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SUMMARY OF SELECTED RESULTS

INTERNATIONAL OBSERVATIONAL STUDY ON THE EFFECTIVENESS OF THE LUMBOTRAIN IN CONSERVATIVE AND POSTOPERATIVE TREATMENT OF SPORTS INJURIES

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ABSTRACT

Back pain is a health problem that affects people worldwide. In Europe, 25% of employees experience back pain, while the global prevalence is 12%. This prevalence increases with age. The high recurrence rate also plays a significant role in the perception of back pain as a health problem worldwide. One study showed that almost half of patients who have suffered from back pain experience it again within a year[1].

Playing sports is a healthy pursuit, but one that comes with risks. Orthopedic specialists recommend swimming and running as sports that are gentle on the spine. At the other end of the scale, squash and weightlifting can cause damage to the spine. 15% of all sports injuries concern the spinal column. Sports that involve little movement and encourage participants to adopt an unhealthy posture (such as sailing and golf) carry an especially high risk of injury[2].

The conservative treatment of such injuries involves measures such as supports and orthoses, physical therapy, or painkillers. The LumboTrain relieves pain and exerts a stabilizing effect[3]. How do patients perceive the effect of the support after a sports injury? Do they feel more mobile in their everyday lives by the end of treatment? Answering these questions was the aim of the observational study.

STUDY DESIGN

prospective, transnational, multicenter observational study

METHODS

Sample:	The study centers were recruited from various international Bauerfeind companies. International medical specialists from the fields of orthopedics, surgery, trauma surgery, and sports medicine were involved. 153 patient cases were treated using LumboTrain.
Product:	LumboTrain back support (Bauerfeind AG)
Data collection:	July 2015 – March 2016 Documentation form filled in by physician and patient Measurement of patient's range of motion using the neutral-zero method[4]
Assessment dates:	T0*: Time before injury T1*: Initial examination (prescribing of aid, or shortly after aid is dispensed to the patient) T2*: during recovery T3*: Final examination (recovery is foreseeable) * The intervals between these dates were defined by the examiner based on the indication and the expected regeneration time.
Evaluation of data:	Descriptive statistics for the time points T0, T1, T2, T3 a) based on the overall data b) Examination of the effectiveness based on treatment regime clusters: Product without additional prescription, product and physiotherapy, product and painkillers, mix (product, physiotherapy, painkillers)
Inclusion criteria:	• Patients with a sports injury: Instability (functional instability, instability due to anatomical deficits e.g. ligament insufficiency, ligament rupture), joint pain with restriction of movement due to inappropriate or excessive mechanical stress (e.g. tendomyopathy, injuries to the capsular ligament, bruising, compression injuries, sprains), inflammation (e.g. tendinitis) • ≥ 29 prescriptions • Documentation of at least two of the three visits following primary treatment

[1] Daniel Steffens, PhD; Chris G. Maher, PhD; Leani S. M. Pereira, PhD; Matthew L Stevens, MScMed (Clin Epi); Vinicius C. Oliveira, PhD; Meredith Chapple, BPhty; Luci F. Teixeira-Salmela, PhD; Mark J. Hancock, PhD - Prevention of LowBack Pain A Systematic Review and Meta-analysis. 2016

[2] Krämer J., Wilcke, A., Krämer R., - Wirbelsäule und Sport. Empfehlungen von Sportarten aus orthopädischer und sportwissenschaftlicher Sicht. Deutscher Ärzte-Verlag. 2005: 1-2

[3] Valle-Jones J, C, Walsh H, O´Hara J, O`Hara H, Davey N, B, Controlled trial of a back support (LumboTrain) in patients with non specific low back pain ; Curr. Med. Res. Opin., (1992), 12, 604,

[4] Neutral-zero measurement: standardized orthopedic evaluation and documentation index for joint mobility

RESULTS

The demographic data of the patients treated with the LumboTrain showed the following:

Fig. 1: Demographic data

Prescriptions	n=153
Age	56.1 ± 16.6 years
Men	61
Women	92
Countries	Germany, Austria, Poland, Canada

In these countries (see Fig. 1), the LumboTrain was prescribed most frequently for pain in the spine (93.8%). Fewer patients were prescribed the support for instability (4.6%) and inflammation (1.5%). 46.4% of patients actively played sports at the time of the primary treatment; 53.6% did not.

