Lumbo TriStep

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the Lumbo TriStep. The included studies were identified by a literature search made on PubMed and within the journal *Der Schmerz*.

Table of content:

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. gait analysis, clinical effects, satisfaction, etc.). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		**Category**						
		Functions and Activities						**Participation**
Author	**Year**	**Biomechanics – Static measures**	**Biomechanics – Gait analysis**	**X-Ray**	**EMG**	**Functional tests**	**Clinical effects**	**Satisfaction**
Rohlmann	**2013**					**x**		
Total number: 1		**0**	**0**	**0**	**0**	**1**	**0**	**0**

2 Summaries of categories

On the following pages you find the summary of categories researched in several studies (e.g. gait analysis, functional tests, clinical effects, etc.). At the end of the summary you will find a list of reference studies contributing to the content of the particular summary.

Functional tests

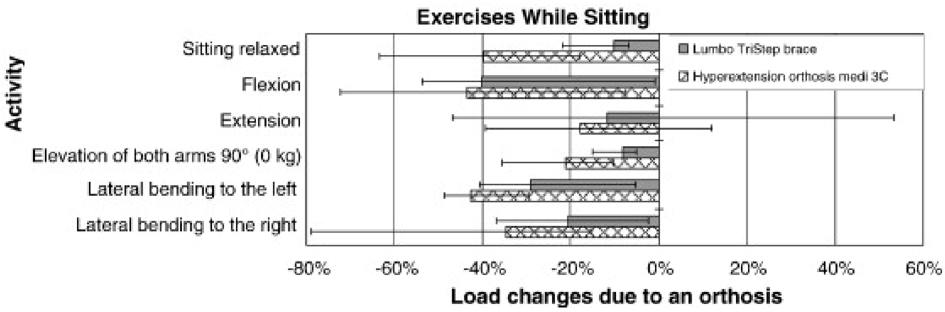
Major Findings

With Lumbo TriStep:

→ **The average resultant force on the vertebral body for 26 activities was reduced**

- by 9% with Lumbo TriStep (LTS)
- by 19% with hyperextension orthosis (HEO)
- The force reduction is usually more pronounced for activities performed during sitting

Load changes due to orthosis use



Changes of max. resultant force on vertebral body replacement (VBR) due to an orthosis for some activities while standing. The median values and the ranges are shown. For LTS n=5, for HEO n=4. (Rohlmann et al., 2013)

Clinical Relevance

Lumbo-sacral-orthoses (LSO) or hyperextension orthoses (HEO) are intended to support and/or to immobilize the spine. The goals may be any combination of support, rest, immobilization, protection, correction and reminder. The effect of an orthosis increases with increased stiffness of the product (Cholewicki et al., 2010; van Poppel et al., 2000). Orthoses with a high stabilization potential are used not only for the treatment of severe back pain, but also for stabilizing stable vertebral body fractures and after surgical stabilization of the spine (White & Panjabi, 1990).

Back pain is one of the most common conditions in industrialized countries. In Germany alone, between 80% - 85% of the population develop at least once in their life complaints in the back. In one tenth of the affected patients, the pain manifests itself as chronic. (Brömme et al., 2015)

There are an estimated 700,000 osteoporotic vertebral compression fractures in the United States each year, of which more than one third become chronically painful (Liebermann et al. 2001). Severe, unstable compression fractures of a vertebral body are often posteriorly stabilized with a pedicle-screw-based implant and anteriorly with a vertebral body replacement (Rohlmann et al. 2013).

The spinal load reduction by an orthosis is still a matter of debate. Some studies predicted a load reduction while others found no effect.

Summary

Lumbar orthoses are often utilized to restrict lumbar motion as part of a treatment regimen for a wide range of degenerative or musculoskeletal conditions in an attempt to provide mechanical support and to enhance patient comfort. Aside from limiting the range of motion of the spine, lumbar orthoses may also unload the spinal column indirectly by acting as an external splint. (Jegede et al. 2011)

Rohlmann et al. (2013) measured the in vivo effect of the Lumbo TriStep (LTS) and a hyperextension orthosis (HEO) on spinal impact load with telemeterized vertebral body replacement (VBR). The average resultant-force reduction for the 10 activities while sitting and the 15 activities while standing was 14% and 6% for LTS and 26% and 14% for HEO, respectively. Averaged over all 26 activities (walking, 10 exercises while sitting, 15 exercises while standing) assessed, the maximum resultant force was 9% lower when wearing LTS and 19% lower when wearing HEO.

