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COMPLIANCE WITH WEARING A THORACOLUMBAR ORTHOSIS IN NONOPERATIVE TREATMENT OF OSTEOPOROTIC VERTEBRAL FRACTURES: A PROSPECTIVE SENSOR-CONTROLLED STUDY

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Clinical Study

**COMPLIANCE WITH WEARING A THORACOLUMBAR
ORTHOSIS IN NONOPERATIVE TREATMENT OF
OSTEOPOROTIC VERTEBRAL FRACTURES: A
PROSPECTIVE SENSOR-CONTROLLED STUDY**

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ABSTRACT

Background Context: Hyperextension orthoses (HOs) for non-operative treatment of osteoporotic vertebral fractures (OVFs) are widely prescribed. However, the compliance, how much an HO is worn after it has been prescribed, is widely unknown.

Purpose: This study was performed to assess the wearing time of HOs for OVFs in a prospective blinded, sensor-controlled manner.

Study Design / Setting: A prospective, single blinded observational study was performed.

Patient sample: This study prospectively included 18 patients who were treated non-operatively with an HO for OVFs.

Outcome measures: The true wearing time was measured using a hidden temperature-based sensor. The patients were invited to return for regular follow-up every 2 weeks for 6 weeks, at which time clinical evaluation (including a visual analog scale for pain and the Oswestry disability questionnaire) and radiographs of the spine were performed.

Methods: Full compliance was defined as a wearing time of 15 hours per day. Correlation between compliance and demographic differences, patient reported outcomes and radiographic changes of the vertebral structures were calculated.

Results: The mean HO wearing time was 5.5 ± 3.3 hours ($37\% \pm 22\%$ compliance). Female patients used the HO significantly longer per day than did male patients (6.5 ± 3.2 vs. 2.9 ± 2.0 hours, $p = 0.039$). Age and body mass index had no influence on wearing behavior.

Conclusions: Overall, compliance with wearing HOs is poor and shows great variability with significant gender-dependency but not associated with BMI, age, or pain-level. Further studies are required to confirm our results that the wearing time does not have an influence on kyphotic progression of the osteoporotic fractured segment, nor on clinical outcome at short term.

Level of evidence: I

Keywords: *vertebral fractures, thoracolumbar orthosis, orthotics, brace, osteoporotic fracture, temperature-based sensor*

INTRODUCTION

Osteoporosis is a global disease with an enormous impact not only on individual patients' health but also on the healthcare system. Its estimated prevalence exceeds 10%, and up to 24% of women aged ≥ 50 years in the United States sustain an osteoporotic insufficiency fracture in their lifetime [1, 2]. The thoracolumbar region is at high risk for osteoporotic vertebral fractures (OVFs). Such fractures are associated with persistent pain and fatigue and increased changes to the spinal alignment, such as vertebral kyphosis and sagittal imbalance, which may lead to a reduced quality of life [3-8]. Treatment of OVFs may be conservative or operative depending on the fracture type and clinical findings. The conservative treatment regimen for OVFs consists of short-term bed rest, early mobilization and rehabilitation, pain medication, application of a hyperextension orthosis (HO), and implementation of a back strengthening program [7, 9, 10]. In biomechanical studies, HOs have been shown to reduce the axial forces and limit the range of motion; this should reduce pain and allow early mobilization, thereby reducing comorbidities associated with bed rest [11-13]. Whether to prescribe such an orthosis is an increasingly debated topic in the literature and seems controversial. Recent literature has shown that the clinical effects of braces are not different from those of therapy without braces in terms of pain, the length

of hospitalization, and kyphotic progression of the fracture [14]. Notably, the extent to which patients are adherent to the prescribed therapy with an HO remains unclear. Reports on orthosis treatments for injuries outside the spine have shown that the real time of use of an orthosis is significantly lower than that reported by the patients [15, 16]. Why patients do not comply with the therapy prescribed by the physician is a highly complex matter and certainly multifactorial. Thus, the true effect of an orthosis can only be determined if the clinician knows the real wearing time, which must be measured independent of the patient's report.

This study was performed to assess the objective wearing time of an HO after treatment of OVFs using a temperature sensor in a blinded fashion and to investigate relations of wearing-time on kyphotic fracture progression and/or pain reduction. We hypothesized that the wearing compliance is much lower than prescribed.

MATERIALS AND METHODS

Study cohort

This single-center, single-blinded, prospective study included all consecutive patients with OVFs who were assigned to the orthopedic department of XXX (blinded for review purposes) from August 2018 to June 2021. Patients who underwent conservative treatment of a thoracolumbar OVF were included. The fractures were classified using the thoracolumbar injury classification and severity score (TLICS) [17]. Patients who underwent operative treatment and

patients with neurological deficits were excluded. Surgery was indicated for unstable fractures, prolonged lumbar pain, or rapidly progressive kyphotic segmental deformation.

The conservative treatment regimen included routine clinical and radiological follow-up at 2, 4, and 6 weeks. When returning the HO, the patients were informed about the recording sensor and were invited to the study, and only patients who signed the study consent form were included (Figure 1). The study protocol was approved by the local ethics committee of XXX (blinded for review purposes).

