STUDY PUBLICATION OF SELECTED RESULTS

THE EFFECT OF A LUMBAR ORTHOSIS ON PAIN PERCEPTION AND MOBILITY IN PATIENTS SUFFERING FROM LUMBAR BACK PAIN

BACKGROUND

Lightweight lumbar orthoses following the orthopedic design of a traditional lumbar support brace are anatomically contoured. Thanks to the reinforcements/stays or pads integrated at the back, they provide the spine with effective stabilization and relief, and have a muscle-activating effect.

One of the goals of the study is to determine the extent of lightweight lumbar orthosis use. We are also interested in finding out what additional treatment is implemented in combination with a back orthosis. Furthermore, data is recorded showing the clinical effect of the back orthosis and how patients perceive it.

STUDY DESIGN

Non-interventional, clinical, prospective cross-sectional study; case series, one-arm

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METHODS

Sample:	**n = 100 patients;** Age: 59.3 ± 18 years, Gender: male = 36 female = 64
Test supports:	LumboLoc® forte (Bauerfeind AG)
Measurement systems and test procedures:	data collection using a questionnaire
Investigation period:	data collection took place after the second visit T2, on average after five weeks, following initial diagnosis, T1.
Data assessment:	descriptive statistics for the different points in time using the overall data
Inclusion criteria:	diagnosis of an indication relevant to the back orthosis
Exclusion criteria:	additional, acute injuries and/or conditions that have a direct impact on the parameters of the data collected

RESULTS

Indications for a lumbar orthosis

Out of 100 patients who were treated with a lumbar orthosis, 30 per cent were diagnosed with low back pain, followed by 16 per cent who were diagnosed with lumbago. 19 per cent of indications were SI joint syndrome. These three indications make up around two thirds of observed conditions that are treated with lumbar orthoses.
Other indications where lumbar orthoses are prescribed are intervertebral disk conditions (protrusion and prolapse 7 per cent), root irritation (6 per cent), and facet syndrome or spondylolysis (5 per cent) as well as vertebral displacement (4 per cent).
For other, less common indications, see Fig. 1.

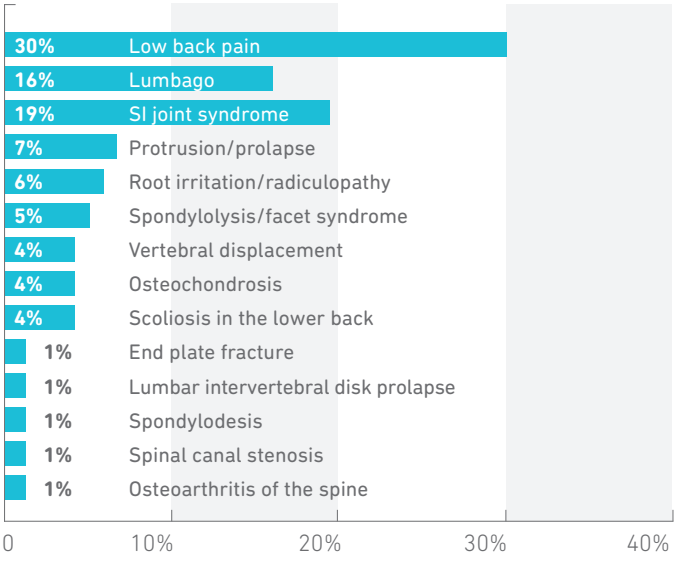

Fig. 1: Indications for lumbar orthosis use, 100 patients surveyed

TREATMENT REGIME

In 34 per cent of cases, only a lumbar orthosis was prescribed, in 66 per cent of cases, at least one other intervention in addition to the lumbar orthosis was implemented.
28 per cent of patients also did physiotherapy. Analgesics (4 per cent), manual therapy (3 per cent), or acupuncture (2 per cent) were prescribed less often as a second treatment measure in addition to the orthosis.
In 29 per cent of cases, **two** other treatment measures were implemented in addition to the orthosis, with the most common combinations being orthosis plus analgesics and acupuncture (6 per cent), and orthosis plus analgesics and physiotherapy (6 per cent). Overall, at 44 per cent, physiotherapy is the most frequently prescribed treatment in addition to a lumbar orthosis. (Fig. 2)