Rohlmann et al. (2013) showed, that the Lumbo TriStep was effective in reducing the load in a vertebral body replacement (VBR) during different tasks while sitting, standing and walking.

References of summarized studies

Rohlmann, A., Zander, T., Graichen, F., & Bergmann, G. (2013). Effect of an orthosis on the loads acting on a vertebral body replacement. *Clinical Biomechanics*, 28(5), 490-494.

Other References

Brömme, J., Mohokum, M., Disch, A. C., Marnitz, U. (2015). Interdisziplinäre, multimodale Schmerztherapie vs. konventionelle Therapie. Der Schmerz, 29(2), 195-202. DOI: 10.1007/s00482-014-1508-1

Cholewicki, J., Lee, A. S., Peter Reeves, N., Morrisette, D. C. (2010). Comparison of trunk stiffness provided by different design characteristics of lumbosacral orthoses. *Clinical Biomechanics (Bristol, Avon)* 25, 2, 110–114.

Jegede, K. A., Miller, C. P., Bible, J. E., Whang, P. G., Grauer, J. N. (2011). The effects of three different types of orthoses on the range of motion of the lumbar spine during 15 activities of daily living. *Spine*, 36(26): 2346-2353.

Lieberman, I. H., Dudeney, S., Reinhardt, M. K., Bell, G. (2001). Initial outcome and efficacy of “kyphoplasty” in the treatment of painful osteoporotic vertebral compression fractures. *Spine*, 26(14), 1631-1637.

van Poppel, M N, de Looze, M P, Koes, B. W., Smid, T., Bouter, L. M. 2000. Mechanisms of action of lumbar supports: a systematic review. *Spine* 25(16), 2103–2113.

White, A. A., & Panjabi, M. M. (1990). Clinical biomechanics of the spine (Vol. 2, pp. 108-112). Philadelphia: Lippincott.

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3 Summaries of individual studies

On the following pages you find summaries of studies that researched Lumbo TriStep. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference	Rohlmann, A., Zander, T., Graichen, F., Bergmann, G.

Effect of an orthosis on the loads acting on vertebral body replacement

Clinical Biomechanics 28, 2013: 490-494.
http://dx.doi.org/10.1016/j.clinbiomech.2013.03.010

Products

Lumbo TriStep (LTS), Hyperextension orthosis (HEO, medi 3C)

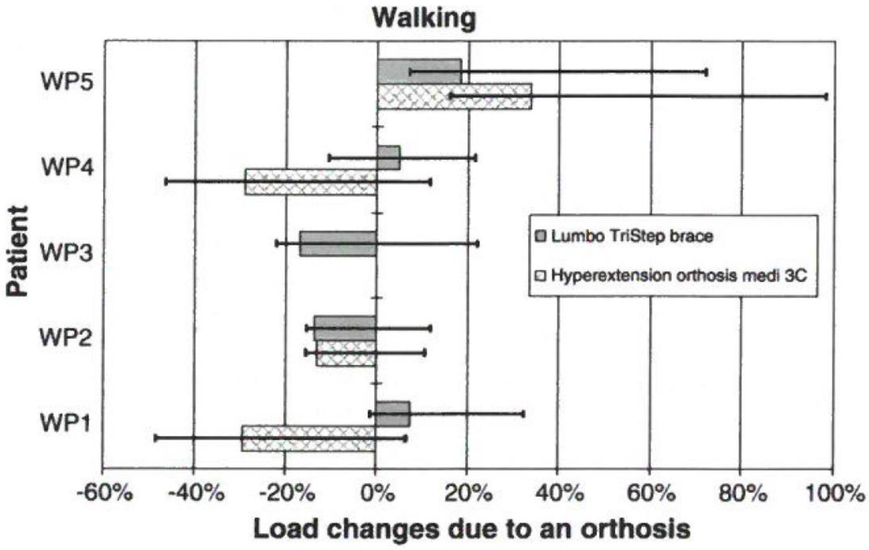
Major Findings

With Lumbo TriStep:

→ **The average resultant force on the vertebral body replacement (VBR) for 26 activities was reduced**

- by 9% with Lumbo TriStep (LTS)
- by 19% with hyperextension orthosis (HEO)
- The force reduction is usually more pronounced for activities performed during sitting

Load changes due to orthosis use



Changes of max. resultant force on vertebral body replacement VBR. The values are related to the situation without an orthosis which was regarded as 100%. The results of the 5 patients are compared.