Bracing and sensory tracking

The patients were treated with a Dorso Arexa HO (Otto Bock Suisse AG, Lucerne, Switzerland). An Orthotimer sensor (CE certified, Rollerwerk Medical Engineering, Balingen, Germany) was placed in the symphysis support of the orthosis to measure the temperature every 15 minutes. The sensor data were read using the official software provided by Orthotimer (Figure 2) and exported to SPSS for statistical calculations.

The patients were unaware of the sensor installed in the HO. A threshold temperature of 30°C (in an alpine country) was set as the cut-off to determine whether the HO was worn. The orthosis was correctly and individually fitted to the patient by our in-house orthotics specialists. Patients were also instructed on how to put the HO on and take it off. The physician instructed the patient to wear the HO whenever in an upright position, which was

calculated to be 15 hours per day on average because the HO did not need to be worn for sleep, in bed or when laying down (8 hours) or during personal hygiene (1 hour). Therefore, wearing the HO for 15 hours per day was defined as 100% compliance. Whenever the HO was removed, the patients were instructed to move with the utmost caution, avoiding possible torsion or bending over. The influence of age, sex, and body mass index (BMI) on the objective wearing time was analyzed. The sensor data were read only if the patient provided written consent after returning the HO.

Radiologic measures

Several radiographic parameters were assessed to analyze the effect of the HO wearing time on kyphotic progression. At the initial presentation, a standing lateral X-ray image was acquired at the level of the fracture. This was routinely performed at 2-week intervals, and the segmental kyphosis angle, vertebral kyphosis angle, and anterior vertebral body compression percentage were calculated [18-20] (*Figure 3*).

Functional outcome

The patients' state of health was regularly assessed using established patient-reported outcome measures (PROMs). A visual analog scale and the Oswestry disability questionnaire were used to assess the patients' pain and their daily life abilities at each follow-up visit [21].

Statistical analysis

The Kolmogorov–Smirnov test was used to test the data for a normal distribution. Data are reported as mean \pm standard deviation unless otherwise indicated. Gender-related differences were calculated using the chi-square test. Radiologic changes between the initial radiograph and latest follow-up were analyzed using Wilcoxon’s rank sum test. Correlations among radiologic progression, the wearing time, PROMs, and patient demographics were evaluated using Spearman’s rank correlation for ordinal data or data with a non-normal distribution. Pearson’s correlation was used for metric data with a normal distribution. Significance was set at $p < 0.05$. Analyses were performed using IBM SPSS Statistics for Windows Version 27.0 (IBM Corporation, Armonk, NY, USA).

Results

Patient population

Eighteen patients were included in this study. Their mean age was 73 ± 15 years, 13 were female (72.2%), and their mean BMI was 25.2 ± 5.4 kg/m². The first lumbar vertebra was the most frequently affected ($n = 10$, 42%) (*Figure 4*). Thirty percent of the enrolled patients had a previous diagnosis of osteopenia or osteoporosis. Ten patients (56%) had a compression type fracture with a TLICS of 1, and eight patients (44%) had a burst type fracture with a TLICS of 2; no patients had a TLICS of >2 . In 88% of patients, magnetic resonance imaging or a computed tomography scan was available in addition to the conventional lumbar X-ray image. (*Table 1*)

Sensor monitoring / wearing time

The mean wearing time in the first 7 days was 5.4 ± 3.4 hours per day and dropped to 4.7 ± 4.9 hours per day in the sixth week. In total, the HO was used for a mean of 230 ± 138 hours during these 6 weeks. This corresponds to a mean compliance rate of $36.6\% \pm 22.9\%$ (Figure 5). Women showed significantly better adherence to the prescribed HO, with a mean wearing time of 6.5 ± 3.2 hours compared with 2.9 ± 2.0 hours in men ($p = 0.045$). None of the other demographic factors, including age and BMI, significantly influenced the wearing compliance (Figure 6, Table 1).

Radiologic measures

Analysis of the plain lateral lumbar radiographs of 15 patients showed that 3 (20%) had insufficient X-ray quality or missing radiographs at the time of returning the HO. The mean time to the radiograph used for the calculation was 49 ± 15.3 days. From the initial X-ray to the last follow-up, the kyphosis angle (Figure 3: β) showed an increase by $3^\circ \pm 4$ ($p = 0.018$), the vertebral kyphosis angle (Figure 3: α) increased by $2^\circ \pm 8$ ($p = 0.476$), and the compression percentage (Figure 3: X/Y) increased from 1.5 to 2.5 ($p = 0.151$). No correlation was found between the compliance with wearing the HO and any of the measured vertebral deformity parameters (β : $r=0.343$, $p=0.211$). Even when the compliance for each individual week was calculated, no correlation was found between patients who wore the HO consistently in the initial phase of the fracture and the radiologic changes. (Table 1)

PROMs

The mean Oswestry disability index and visual analog scale score for pain decreased from 37.4 ± 16.7 to 19.5 ± 16.9 ($p = 0.036$) and from 4.7 ± 2.2 to 3.6 ± 2.3 , respectively ($p = 0.036$). No correlation was found either between the absolute pain score and the wearing time or between the pain reduction and the wearing time (*Table 2*).