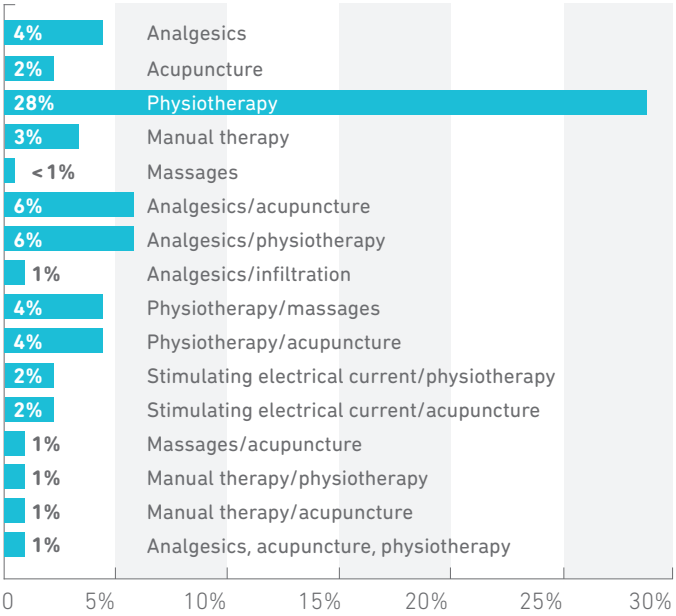

Fig. 2: Frequency of additional treatment options prescribed together with a lumbar orthosis in [%], n = 100

TREATMENT GOALS

The three treatment goals most often mentioned, and therefore most important, were pain reduction (85 per cent), improvement of agility (49 per cent), and the associated increase of patient mobility (42 per cent). Achievement of the goal was rated as good (rating 2.29 to 2.05) after an average of five weeks (5.13 / +- 1.63 calendar weeks) of treatment. (Fig. 3)

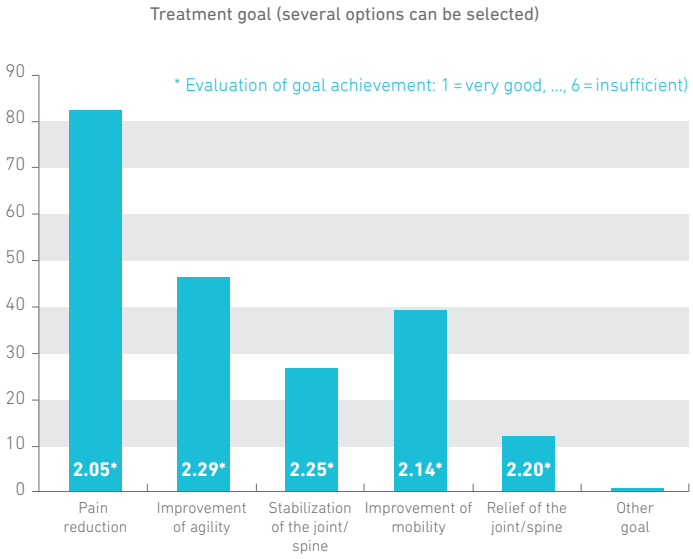

Fig. 3: Treatment goal for prescribing the lumbar orthosis, y axis = number of mentions, n = 97

COMPLIANCE

The majority of patients (61 per cent) indicated that they wore the orthosis for 3 to 4 hours per day. About a third of patients (29 per cent) indicated that they wore the orthosis for 5 to 8 hours per day. Few patients (6 per cent) wore the orthosis only occasionally for 1 to 2 hours per day. 4 per cent of patients wore the orthosis more than 8 hours per day. (Fig. 4)

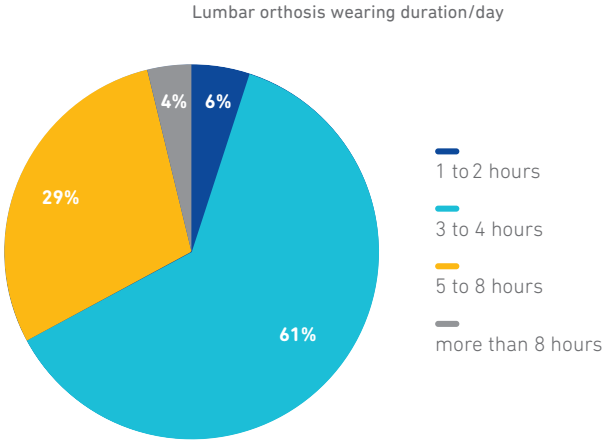

Fig. 4: Proportional distribution of the wearing duration of the orthosis/day, 100 patients surveyed according to their own reports, n = 100

ORTHOSIS USE

A quarter of patients used the lumbar orthosis for the entire day. The majority of patients (41 per cent) used the orthosis at work. 13 per cent of patients wore the orthosis during leisure activities, 5 per cent during exercise, and 2 per cent even at night. (Fig. 5)

93 per cent of patients rated the handling of the orthosis as without difficulty or very easy (average rating = 2.3). 79 per cent of patients rated the fit as good to excellent, 19 per cent of patients rated it as satisfactory (average rating = 2.2).
68 per cent of patients rated the wearing comfort as good to very good, 29 per cent of patients rated it as satisfactory (average rating = 2.3) (no figure).