Population

Subjects:	5 patients with a severe fracture of L1 or L3 vertebral body (4 male, 1 female)
Age:	62 to 71 years
Measurement:	Telemeterized vertebral body replacement (VBR) were implanted. The implant allows the measurement of 6 load components acting on it.
Implantation date:	09/2006 - 07/2008
Time between implantation and measurement:	150 to 774 days
Intervention:	For several activities during standing, sitting and walking, implant loads were measured with and without an orthosis.

Study Design

Descriptive, in-vivo:

Measurements were performed in one session

Measurements without orthosis → Measurements with LTS (n=5) → Measurements with HEO (n=4)

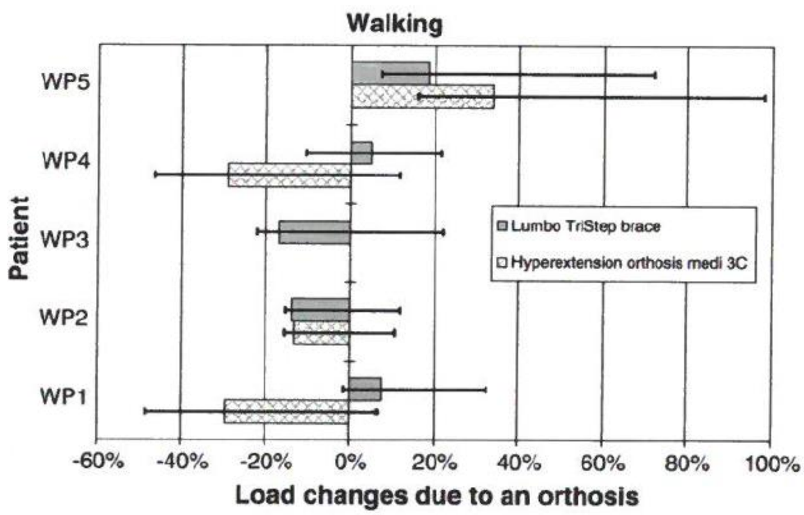
Orthoses:

LTS:	Lumbo TriStep:	stabilizing orthosis with mobilizing function
HEO:	Hyperextension brace:	immobilizing orthosis (thoracic and/or lumbar)

Results

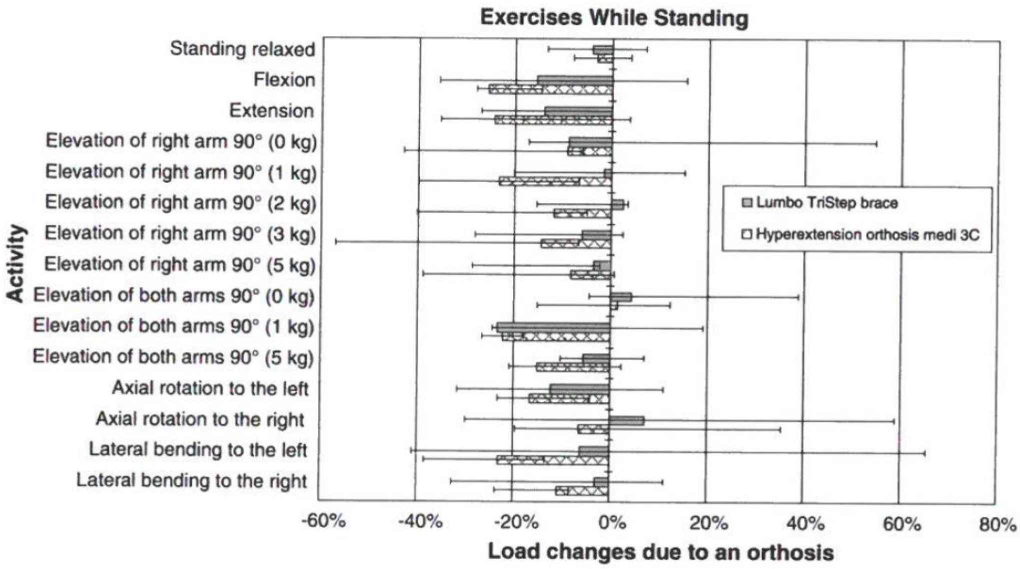
Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	**Functional tests**	Clinical effects	Satisfaction

