis (see Fig. 8).

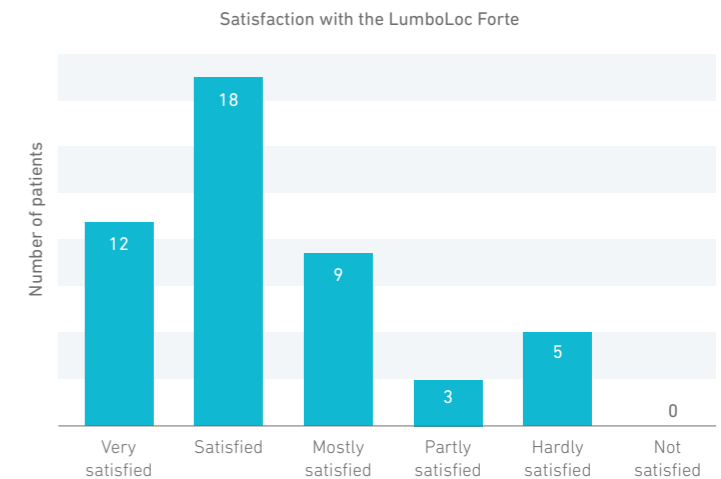


Fig. 8: How satisfied are you with the orthosis overall? Rating: very satisfied to not satisfied



## RESULTS

Handling and donning of the orthosis were perceived as easy to very easy by 66 percent, without problems by 19.1 percent, and as strenuous to problematic by 14.9 percent; nobody found it very difficult.

The fit and non-slip properties of the orthosis during movement were rated as good to excellent by 70.2 percent, as standard by 17 percent, and by 4.3 percent as not very good. 6.4 percent found them poor (see Fig. 9).

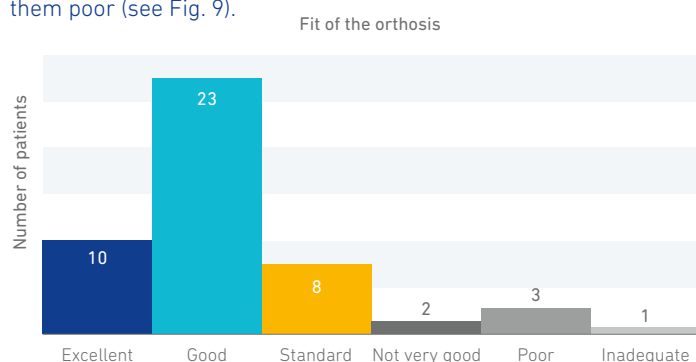


Fig. 9: How satisfied are you with the orthosis overall?  
Rating: very satisfied to not satisfied

Patients rated the wearing comfort with regard to breathability as 2.4 on average, skin friendliness as 2.2, and weight of the orthosis as 2.1 (Fig. 10).

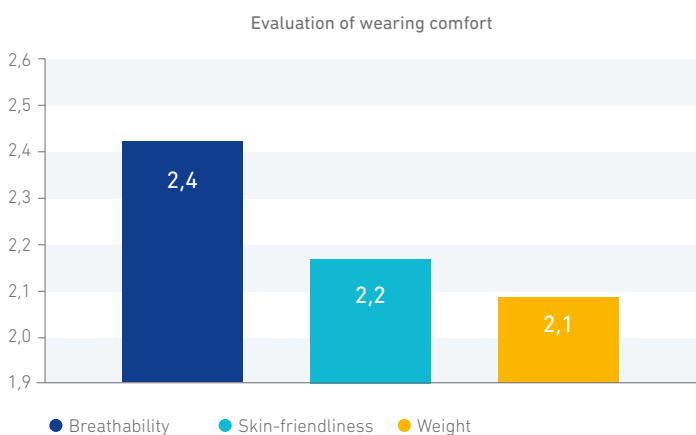


Fig. 10: Assessment of wearing comfort on an ordinal scale from 1 to 6,  
1 = excellent to 6 = inadequate

## ADVERSE REACTIONS, ADVERSE EVENTS

None of the 47 patients suffered any adverse effects caused by the orthosis for the wearing duration.

## CONCLUDING OBSERVATION

The results of this non-interventional study indicate that the examined LumboLoc Forte back orthosis has a clear positive impact on various patient-relevant parameters. In particular, improvements were noted relating to pain perception, the subjectively perceived pain-free walking distance, as well as the ability to perform everyday activities. A large part of patients also reported to being very satisfied to extremely satisfied with the orthosis.

The data collected indicates that wearing the orthosis can reduce functional as well as real-life oriented restrictions, thus contributing to an improvement in quality of life. The effects observed document real treatment conditions without experimental influence and offer practical evidence.

Overall, the results show that the LumboLoc Forte back orthosis provides noticeable benefits for the majority of users with back pain in connection with osteoarthritis of the spine and therefore represents a useful addition to conservative treatment concepts.

## CONCLUSIONS

When used to treat back pain, the LumboLoc Forte

- contributes to significant pain reduction by an average of 45.1 percent
- improves stability, the feeling of stability when standing, and mobility
- offers a high degree of wearing comfort, thanks to its pleasant fit and suitability to be used for everyday activities