Effectiveness of lumbar orthoses in low back pain: Review of the literature and our results

Cordelia Schott,[1] Sonja Zirke,[2] Jillian Marie Schmelzle,[3] Christel Kaiser,[4] Lluis Aguilar i Fernández[5]

[1]Institut für Wirbelsäulenforschung, Essen, Germany; [2]Institut für Wirbelsäulenforschung, Bochum, Germany; [3]American Society of Anesthesiologists, MacNeal Hospital, Berwyn, IL, USA; [4]Department of Orthopedics and Trauma Surgery, University Hospital, Essen, Germany; [5]Clínica Corachán, Barcelona, Spain

Abstract

Back pain and diseases of the spine are today a health disorder of outstanding epidemiological, medical, and health economic importance. The cost of care for patients with lumbosciatic complaints are steadily increasing. Accordingly, the guidelines and treatments are constantly renewed. One concept is the orthotic care. In the following we want to give an overview of the literature and the effectiveness of lumbar orthoses in low back pain supplemented by our own data. A prospective randomized study with 230 patients, divided into three groups, each with two subgroups. Three Orthoses by the TIGGES-Zours GmbH were prescribed; a demountable two-step lumbar orthosis, three-step bridging orthosis and a four-step flexion orthosis modular system. Each were compared to the non-modular equivalent. All six groups showed improvement in pain intensity and functional capacity at 6 and 12 weeks. The modular groups were found to have improvement in the frequency of use. The subjective effectiveness and sensitivity for the modular and non-modular groups was assessed as being good. In the literature, there are no clear guidelines for an orthotic supply. The studies do not seem to be meaningful and universal due to the difficult ascertainability of pain. There is a need for further research here. Nevertheless, the authors of this review are of the opinion that the implementation of trunk orthoses is void of side effects and beneficial to patients. The modular systems seem to have an advantage as well as higher patient satisfaction.

Introduction

Back pain and diseases of the spine are, in Germany and comparable countries today, a health disorder of outstanding epidemiological, medical and health economic importance.

In 2010, 26% of public insured adults in Germany, at least once sought medical help for low back pain.[1] For several years, low back pain has been the leading cause of disability and medical rehabilitation.[2,3] As a cause of early retirement due to reduced earning capacity, the diseases of the musculoskeletal system are the second leading cause only after the mental illness in recent years.[4] A recent survey of nearly 200,000 people across 43 countries showed that people with back pain are at least twice as likely to have one of five mental health conditions (depression, anxiety, stress, psychosis and sleep deprivation) when compared to those without back pain.[5] The cost of illness for back problems in Germany in 2008 was estimated at 9 billion Euros; for non-specific back pain, they amounted to 3.6 billion Euros.[6] The pertinence of low back pain is undisputed and present in everyday medical practice. New care guidelines are constantly being reviewed and revised to optimize the care of patients and reduce costs.

In the diagnosis and treatment, a distinction is made between nonspecific low back pain, subacute and acute low back pain, as well as chronic low back pain. If patients with low back pain have no evidence of dangerous courses or other serious pathologies at initial presentation based on patient history and physical examination, no further diagnostic measures should be performed.[7] A restriction of basic diagnostics can save those affected unnecessary burdens and unnecessary healthcare costs.[8] The basic diagnosis includes the history, including the localization and the transmission of the pain, the duration and the time course of the complaints, as well as triggers, risk factors and concomitant symptoms, and lastly, a detailed physical examination. The nonspecific back pain is objectively not proven by simple clinical means. Different pain thresholds of the patients complicates the matter. There are subjective pain questionnaires for better pain verification.[9,10] Specific low back pain generally includes morphological entities such as lumbar facet syndrome/spondyloarthrosis, discogenic lumbar syndrome to vertebral osteochondrosis, axial spondyloarthritis, M. Baastrup, spinal stenosis, spondylolysis and hernia, herniated disc, osteoporotic sinter fracture, pathologic processes of the sacroiliac joints, as well as the functional entities such as myofascial dysfunctions and the hypomobile segment.[11] Diagnosis of a specific low back pain usually requires diagnostic imaging. The basic diagnosis consists of a conventional x-ray image of the lumbar spine (LWS) standing in two planes, as well as a magnetic resonance tomography (MRI) of the lumbar spine. Additional imaging techniques (computed tomography (CT), full spine imaging, LWS function scans, scintigraphy, myelograhia) may be indicated depending on the clinical picture and question. Imaging of the sacroiliac joints (MRI) would also be required for sacroiliitis.[11]

There is a so-called flag model for better diagnostics and treatment planning.[9,12,13]

If there are "red flag" warnings from the somatic area, such as with pre-existing tumors, infections, fractures and radiculopathies, further imaging or laboratory examinations and / or referrals to specialists should be initiated depending on the suspected diagnosis and urgency.[7] Depression, stress and pain avoidance behavior, as well as negative mental health and somatization tendencies are "yellow flags" and point to psychosocial risk factors and the risk of chronification.