DISCUSSION

The use of an HO for nonoperative treatment of OVFs is controversial. Historically, the benefits of treatment with an HO included a reduction in pain, a shortened hospital stay, and reduced kyphotic progression of the fractured segment; however, these benefits are either in doubt or have been disproven according to the current literature [7, 8]. Notably, the efficacy of an orthopedic device can only be documented if the exact wearing time is known. However, exact compliance with prescribed HO wearing is largely unknown. The main finding in this study is that the average compliance during the first 6 weeks was 36.6% of the prescribed wearing time. The variability of compliance among individual patients and between the two genders was high. The authors know that the HO is certainly not the only factor influencing the progression of kyphosis or the PROMs; there is a multifactorial complex of influences. However, we correlated the wearing times with the kyphotic progression, which showed no significant influence, neither on the radiologic change, nor the PROMs. However, this is more of a theoretical consideration

and should be certainly confirmed with further and especially larger studies and studies with control groups without an orthosis at all.

Our finding, that the HOs were worn for a much lower duration of time than prescribed is consistent with the existing literature on patient compliance for other indications. For example, previous studies showed that patients wore a postoperative abduction brace after rotator cuff repair for only about 75% of the prescribed time, or also lower wearing time for scoliosis braces were documented [15, 22, 23]. Although it is surprising that compliance with the HOs was much worse in this study than that of the abduction braces in previous research, there may be some possible explanations for this. On the one hand, patients of advanced age (the main population affected by OVFs) do not tolerate HOs very well and require time to adjust to wearing them [10]. This could be because this group of patients is more sensitive to skin breakdown, respiratory restrictions, and pain, all of which may occur in correlation with wearing an HO [8]. In the present study, however, no correlation was found between age and compliance. On the other hand, rotator cuff reconstructions are planned elective procedures, and the patients are informed about the postoperative care so that they can prepare for wearing the prescribed brace. No such preparation is possible in patients with OVFs. Speaking of information, non-compliance is not necessarily the intention of the patient; it can also be, for example, a failure on the part of the doctor to explain the aid.

For most externally supported orthoses or even custom-made spinal orthoses, previous literature has shown worse compliance with increasing BMI [24]. Surprisingly, our study showed no correlation between the patients' BMI and HO-wearing behavior.

Some studies have focused on the analgesic effect of HOs [25, 26]. However, based on our PROMS, there was no correlation between the wearing time and either quality of life or pain reduction.

Biomechanical analyses have shown that wearing an HO can result in significant reduction of forces to the anterior column (reduction of almost 20%) as well as reduced motion in the thoracolumbar system [12, 13]. Despite these findings, no effect on kyphotic progression with the use of a thoracolumbar orthosis has been reported in previous studies[14, 27]. This can be the expression that the HO does not achieve the desired success, or that there are too many influencing causes that can change the kyphosis and thus the causal factors are not correctly investigated. Calculated on our small population size, however, we found no correlation between the actual time the HO was used and the kyphotic progression, which may more be of a theoretical consideration.

The data from this study contribute in part to the controversy surrounding the use of HOs, which is a constant discussion in the literature with major impact to thousands of patients.

There are certain limitations to this study. First, the patient cohort was rather small, which naturally reduces the power of the study. The wearing time, which is a single factor, can thus be well determined and can also be extrapolated to the population from a small size study group. However, the influence of wearing time on PROMs or kyphosis is multifactorial, which is why this extrapolation is only theoretically possible. The small patients group was due to exclusions, others were lost from the study because they would have liked the information about the recording of the sensor beforehand. However, this would have distorted the results and would not have answered our exact study question, which is why we chose this study design. Second, our regular standardized follow-up protocol was used in every patient. Unfortunately, this could not be implemented in all cases because of patient-related factors, leading to inhomogeneous documentation of radiographs, PROMs, and return of the sensors. However, because the sensor consistently records the body temperature every day, the duration of wear can be retrospectively calculated for each day, even if the sensor is returned a few weeks or even months later. Therefore, in our opinion, the slightly different follow-up unlikely influence the main statements of this study. Third, the patients were informed about the wearing behavior and the permitted movements and loads. However, there is a certain lack of clarity as to how the patients understand and then implement this. This is a non-influenceable factor which cannot have an impact on the wearing time but can have a major

impact on the other outcome parameters measured in this study. Fourth, in our study, only one type of brace was tested. The HO braces should all have the same function, but there are small differences between the different manufacturers, and it sure influences the comfort of wear. The compliance of the different HOs could be investigated in further studies.

CONCLUSION

Overall, compliance with wearing HOs is poor and shows great variability with significant gender-dependency but not associated with BMI, age, or pain-level. The wearing time did not have an influence on kyphotic progression of the osteoporotic fractured segment, nor on clinical outcome at short term in this study on a small sample size, which needs to be proven with further studies.