Fig. 2: Patient symptoms

Symptoms	Back pain: 93.8% Inflammation of the spine: 4.6% Instability of the spine: 1.5%

The study results revealed a trend toward improvement of spinal mobility with regard to side bending and rotation:

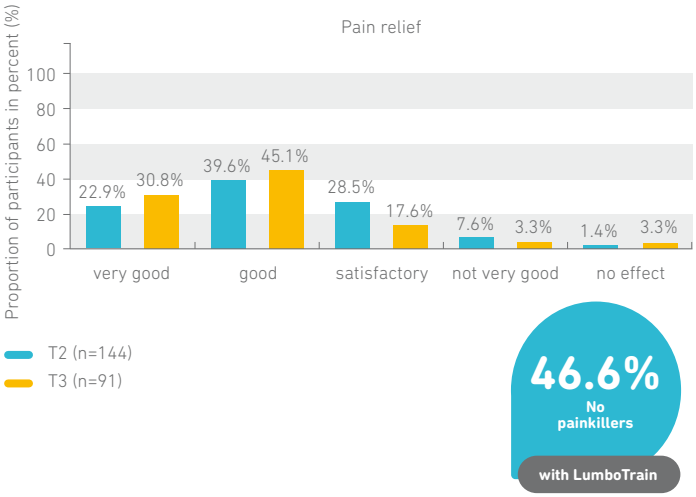
Fig. 3: Range of motion of the spine according to the neutral-zero measurement

ROM, side bending (30°–40°)			
left	**T1 (n = 152)**	**T2 (n = 146)**	**T3 (n = 91)**
mean	22.5	24.6	27.1
SD	9.3	9.4	10.5
right	**T1 (n = 152)**	**T2 (n = 147)**	**T3 (n = 91)**
mean	22.3	24.9	27.4
SD	9.4	9.3	10.7

ROM, rotation (30°)			
left	**T1 (n = 132)**	**T2 (n = 118)**	**T3 (n = 66)**
mean	20.8	21.7	22.4
SD	8.6	8.1	9
right	**T1 (n = 131)**	**T2 (n = 117)**	**T3 (n = 65)**
mean	20.3	21.6	22.8
SD	8.6	8.2	8.7

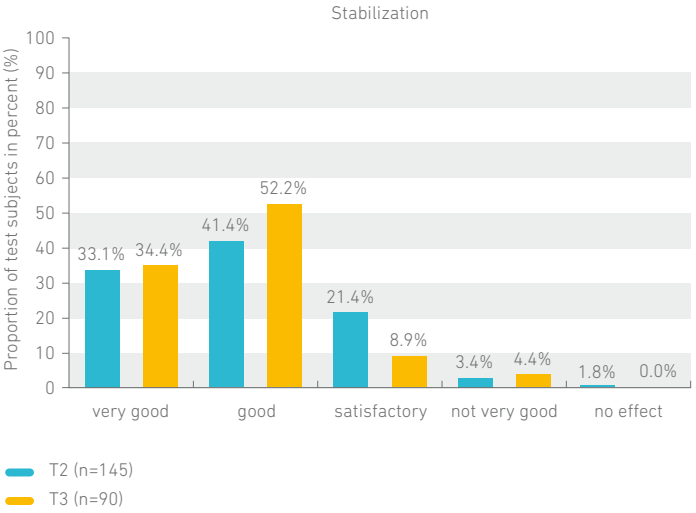
In addition to the range of motion of the spine, the patients' individual perceptions of pain were also examined over the course of treatment. Here, 62.5% of patients reported "good" to "very good" pain relief (T2). At the end of treatment, this figure increased to 75.9% (T3).

Fig. 3: Assessment of patients' pain relief when wearing the support (T2, T3) Overall data (options: very good, good, satisfactory, not very good, no effect)