Therapeutically, there are numerous surgical and non-surgical therapies available including physical therapy, drug therapy, and interventional therapy. Clinical review shows a short-term analgesic and functional improvement with oral non-steroidal anti-inflammatory drugs in acute

Correspondence: Cordelia Schott, Institut für Wirbelsäulenforschung, Hindenburgstraße 27, 45127 Essen, Germany.
Tel.: +49.201.8214690 - Fax +49.201.82146929.
E-mail: info@dr-cordelia-schott.de

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and chronic nonspecific low back pain compared to placebo with a median difference within 16 weeks of -5.96 on a 0-100 visual analogue scale.[14-16] Due to the side effect potential, they should be low-dose and only be used for a short time. Medical pain therapy is increasingly meeting patients' rejection due to the side effects and the increasing media presence of intolerance cases. Also, is of concern is the opioid epidemic. Further, reviews have shown that bed rest in acute nonspecific low back pain either has no effect or delays healing and resumption of daily activities and leads to longer sick leave.[17] According to the study, exercise therapy is superior to passive therapies and more effective in terms of pain reduction and better functioning.[18-20] There are numerous forms of exercise therapy. According to current studies, it is not possible to deduce which specific form of exercise therapy most effectively contributes to pain relief and functional improvement.[19,20]

Another therapeutic approach is the corset care. There are ready-made, prefabricated orthoses, which are adapted in a modular system. As 3-7% of the population suffers from a chronic lumbago, lumbar orthoses and corsets are widely used for therapy as well as primary and secondary prevention.[21,22] The aim of orthotic treatment is to correct existing deformity or prevent progression by stabilizing and immobilizing weak or damaged spinal segments, reducing axial load bearing of affected spinal segments, and controlling movement.[23,24]

Table 1 presents an overview of the individual orthosis types and their indications.

Braces and corsets are supposed to support the spine from the outside, and are worn over the trunk. They are tight fitting to the body and can be classified according to function, inventor, or the processed material. Here, the supporting braces are shown opposite the stabilizing braces. The lumbar support braces are one of the simplest forms of supportive braces.

The bodice can be semi-finished, finished, or custom made. It's a textile construction made of elastic or partially elastic material which encircles the body. The corset can be strengthened by straps coming from behind which connect to the ventral support flap. The lumbar support should improve the proprioception and lead to more stabilization. Furthermore, the resulting heat on the trunk leads to hyperemia, which causes relaxation of the tense musculature.

The brace is indicated for simple pain syndromes at the lumbosacral junction, minor instability syndromes, and lumbago.

Some of these braces may include a dorsal pad. The sacral pad, ending below the lumbo-sacral junction, is distinguished from the cruteal pad which extends from the upper third of the crura to the middle of the lumbar spine, and from the bridging pad which extends from the lower crotch to the lower third of the thoracic spine, thus bridging the entire lumbar spine. The dorsal pads lead to support magnification and pressure distribution and it is said to have a massaging and warming effect. The braces do not restrict movement due to the dynamic construction and the use of elastic material. These are indicated for chronic recurrent pain, muscular insufficiencies and lumbar instability.

Differing from the supporting braces, are the stabilizing braces. These include the lumbar supporting braces with steel rods, which are introduced paravertebrally. This limits the extension and flexion. They are especially indicated for spondylolisthesis, as well as chronic lumbalgia and lumboischialgia, and for instability syndromes of the lumbar spine. The frame support corset has an even stronger stabilizing effect. This is also a textile construction with a plastic frame, which cranially includes the trunk with a thoracic brace and caudally with a pelvic frame. For further stability, dorsal paravertebral steel rods can be introduced and, if necessary, a ventral abdominal pad. The frame support corset causes a limitation of the extension, flexion, lateral tilt, and rotation. In conjunction with the ventral pad and ventral girdles, the three-point effect and flexion are additionally achieved. It is indicated for acute and chronic lumbago, pain in the thoracic spine or at the thoracolumbar junction, postnucleotomy syndrome, instability with increased lordosis and compensatory kyphosis, as well as postoperatively. The frame braces include, among others, the flexion orthosis, which stabilizes the lumbar spine in a slight flexed position. It is especially prescribed for lumbosciatica, root irritation of the lumbar spine, facet syndrome and spondylosis. The counterpart is the hyperextendent orthosis. It keeps the patient in the lordosis position and thus prevents the inclination in the thoracic spine. Indications include, for example, conservatively treated vertebral body fractures. Another example is the plastic orthosis. This circular plastic shell surrounds the body, which is closed ventrally with Velcro, has a particularly strong impact on the spine and is used in scoliosis patients. The cut of the plastic shell determines the degree of fixation.

