

CORRESPONDENCE

The Orthotic Treatment of Acute and Chronic Disease of the Cervical and Lumbar Spine

by Dr. med. Kourosh Zarghooni, Dr. med. Frank Beyer, Dr. med. Jan Siewe, Prof. Dr. med. Peer Eysel in volume 44/2013

Use New Approaches

The authors lament the fact that “Despite the widespread clinical use of orthoses, for many spinal indications there are no high-quality controlled trials demonstrating that they are effective” (1).

I have been treating patients with fracture-causing osteoporosis for more than 40 years and have conducted studies to elucidate the pathophysiology and therapy of this epidemic. In the early days this was laborious, since specialists for bone and joint disorders were mostly convinced that osteoporosis is a sign of aging and had to be accepted as such; the view was also that it was a “fashionable” diagnosis, and did not require, or respond to, treatment.

Clinical experience in those days reflected primarily that the available aids were inappropriate, which, among others, became obvious through the fact that compliance on the patients’ part was woeful. Most of the orthoses that were custom-made at great expense and mostly immobilizing were found on, in, or behind patients’ wardrobes after a very short time.

This prompted us to develop an orthosis especially for patients with osteoporotic vertebral fractures, in spite of the fact that, as specialists in internal medicine, we were not in any way entitled to do so, as the “genuine specialists” soon assured us.

As specialists in internal medicine, we are used to investigate new treatment methods in clinical studies in order to confirm their efficacy; naturally we did this with regard to our new orthosis (Spinomed R), although the “real specialists” were of the opinion that clinical studies were redundant for orthoses and, furthermore, were not even possible. This did, however, not stop us from carrying on, and our studies resulted in two original articles that were published in one of the leading speciality journals (2, 3).

The situation is therefore not as desolate as the authors of the article fear. All that is required is the planning and conducting of further studies. This will, however, be a task for specialists for the remaining disorders of bones and joints, because as internists we would not wish to enter into the subject of arthritis, scoliosis, and narrow spinal canals.

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Conflict of interest statement

Spinomed R was developed and tested by Bad Pyrmonter AG around Professor Minne, in collaboration with affected patients and the medi company.

Prof Minne owns a patent for Spinomed and receives annual licensing fees. He has received delegate fees, and travel and hotel expenses from the Umbrella Organization of German Speaking Scientific Societies of Osteology (DVO). He has received honoraria for conducting commissioned clinical studies and for a research project initiated by himself from Spinomed.

Multiple Causes

The present review article requires critical discussion (1). Regarding the analysis of the literature, the article does not give rise to any complaints.

A central problem of such meta-analyses is the fact that the evidence is assessed on the basis of only a selected number of “high methodological quality” studies. If these are lacking, then the argument that is often heard is that evidence is lacking. However, methodologically good studies are difficult in view of the multitude of causes of back pain. In many studies, an exact definition of the symptoms is lacking, as is a clear focus on specific disease entities, a precise description of the orthosis, and, in particular, a clear indication. There is, for example, a crucial difference as to whether a lordosing or delordosing lumbar orthosis is prescribed for zygapophyseal joint syndrome (facet syndrome). Often, chronic, non-specific back pain (often with psychological comorbidities) and specific causes are investigated together in the same study.

The present article by Zarghooni and colleagues also tends to give too much weight to the Anglo-American literature. German-language articles, which do exist, are rarely given any consideration—and that is the case for this review article.

Another point of criticism is the fact that the same review article deals with multiple symptoms. Furthermore, I noticed that the authors’ assessments are in some cases impossible to follow. With regard to chronic cervicobrachial syndrome, the authors say that a comparator study showed significant reductions in pain symptoms after six weeks versus a control group, but not as a long term success. The authors reach the conclusion that orthoses are therefore not indicated in such syndromes. Since it is common knowledge that radicular cervicobrachial syndromes can actually substantially exacerbate for a limited, short period of time,

however, this conclusion is doubtful in view of the fact that orthoses were effective.

In conclusion, one could have wished for a more critical discourse.

Orthotic treatment has been empirically tried and tested as a therapeutic modality for decades, and the number of prescriptions—which the authors mentioned in their article—underline this fact.

Empirical knowledge gained through experience continues to have its place, and the absence of high methodological quality studies signifies merely that more research is needed. The conclusion that really should not be drawn from this review article is that orthoses are generally ineffective.

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Professor Greitemann has received consultancy fees from Bauerfeind.

In Reply:

We thank Professor Greitemann and Professor Minne for their letters to the editor, which lend further support to our own request for further clinical studies on orthotic treatments for the spinal disorders we discussed in our article.

The study by Kuijper et al. was the only randomized controlled trial (RCT) that showed a similar effect when using semirigid orthoses in patients with acute cervicobrachialgia after three and six weeks' treatment as when using a physiotherapeutic approach. No efficacy has thus far been shown for soft orthoses or for chronic cervical facet syndromes.

For reasons of restricted space we did not discuss fractures in our article. Prof. Minne rightly points out that two RCTs have been published of the treatment of acute osteoporotic vertebral fracture that showed a positive effect for the Spinomed R orthosis. Longo and colleagues mentioned one of these studies in their 2012 systematic review (1) as the only RCT on this subject. For this reason, these studies are a great example for good quality clinical studies of orthoses.

Clinical studies are indispensable for the purpose of assessing medical treatment approaches. Medicine's recent history has numerous examples of empirically based treatment measures that were found to have been useless or even harmful (2). Clinical and biomechanical studies of orthotic treatment of the spine have been published multifariously but have often been methodologically inadequate for the purposes of confirming the efficacy of orthotic treatment, and for this reason these have not been included in meta-analyses and systematic reviews. This situation is unlikely to improve, as a glance at the large study registries (Deutsches Register klinischer Studien [German Clinical Trials Register, DRKS], ClinicalTrials.gov) confirms, because no studies assessing the efficacy of spinal orthoses—except in scoliosis and fractures—are currently registered. In view of the volume of prescriptions in Germany alone, it should be exceptionally easy to conduct high-quality studies to get closer to answers to open questions. The problems of heterogeneity of diagnoses and patient groups, as mentioned by Professor Greitemann, could be adjusted for in an adequate study design. The motivation for high-quality studies in the industry is low, for understandable reasons: license approval exists and the volume of prescriptions is high. It is therefore our responsibility as physicians to critically question orthotic treatment of the spine. Unfortunately, for clinical research of orthotic treatment of the spine, Altman's 1994 quote still applies: "We need less research, better research, and research done for the right reasons" (3).

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