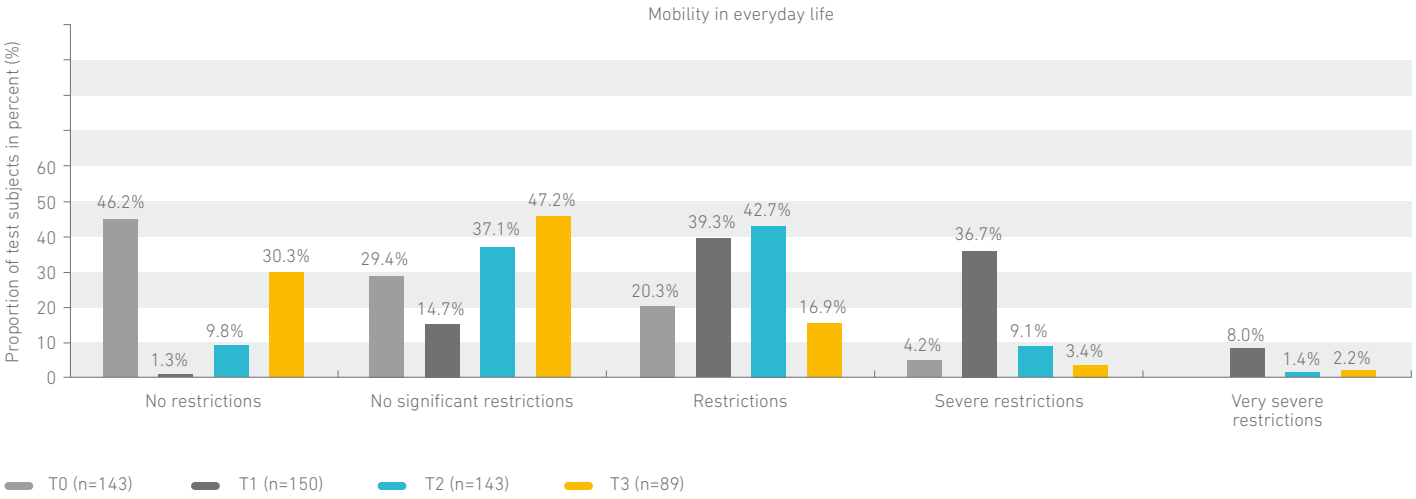
The consumption of painkillers was also closely linked to pain relief. At the start of treatment (T1), 57.5% of patients recorded taking an average of one to three doses of painkillers a day. One-quarter of patients reported occasional use of painkillers (T1). One-quarter consumed no painkillers (T1).
At the end of treatment (T3), the number of patients taking one to three doses of painkillers decreased to 14.9%. 46.6% of patients were no longer consuming any painkillers (T3).
Patients were also asked about their feeling of stability. During treatment (T2), three-quarters of patients reported good to very good stabilization as a result of wearing the support. This figure was 86.6% at the end of treatment (T3).

Fig. 4: Assessment of stabilization effect on patients as a result of wearing the support (T2, T3)



Patients were also asked how they rated their feeling of mobility during treatment. At the start of treatment (T1), 84% reported a restriction in mobility due to symptoms related to their injury. The vast majority in fact even rated this restriction as "severe" to "very severe." By the end of treatment (T3), a different picture had emerged. More than three-quarters of patients no longer experienced any restrictions in their everyday lives due to the injury.

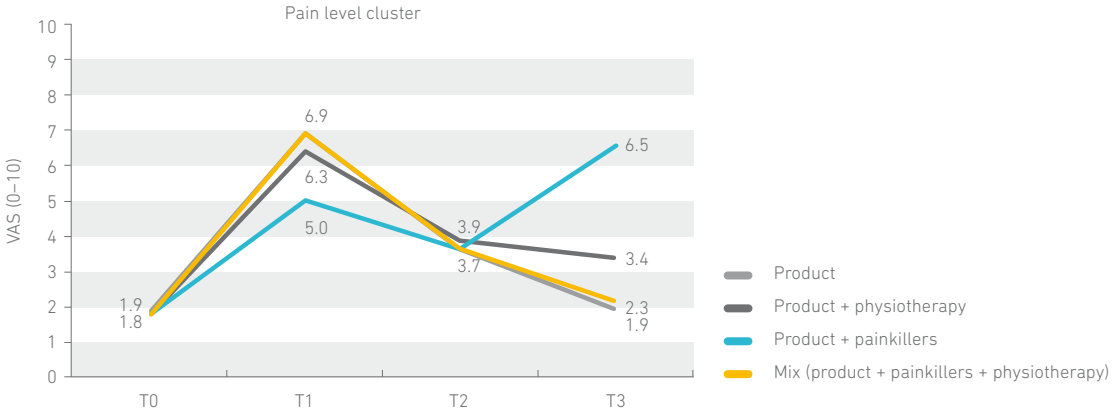
Fig. 4: Evaluation of mobility in everyday life (T1, T2, T3)
Overall data



In addition, the different treatment regimes were looked at separately in terms of patients' perceptions of pain and stability after a sports injury. For the same initial pain level (VAS: 6.9) at the point of injury (T1), prescription of the LumboTrain on its own achieved a greater reduction in pain than the "mix" of all the above-mentioned treatment measures.