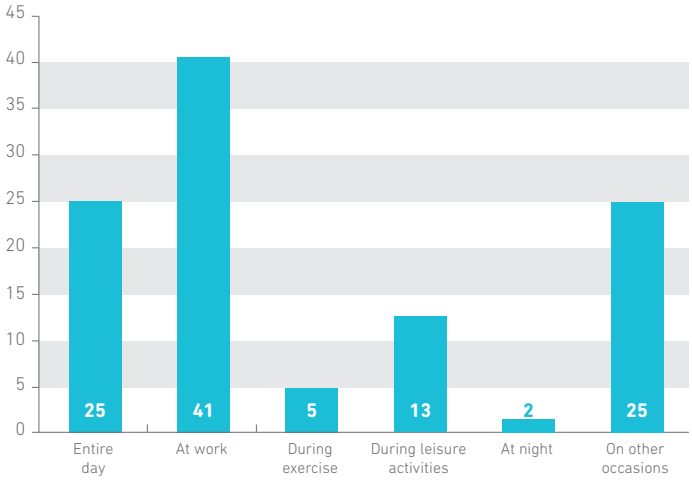

Fig. 5: Situations in which patients wore the lumbar orthosis during an average period of five weeks, n = 100, several options could be selected; (y axis = number of mentions)

STABILIZATION AND FEELING OF PROTECTION

78 per cent of patients rated the perceived stabilization of the orthosis and the associated feeling of protection as good to very good, 20 per cent rated it as satisfactory. 2 per cent of patients noted very little to no stabilization as a result of wearing the orthosis. (Fig. 6)

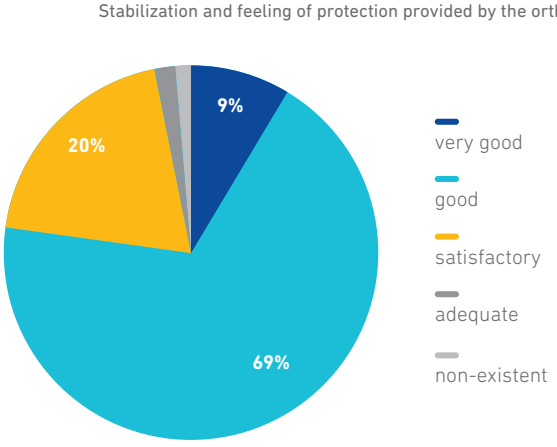

Fig. 6: Assessment of stabilization and feeling of protection provided by the orthosis, rated by 100 patients after an average orthosis wearing duration of five weeks, n = 100

PAIN REDUCTION

The 100 patients surveyed before treatment with a lumbar orthosis rated their pain level at an average of 6.5 on a 10-step VAS scale. After using the orthosis, pain perception significantly reduced by 2.2 to 4.3 on the 10-step VAS scale after an average of five weeks. (Fig. 7)
50 per cent of patients indicated that they were not taking pain medication in addition to their treatment with the orthosis. 1 per cent of patients indicated that they were taking pain medication three times a day, 26 per cent once to twice a day, 14 per cent every other day, and 9 per cent only once a week.
Since only 18 per cent of patients were prescribed analgesics, the other patients (32 per cent) must have been taking additional pain medication at their own discretion.
Of the 50 patients who took pain medication, 72 per cent indicated that they were able to reduce their previous pain medication consumption as a result of wearing the orthosis.

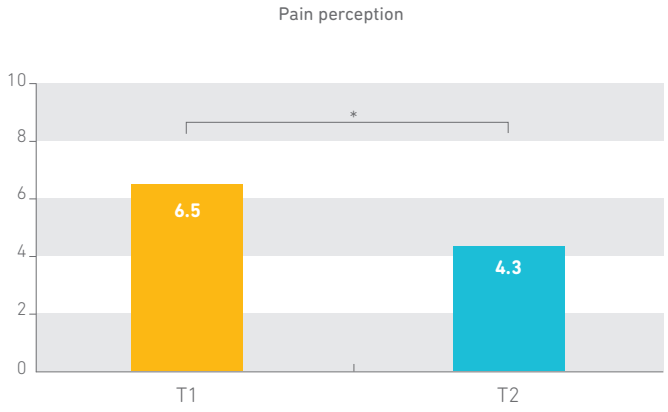

Fig. 7: Pain perception, averages; at T1 (before treatment with the lumbar orthosis) and at T2 (after an average of five weeks' treatment with the orthosis), y axis: 10-step VAS scale; n = 100; (* $p < 0.001$, $\alpha < 0.05$; power, $\beta = 80$ per cent; paired t-test)