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

DISCLOSURES

The authors have nothing to disclose.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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REFERENCES

1. Wright NC, Looker AC, Saag KG, et al. The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. *J Bone Miner Res.* 2014;29:2520-6.
2. Ballane G, Cauley JA, Luckey MM, El-Hajj Fuleihan G. Worldwide prevalence and incidence of osteoporotic vertebral fractures. *Osteoporos Int.* 2017;28:1531-42.
3. Johnell O, Kanis JA, Odén A, et al. Mortality after osteoporotic fractures. *Osteoporos Int.* 2004;15:38-42.
4. Kado DM, Huang MH, Karlamangla AS, et al. Factors associated with kyphosis progression in older women: 15 years' experience in the study of osteoporotic fractures. *J Bone Miner Res.* 2013;28:179-87.

5. Glassman SD, Bridwell K, Dimar JR, Horton W, Berven S, Schwab F. The impact of positive sagittal balance in adult spinal deformity. *Spine (Phila Pa 1976)*. 2005;30:2024-9.
6. Schlaich C, Minne HW, Bruckner T, et al. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int*. 1998;8:261-7.
7. Longo UG, Loppini M, Denaro L, Maffulli N, Denaro V. Conservative management of patients with an osteoporotic vertebral fracture: a review of the literature. *J Bone Joint Surg Br*. 2012;94:152-7.
8. Newman M, Minns Lowe C, Barker K. Spinal orthoses for vertebral osteoporosis and osteoporotic vertebral fracture: a systematic review. *Arch Phys Med Rehabil*. 2016;97:1013-25.
9. Bennell KL, Matthews B, Greig A, et al. Effects of an exercise and manual therapy program on physical impairments, function and quality-of-life in people with osteoporotic vertebral fracture: a randomised, single-blind controlled pilot trial. *BMC Musculoskelet Disord*. 2010;11:36.
10. Prost S, Pesenti S, Fuentes S, Tropiano P, Blondel B. Treatment of osteoporotic vertebral fractures. *Orthop Traumatol Surg Res*. 2021;107(1S):102779.
11. Allen C, Glasziou P, Del Mar C. Bed rest: a potentially harmful treatment needing more careful evaluation. *Lancet*. 1999;354:1229-33.

12. Rohlmann A, Zander T, Graichen F, Bergmann G. Effect of an orthosis on the loads acting on a vertebral body replacement. *Clin Biomech (Bristol, Avon)*. 2013;28:490-4.
13. Lang G, Hirschmüller A, Patermann S, et al. Efficacy of thoracolumbar bracing in spinal immobilization: precise assessment of gross, intersegmental, and segmental spinal motion restriction by a 3D kinematic system. *World Neurosurg*. 2018;116:e128-46.
14. Wallace N, McHugh M, Patel R, Aleem IS. Effects of bracing on clinical and radiographic outcomes following thoracolumbar burst fractures in neurologically intact patients: a meta-analysis of randomized controlled trials. *JBJS Rev*. 2019;7:e9.
15. Blinded due to review purposes
16. Sharifi P, Kamyab M, Babae T, Ganjavian MS. Objective monitoring of brace wearing time in adolescents with Scheuermann's kyphosis. *Asian Spine J*. 2019;13:942-8.
17. Vaccaro AR, Lehman RA, Hurlbert RJ, et al. A new classification of thoracolumbar injuries: the importance of injury morphology, the integrity of the posterior ligamentous complex, and neurologic status. *Spine (Phila Pa 1976)*. 2005;30:2325-33.
18. Kuklo TR, Polly DW, Owens BD, Zeidman SM, Chang AS, Klemme WR. Measurement of thoracic and lumbar fracture kyphosis: evaluation of

intraobserver, interobserver, and technique variability. *Spine (Phila Pa 1976)*. 2001;26:61-5; discussion 66.

19. Polly DW, Kilkelly FX, McHale KA, Asplund LM, Mulligan M, Chang AS. Measurement of lumbar lordosis. Evaluation of intraobserver, interobserver, and technique variability. *Spine (Phila Pa 1976)*. 1996;21:1530-5; discussion 1535-6.

20. Isomi T, Panjabi MM, Kato Y, Wang JL. Radiographic parameters for evaluating the neurological spaces in experimental thoracolumbar burst fractures. *J Spinal Disord*. 2000;13:404-11.

21. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy*. 1980;66:271-3.

22. Rahman T, Borkhuu B, Littleton AG, et al. Electronic monitoring of scoliosis brace wear compliance. *J Child Orthop*. 2010;4:343-7.

23. Rahman T, Sample W, Yorgova P, et al. Electronic monitoring of orthopedic brace compliance. *J Child Orthop*. 2015;9:365-9.

24. Goodbody CM, Asztalos IB, Sankar WN, Flynn JM. It's not just the big kids: both high and low BMI impact bracing success for adolescent idiopathic scoliosis. *J Child Orthop*. 2016;10:395-404.

25. Giele BM, Wiertsema SH, Beelen A, et al. No evidence for the effectiveness of bracing in patients with thoracolumbar fractures. *Acta Orthop*. 2009;80:226-32.