With modern materials, the function of orthoses can be improved.[25]

The therapeutically correct concept warrants that at the beginning of the therapy, the patient receives as much support as is required through an orthosis.[25-27] During the course of the natural healing process, the degree of stabilization of the patient is successfully enhanced through consequent physical therapy and, if necessary, further therapeutic measures. Throughout the course of therapy, an appropriate orthosis should be adjustable to complement the patient's own steadily increasing degree of body stabilization.[25-28] Modular orthosis systems should be demounted over multiple steps, providing off-training measures that allow the body to start using and recruiting its own strut support. Thus, lumbar orthoses not only should consist of a single stabilizing component in the first phase of therapy but also should have the capability to reduce the support to the individual affected areas of the lumbar spine.[25-27]

In the following, we would like to briefly present our own data. A prospective randomized study, which we conducted with the aim of evaluating the therapeutic usage of three lumbar orthoses and their effects on pain intensity, functional capacity, frequency of use, subjective sensitivities and subjective effectiveness.

Materials and Methods

In the study three orthosis types donated from TIGGES-Zours GmbH were used. Theses orthoses consist of a plastic bodice and rigid, as well as flexible spring steel rods. The first lumbar orthosis has a dorsal rigid 6-part pad, which can be reduced into a flexible 4-part pad in the second phase. The orthosis holds the vertebral bodies L2-S1. The second lumbar orthosis is the bridging orthosis with a dorsal rigid splint and follows a 3-step removal process. It holds the vertebral bodies L1-S1. The third lumbar orthosis is the flexion orthosis with dorsal rigid splints and a ventral abdominal pad. It is reduced over 4 steps. First the ventral abdominal pad is removed. Next, the rigid splints are replaced by flexible splints. Following that, the dorsal bridging element is replaced by a 6-part pad and in the last step by a 4-part pad. This orthosis also holds the vertebral bodies L1-S1.

230 patients with degenerative spinal disorders were included in the study regardless of gender or age. The diagnosis was made by X-ray of the lumbar spine in two planes, as well as functional recordings and MRI of the lumbar spine. Contraindications for MRI, such as pacemakers in situ, were followed by CT of the lumbar spine. For all three orthosis types, patients were randomly

split into two groups with simple randomization using the random number table method.[29] The groups for each orthosis type did not differ significantly in the duration of the condition prior to diagnosis (first measurement, t0). For each orthosis type, patients were randomly assigned to either wear the orthosis for 6 weeks, after which it was completely removed, or to demount the orthosis after 3 weeks, according to the requirements of the spine specialist.[25-27,30] At 6 weeks (t1), patients in each group had reached complete removal of the orthosis. The random sample for the lumbar orthoses consisted of 59 patients, 21 of which were assigned to wear the orthoses without interval removal or demounting (the off-training measures) and 38 were assigned the other arm, demounting the orthosis at specific intervals with off-training measures. The difference between the two groups can be explained by different drop-out rates. The reasons for the drop-out rates were additional illnesses of the patients, which made the continuation of the study impossible and the lack of compliance of the patients to participate in the study.

The overall bridging orthosis group consisted of 69 patients, of whom 35 were allotted to the group without off-training measures and 34 to the group with off-training measures.

A total of 102 patients made up the sample for the flexion orthosis group, of which 49 were allotted to receive no off-training measures and 53 were in the group with off-training measures. The average age for all patients was 50.0 years. Contraindications for all three orthoses include skin conditions in the covered area, as well as sensory disturbances and cardiopulmonary restrictions. Furthermore, the orthoses are contraindicated from the 3rd month of pregnancy. Side effects of treatment with orthoses did not occur at any time.