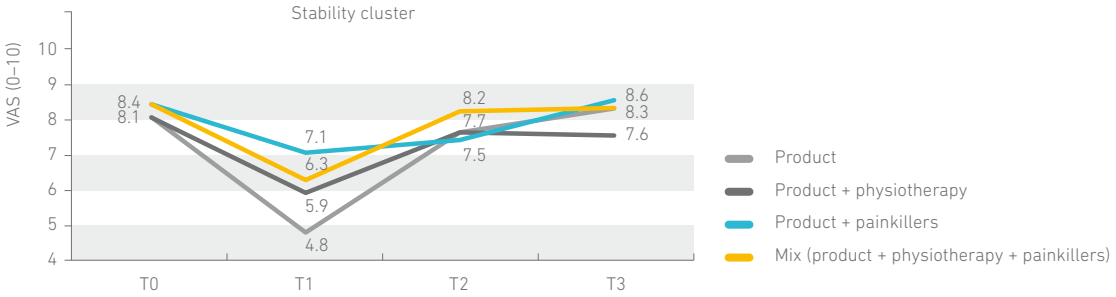
Compared to the time of primary treatment, patients given the treatment regime of the LumboTrain and additional physiotherapy did not achieve any reduction in pain by the end of treatment (VAS: 3.4). When painkillers were prescribed in addition to the product, a slight reduction in pain was attained during treatment. However, at the end of treatment (T3), patients reported an increased pain level (VAS: 6.5).

Fig. 5: Pain level T0–T3 – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy and painkillers))



Another aim of the observational study was to investigate the impact of the different treatment regimes on the patients' perception of stability. Patients who were given the LumboTrain on its own reported the lowest feeling of stability on average at the time of injury (VAS (T1): 4.8). By the end of treatment, this regime had restored the patients' stability to the same level as before their symptoms began (VAS: 8.3). The constant improvement in stability during treatment was perceived to a greater degree with this treatment regime than in the cases where additional physiotherapy or painkillers had been prescribed. Where the "mix" regime or additional physiotherapy had been prescribed, patients only reported an improvement in their stability during treatment and/or at the second visit to the physician (T2). From this point on, the feeling of stability remained the same up until the point of foreseeable recovery (T3).

Fig. 6: Feeling of stability T0–T3 – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy and painkillers)



In addition, the patients rated the LumboTrain with a high level of wearing comfort (8 out of 10 points on the VAS) at two points in time (T2, T3). During treatment, 80% of patients said that the support was "easy" to "very easy" to handle, with this figure rising to 90% by the end of treatment.

SUMMARY & DISCUSSION

When treating patients suffering from back pain, it takes more than just restrictive practices when prescribing medication to save money. A much more desirable goal is an effective form of treatment that reduces the number of days of inability to work, the number of relapses, and the risk of the injury becoming chronic, all while helping to prevent back pain[5].

In the international observational study, patients felt the most effective treatment following acute and chronic back pain was in wearing the LumboTrain exclusively. Their pain reduced continually until the end of treatment and their feeling of stability increased. During treatment (T2), patients also reported a reduced consumption of painkillers. Furthermore, all the treatment regimes plus additional use of the LumboTrain reduced the restrictions experienced by patients in daily life and improved their mobility. At the end of treatment (T3), three quarters of patients could go about their daily lives with no restrictions.
A randomized and controlled study conducted by Valle Jones et al. confirmed the action of the LumboTrain in cases of back pain[6]. Patients who wore the support experienced significantly less pain during activity, while at rest, and at night. They also reported less restriction of movement than the control group without the support. After as little as three days, 18% more patients had recovered in the group with the support than in the control group receiving standard treatment. As a result, 18% of the patients were once again able to work[6]. The use of back supports to treat back pain is further underscored by a study conducted by Branzk. Significantly, the effect on the patients' pain level and feeling of stability was increased in this case only in combination with concomitant muscle-strengthening training[7].

In the international observational study, a training program was part of the additional physiotherapy measures used. Alongside training, however, patients also received passive treatments, such as electric current, massage, and manual therapy. Here, the use of the LumboTrain on its own resulted in a more significant reduction in pain. The same results were found for patients' perceptions of stability. While using the LumboTrain on its own resulted in a continuous improvement in stability, this effect failed to materialize with additional physiotherapy. A comparison of the use of the LumboTrain alone and supplementary muscle training would constitute a strong overarching study objective in view of the promising effect observed.

As the observational study concerned non-interventional documentation of treatment, the end point of the treatment duration or the point of foreseeable recovery were determined using qualitative instead of quantitative data. Based on the study design, a period of 8 to 12 weeks can be assumed.
The investigation results postulate the use of the LumboTrain as a first priority as a result of pain and instability in an international context.

[5] Bolten, W., Kempel-Waibel, A. & Pförringer, W., Medizinische Ökonomie, Med Klin (1998) 93: 388. doi:10.1007/BF03044686https://link.springer.com/article/10.1007/BF03044686

[6] Valle-Jones J, C, Walsh H, O´Hara J, O`Hara H, Davey N, B, Controlled trial of a back support (LumboTrain) in patients with non specific low back pain ; Curr. Med. Res. Opin., (1992), 12, 604

[7] Brzank K,D, Bandagenanwendung und Trainingstherapie, The Use of Functional Back-Support Bandagen in Active Training Therapy; Orthopädie- Technik, (2001), 7, 513