MOBILITY

Before treatment, patient mobility was rated at an average of 5.1 on a 10-step VAS scale. After five weeks of treatment with the lumbar orthosis, patient mobility increased significantly. On average, an improvement by 1.3 points, i.e. a value of 6.4 was reported. (Fig. 8)

69 per cent of patients reported no problems or restrictions when carrying out everyday activities with the orthosis, 28 per cent of patients reported minor restrictions only (no figure).

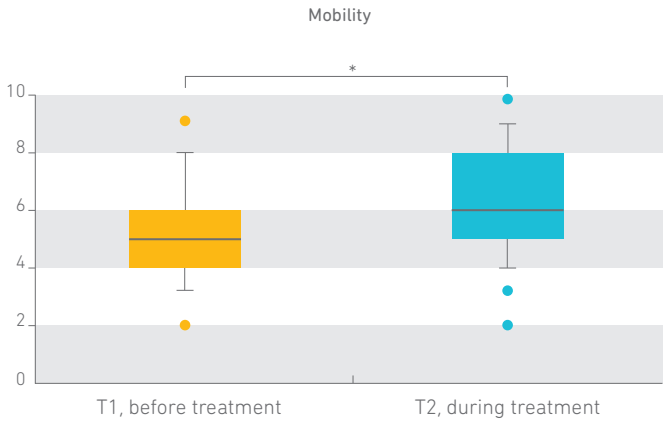

Fig. 8: Box plot showing: Median with quartiles; comparing patient mobility before treatment with the lumbar orthosis and after an average of five weeks' treatment with the orthosis, y axis: 10-step VAS scale; n = 95; (* $p < 0.001$, $\alpha < 0.05$; power, $\beta = 80$ per cent; Wilcoxon Signed Ranks Test)

DISCUSSION

Previous studies already showed a clinical effect of lumbar orthoses.
Even during an observational period of two weeks, wearing an orthosis in cases of acute, subacute, and chronic LBP resulted in an improvement of the self-assessed functionality of avoidance posture as well as patients' pain perception. [1]
This corresponds to patient statements from this study concerning pain perception and mobility with both comparable indications as the previous study and additional indications in the lumbar spine area, see Fig. 1.

Another study with patients suffering from degenerative lumbar spinal stenosis proved a mobilizing effect as a result of wearing the orthosis. Neurogenic claudication was improved so much by wearing an orthosis that patients' pain-free walking distance significantly increased compared with walking without an orthosis. [2]

Effects of lumbar orthoses were also confirmed during extended treatment of several months. Significant improvement was recorded when examining functional relief of patients being treated with orthoses for subacute LBP for three months, compared with patients who did not receive an orthosis. [3]
Additionally, the study recorded a decreased consumption of LBP-related medication in patients who were treated with an orthosis. This observation was also made in this study where the majority of patients reported that they were able to decrease their pain medication, thanks to the lumbar orthosis.

CONCLUSION

The LumboLoc forte lumbar orthosis is used for a **wide range of indications.**

Overall, the majority of patients (71 per cent) was **happy to very happy with the orthosis.**

The orthosis provides **clinically relevant pain reduction**. This also manifested in the fact that, according to patients, wearing the orthosis **decreased consumption of pain medication**.

Less pain, additional stabilization, as well as an improved feeling of protection all resulted in a significantly noticeable increase in patient mobility.

SOURCES

[1] Morrisette DC, Cholewicki J, Logan S, Seif G, McGowan S. A randomized clinical trial comparing extensible and inextensible lumbosacral orthoses and standard care alone in the management of lower back pain. Spine (Phila Pa 1976). 2014;39(21):1733-42.

[2] Prateepavanich P, Thanapipatsiri S, Santisatisakul P, Somshevita P, Charoensak T. The effectiveness of lumbosacral corset in symptomatic degenerative lumbar spinal stenosis. Journal of the Medical Association of Thailand = Chotmaihet thangphaet. 2001;84(4):572-6.

[3] Calmels P, Queneau P, Hamonet C, Le Pen C, Maurel F, Lerouvreur C, et al. Effectiveness of a lumbar belt in subacute low back pain: an open, multicentric, and randomized clinical study. Spine (Phila Pa 1976). 2009;34(3):215-20.