Patients were consented after a detailed explanation about the study. For all evaluations reported here, the first measurement (t0) was taken at the time of diagnosis and prescription of the lumbar orthoses. The second measurement (t1) was taken at 6 weeks, and the third (t2) and final measurement after 12 weeks in the outpatient department. At the time of the measurements (t0, t1, and t2) each patient answered questions pertaining to pain intensity based on the Numeric Rating Scale (NRS), degree of functional capacity (Oswestry Disability Questionnaire; ODQ)[31] frequency of usage of the orthosis, subjective sensitivities and subjective effectiveness. At t0 patients were instructed to keep a pain diary at home for use during the study

Results

In the lumbar orthosis subset, the off-training group showed a significant advantage in frequency of use and subjective sensitivity at t1. For all other measured outcomes both therapeutic approaches were equally effective, an outcome that is possibly explained by the fact that only minimal modifications (2 step removal) are made with off-training.[32] The modular three-step bridging orthosis had additional significant advantages in pain reduction and function, and the maximum advantage was obtained with the prescription of the four-step off-training flexion orthosis. Among the flexion orthosis patients, at 4 weeks (one week after initiation of off-training) pain intensity scores were significantly reduced for those in the off-training group compared to the group without off-training, but in the fifth and sixth week there were no significant differences between the two groups. However, there was a significant pain reduction within the respective groups, most likely due to the normal healing process during the 12 weeks of study. The biggest difference in pain reduction was observed between the two groups after removal of the orthosis (Figure 1). Furthermore, the degree of pain increased significantly after the complete removal of the orthosis for the group without off-training. After 12 weeks (t2), however, the two groups did not differ significantly and both reported less pain.

Discussion

The indication for the use of the orthoses is currently still controversial in the literature. A Cochrane Review from 2001 analyzed 13 studies on the use of lumbar orthotics and bandages for the prevention and treatment of lumbago. The indication could not be clarified here. In the more current draft of 2008 the results were still controversial.[24] The effectiveness of orthoses in postoperative use is not yet evidence based as there are no data from controlled studies or data without clear advantage or disadvantage of the orthoses.[33,34] In conservative therapy of spondylodiscitis, corset treatment for 6-10 weeks is recommended in addition to antibiotic therapy.[35,36] The National Guideline for low back pain did not recommend the use of orthoses for the treatment of acute or chronic non-specific low back pain, based on data from 10 studies, half of which had positive effects of corset treatment and the other half did not find a positive result. However, the study design of the positive results was of moderate methodological quality, giving priority to studies with no positive outcome.

Our own results confirm the effectiveness of orthoses for low back and low back and leg pain and further suggest a clear improvement in pain intensity and functional capacity for both modular and non-modular orthoses as it has been shown in former studies.[27,32,37]

Patients in both groups evaluated the effectiveness of the prescribed orthoses as good to very good. There were no side effects from the orthoses in our study, nor have any been reported in the literature.[38-40] The study does show the advantages of orthotic care in low back pain. In particular, the modular orthoses reduce the pain early on and comes with higher patient satisfaction compared to the non-modular orthoses. But what are the differences in the literature and where are the difficulties?

While participants were taught how to use the orthosis and were given specific instructions on how to wear it, we were unable to directly verify that they were worn according to the instructions, or that they did not displace on the subject during activity.

None of the participants reported discomfort with the orthoses and the compliance rate of 62-78% was similar to the literature.[22,27-29,32,39-50] Further complicating this study is that pain is something subjective and not fully comprehensible for the examiner. One can try to objectify the pain only on questionnaires. The sense of pain and the ability of each individual is different. This limits the meaningfulness of the study.

There are also different indications for each orthosis. These indications range from degenerative diseases to fractures or metastases. A creeping back pain over years cannot be compared with the sudden pain of a fracture. Similarly, the psychological burden of a patient with metastasis in the vertebrae influences the subjective evaluation of pain behavior. Also, the back musculature and the physical requirements are different for each patient.

Thus, a physically active and healthy patient with suddenly occurring disc herniation achieved a faster mobility than a same-aged unsportsmanlike obese patient, or than compared to a patient with tumor disease.

Among the flexion orthosis patients in our study, at 4 weeks (one week after initiation of off-training) pain intensity scores were significantly reduced for those in the off-training group compared to the group without off-training, but in the fifth and sixth week there were no significant differences between the two groups. The pain reduction after four weeks speaks to the

advantage of the orthosis. But the reduction after six weeks is limited to judge because, for example, a fracture should be healed even after six weeks and automatically associated with pain reduction. In addition, the orthoses have a placebo effect and are intended to remind patients to prevent excessive mobility and to improve posture through tactile stimuli.[49] Thus, the orthotic care seems to be useful for active patients to slow them down and to remind them of their illness. Another effect of the corset is the secondary disease gain for the patient. The patients get more attention for their disease as soon as it becomes visible through the corset.