26. Karimi M. The effects of orthosis on thoracolumbar fracture healing: a review of the literature. *J Orthop.* 2015;12(Suppl 2):S230-7.
27. Ohana N, Sheinis D, Rath E, Sasson A, Atar D. Is there a need for lumbar orthosis in mild compression fractures of the thoracolumbar spine? A retrospective study comparing the radiographic results between early ambulation with and without lumbar orthosis. *J Spinal Disord.* 2000;13:305-8.

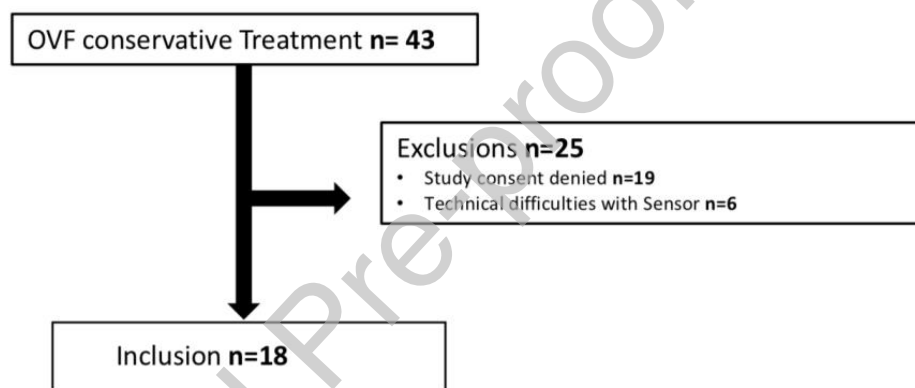


Figure 1. In total, 43 consecutive patients who underwent conservative treatment of an OVF were prescribed a sensor-equipped (blinded) corset and qualified for the study. Nineteen did not provide consent for inclusion in the study and were directly excluded without a readout of the sensor. Six patients were excluded because of technical difficulties either with the sensor mounting or the data transfer software of the sensor. OVF, osteoporotic vertebral fracture

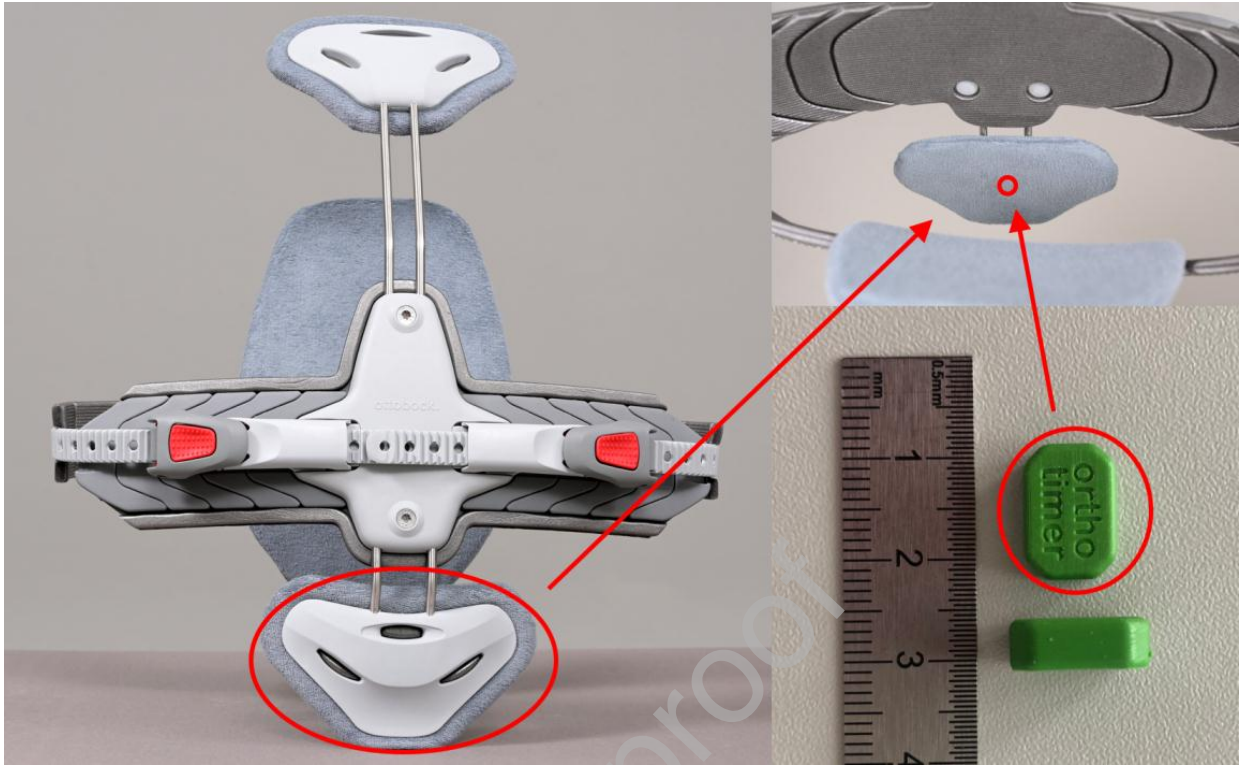


Figure 2. Left: The hyperextension orthosis (Dorso Arexa; Otto Bock Suisse AG, Lucerne, Switzerland) (front view). Top right: The sensor was installed in the abdominal support panel below the washable cover and was worked into the foam prop; it was not visible to the patients. Bottom right: The temperature sensor (Orthotimer; Rollerwerk Medical Engineering, Balingen, Germany) and its dimensions.