Category	Outcomes	Results for Lumbo TriStep and hyperextension orthosis
Functional tests	Max. resultant force on VBR	The average resultant force on the vertebral body replacement (VBR) for all 26 activities measured was reduced - by 9% with Lumbo TriStep (LTS) - by 19% with Hyperextension brace (HEO)
Functional tests	Max. resultant force on VBR while walking	Changes of maximum resultant force on a vertebral body replacement (VBR) due to an orthosis during walking. A negative value indicates an unloading of the VBR. Considerable inter- and intra-individual variations were observed.



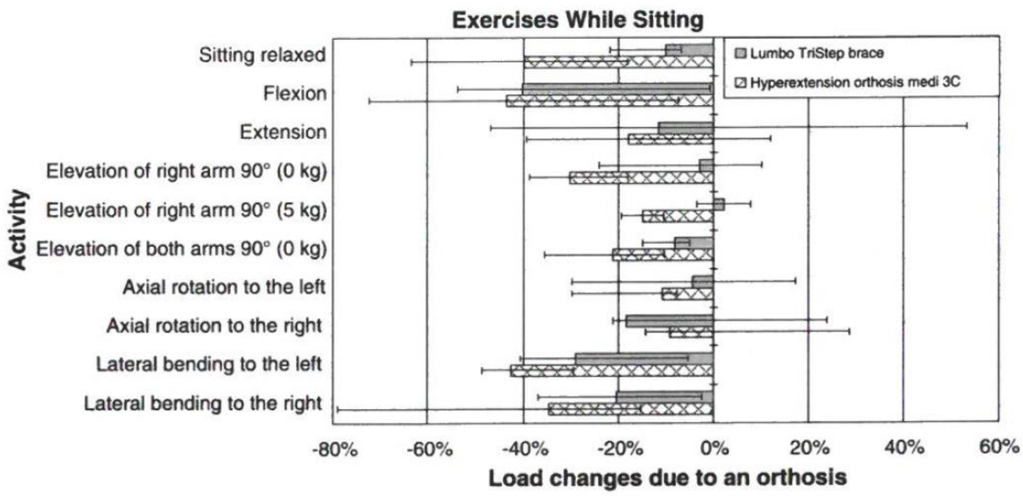
Changes of maximum resultant force on the vertebral body replacement due to an orthosis for walking. The values are relative to the situation without an orthosis which was regarded as 100%. The results for 5 patients (WP1-WP5) are compared.

Category	Outcomes	Results for Lumbo TriStep and hyperextension orthosis
Functional tests	Max. resultant force on VBR while standing	Changes of maximum resultant force on a vertebral body replacement (VBR) due to an orthosis while standing (15 exercises). A negative value indicates an unloading of the VBR. Considerable inter- and intra-individual variations were observed.



Changes of max. resultant force on VBR due to an orthosis for 15 different activities while standing. The median values and the ranges are shown. For LTS n=5, for HEO n=4.

Category	Outcomes	Results for Lumbo TriStep and hyperextension orthosis
Functional tests	Max. resultant force on VBR while sitting	Changes of maximum resultant force on a vertebral body replacement (VBR) due to an orthosis while sitting (10 exercises). A negative value indicates an unloading of the VBR. Considerable inter- and intra-individual variations were observed.



Changes of max. resultant force on VBR due to an orthosis for 10 different activities while sitting. The median values and the ranges are shown. For LTS n=5, for HEO n=4.

Author's Conclusion	"The forces on a VBR and thus on the anterior column of the spine are on average slightly reduced when wearing a LTS brace and more pronounced due to a hyperextension orthosis. However, large inter- and intra-individual variations exist. Therefore, from the biomechanical point of view, no clear recommendation to wear an orthosis can yet be given since the clinically relevant reduction of the implant force is unknown." (Rohlmann et al. 2013)

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