Modular orthoses seem to promote faster patient agility and therefore, they have a lot of patient compliance. The faster mobility should prevent the muscle breakdown. However, this also does not seem to be proven in the literature. The concern that prolonged wearing of an orthosis weakens the trunk stabilizing muscles is also still controversial. There were studies in which a strengthening of the muscles was found,[51,52] some that showed a reduction of strength and one study with equal musculature before and after wearing orthosis.[53,54] Another hypothesis is the increase in intra-abdominal pressure leads to a reduction in strength required by the lumbar muscles while standing upright. However, the hypothesis could not be proven.[49]

Conclusions

In the literature, there are no clear guidelines for an orthotic supply. The studies do not seem to be meaningful nor universal due to the difficult ascertainability of the pain. There is a need for further research here. Nevertheless, the authors of this review are of the opinion that the implementation of trunk orthoses is void of side effects and beneficial to patients. Treatment regimens that include the prescription of lumbar orthoses result in significant improvements in functional capacity, pain reduction and patient compliance. The advanced concept of a demountable orthosis that provides off-training measures has proven to be superior when compared to orthoses without off-training and seems to lead to a higher degree of patient satisfaction overall.

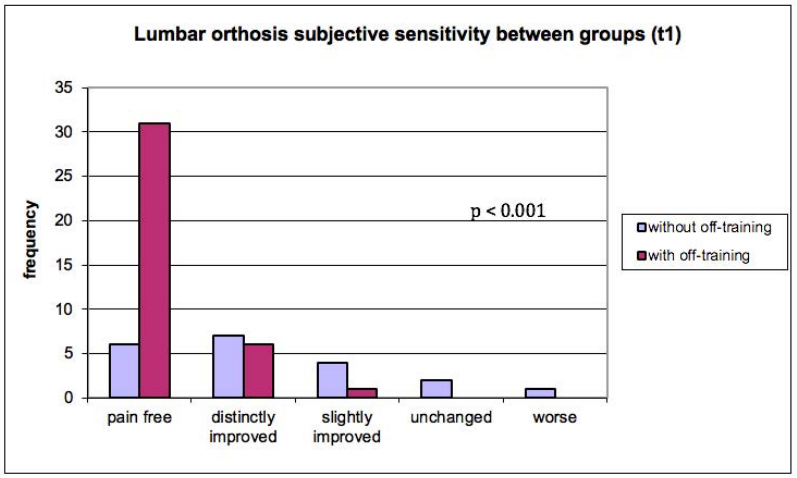

Figure 1. Subjective sensitivity for lumbar orthosis.

Table 1. Overview of the individual orthosis types and their indications depending on the function.

	Hull supporting braces		Stabilizing braces	
	Lumbar support garment	Hull supporting brace with pad	Hull supporting brace with steel rods	Frame brace
Construction	Textile construction - circular, elastic or partially elastic material - reinforced with straps coming from the dorsal end on the ventral support flap	Textile construction with: a) sacral pad ending below the lumbo-sacral joint; b) the cruteal pad extending from the upper third of the crura to the middle of the lumbar spine; c) the bridging pad extending from the lower crotch to the lower third of the thoracic spine, thus bridging the entire lumbar spine	Textile construction with incorporated paravertebral steel rods	Textile construction with plastic frame (surrounds trunk cranially with thoracic brace and caudally with pelvic hanger), fixed connection by paravertebrale steel rods, possible ventral pad
Function	Support proprioception and thus static, heat > hyperemia, relaxation of tense muscles	Increased edition, massaging and warming effect, allowing protected movement delordosing	Restrict dorsal movement limitation, extension and flexion	Limitation extension, flexion, lateral tilt, as well as rotation. In conjunction with ventral pad and ventral straps three-point effect for delordosing
Indication	Simple pain syndromes lumbosacral transition, minor instability syndromes, lumbago	Chronic recurrent pain in static and muscular insufficiencies, lumbar instability	Spondylolisthesis, chronic lumbalgia, lumbociatica and instability syndromes of the lumbar spine	Chronic recurrent pain lumbar spine or thoracolumbar junction, lumbalgia, dorsalgia, postneutrophic syndrome, lordosis instability, and tendency to compensate with kyphosis, postoperatively

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