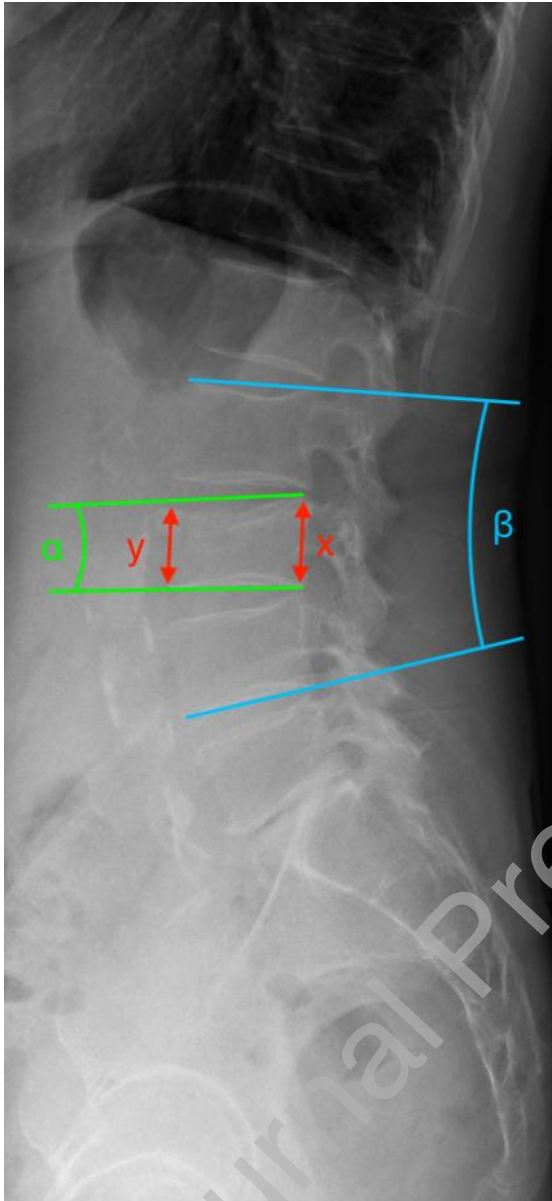


Figure 3. Plain radiograph of a patient with an L3 compression fracture with the analyzed radiological parameters depicted. α : vertebral kyphosis angle, β : kyphosis angle, arrows: anterior vertebral body compression percentage (X divided by Y).

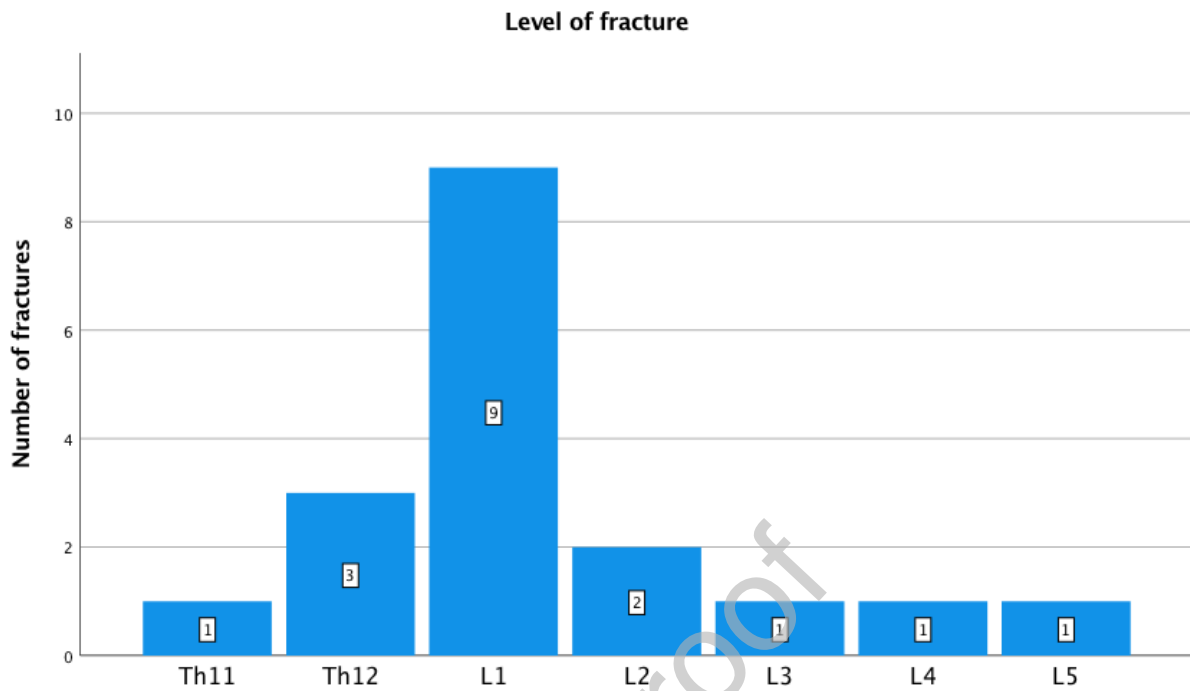


Figure 4. Numbers and levels of fractures in the 18 patients

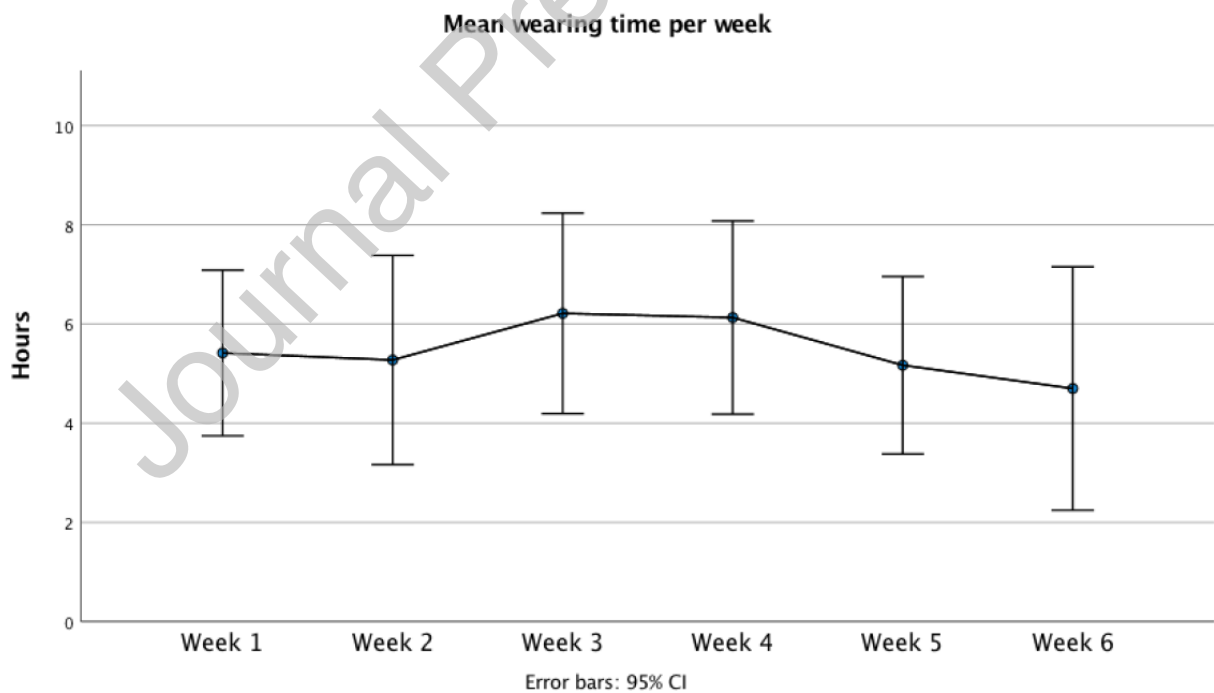


Figure 5. Mean wearing time and overview 6 weeks subdivided by mean for each week. CI, confidence interval

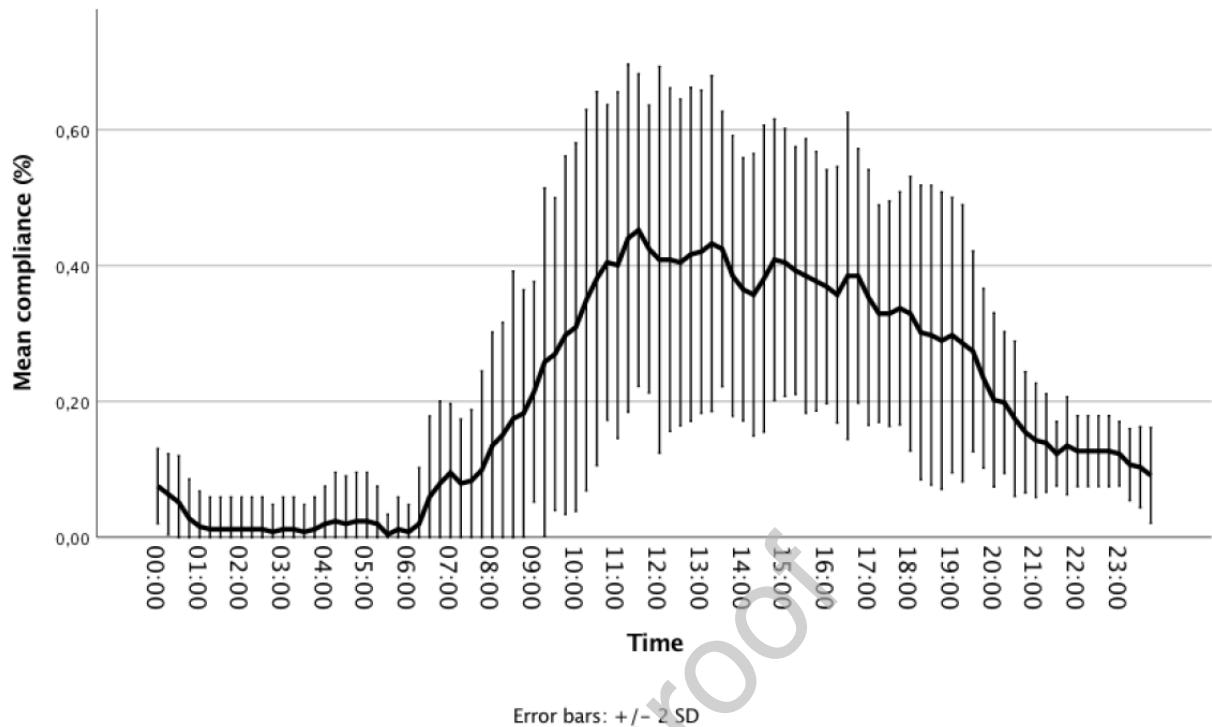


Figure 6. Wearing pattern throughout the day. The bold black line is the mean wearing time of all patients per day for the first 6 weeks. SD, standard deviation

Table 1. All patients are listed above. Patient demographics, comorbidity, type of fracture, radiologic change of the fractured vertebra and the segment and result of the temperature sensor. α = positive value, additional kyphosis, Beta = negative value, additional kyphosis

	Patient demographics	Co-morbidities	Fracture	Sensor tracking

Pati ent nr.	A g e (y)	Ge nd er	H ig ht (c m)	W eig ht (K g)	B M I		T LI Cs Sc or e	Fra ctu re lev el	Del ta of ver teb ral kyp hos is ang le α ($^{\circ}$)	Del ta of ky ph osis ang le β ($^{\circ}$)	Com plian ce (%)	We ari ng tim e per day (h)
1	90	w	165	64	23.5	hyperte nsion	2	L1	6	-1	60.4 8	9.1
2	86	m	153	66	28.2	breast cancer, hyperch olestere mia, hyperte nsion	1	L1	2	-3	63.0 2	9.5

3	4	m	18	85	2	-	1	L1	7	-9	30.7	5.2
	4		0		6.						9	
					2							
4	7	w	17	75	2	-	1	L1	-	-	49.6	4.6
	3		2		5.						8	
					4							
5	8	w	15	64	2	renal	1	L2	2	-1	65.6	7.5
	9		6		6.	insuffiie					3	
					3	ncy,						
						hyperte						
						nsion,at						
						rial						
						fibrilati						
						on,						
						cardial						
						insuffici						
						ency,						
						hypothy						
						reosis						
6	6	m	18	98	2	-	1	L1	-	-	13.4	2
	6		4		8.						9	
					9							

7	5	w	17	62	2	-	2	L2	-17	-5	15.2	9.9
	5		2		1.						4	
					0							
8	6	w	15	64	2	bechtere	1	T12	-3	-4	12.7	2
	9		2		7.	w						
					7	disease,						
						hyperte						
						nsion,						
						COPD						
9	8	w	16	74	2	sick-	1	L1	5	-8	30.5	2.3
	2		8		6.	sinus					2	
					2	syndro						
						m,						
						hyperte						
						nsion						
10	7	w	16	11	4	diabetes	1	L1	-1	1	77.9	1.9
	0		4	4	2.	mellitus					4	
					4	typ II,						
						hyperte						
						nsion,						
						dyslipid						
						emia,						

						hypothy reosis						
11	8 7	w	15 6	67	2 7. 5	hyperte nsion, cerebral ischemi a, polyneu ropathia	2	L1	5	0	42.3 8	4.6
12	7 7	w	16 3	66	2 4. 8	-	1	L1	2	-6	49.0 5	11. 7
13	5 3	w	16 8	59	2 0. 9	-	2	T12	2	-5	49.3 7	6.4
14	5 3	m	17 2	57	1 9. 3	-	2	L5	-	-	34.7 6	3.4
15	8 9	m	16 8	60	2 1. 3	prostate carcino ma	2	L4	18	-3	13.4 9	0
16	6	w	16	66.	2	-	2	T12	6	-1	22.3	7.4

	7		4	7	4.						8	
					8							
17	8	m	17	60	2	-	2	T12	-1	-7	0	4.1
	9		0		0.							
					8							
18	6	w	16	47	1	COPD	1	L3	-11	8	27.2	7.4
	5		0		8.						6	
					4							

Table 2. Patient reported outcome measures

Time after fracture (d)	14 ± 2.3	41 ± 11	p-value
Patients (n)	10	14	
Vas	4.7 ± 2.2	3.6 ± 2.3	0.036
ODI	37.4 ± 16.7	19.5 ± 16.9	0.036

Data are given as mean ± standard deviation unless otherwise indicated.

Boldface type indicates statistical significance. VAS = Visual analog scale,

ODI = Oswestry disability index. Reduction in VAS score and Oswestry

disability index during the observation period with significant reduction.