



Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study

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comparative study

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orthosis represents an alternative.

AQ1

Aims

We compared efficacy and safety of these two types of brace in treating osteoporotic vertebral fractures.

Methods

One hundred forty patients, aged 65–93 years, sustaining osteoporotic vertebral fracture were consecutively recruited and divided into two groups and treated with either three-point orthosis or dynamic corset. Patients were evaluated with Visual Analogue Scale, Oswestry Low Back Pain Disability Questionnaire, and measurement of forced expiratory volume in the first and second second. Regional kyphosis angle, Delmas Index, and height of the fractured vertebral body were also measured on full-spine X-rays. Follow-up intervals were 1, 3, and 6 months after trauma. The complications encountered during the 6-month follow-up were recorded.

AQ2

Results

At the 3- and 6-month follow-ups, there was a significant difference ($p < 0.05$) in pain, disability, and respiration in favor of the dynamic orthosis group. At 6-month follow-up, there was no significant difference ($p > 0.05$) in all the radiological parameters between groups. Complications were reported for 28 patients in the three-point orthosis group, and for 12 patients in the dynamic corset group ($p < 0.05$).

AQ3

Compared to three-point orthosis, patients treated with dynamic orthosis had a greater reduction in pain and a greater improvement in quality of life, respiratory function, with equal effectiveness in stabilizing the fracture, fewer complications.

Keywords

Vertebral fracture

Osteoporosis

3-Point corset

Dynamic corset

Quality of life

Introduction

The incidence of vertebral fractures caused by osteoporosis is rapidly rising with aging in both sexes. The age-standardized incidence of vertebral fracture over 50 years of age, as reported in a large European study, was 12.1/1000 per year in women and 6.8/1000 per year in men [1]. Kyphotic postural change is the most physically disfiguring and psychologically damaging effect of osteoporosis, and it is related to an increased risk of falls and vertebral fracture [2]. Moreover, osteoporotic compression fractures can result in progressive kyphosis, reduced pulmonary function, chronic pain, and limitation of patient activity of daily living [3–6]. Traditional treatment for these patients included bed rest, analgesics, and bracing. Augmentation of vertebral compression fractures with polymethyl methacrylate by kyphoplasty and vertebroplasty is also used to treat pain and improve the quality of life [7]. Medical therapy with medicines improving bone quality, such as bisphosphonates, has proven to be effective, although they can only prevent approximately 50 % of spinal fractures [8]. Improving back muscle strength is recommended to prevent falls and fractures because muscle atrophy parallels the decline of bone mineral density.

with or without bracing [11]. Nevertheless, 3-point orthoses (3PO) are the commonly used means in the treatment of vertebral fractures in thoracic or lumbar spine, so far. They support the thoracic–lumbar spine by leaning on sternum and the pubic symphysis. They have proved to be effective in OVF too. However, the benefit of the use of rigid thoracolumbar braces in osteoporosis is limited by factors such as trunk muscles atrophy and restricted respiration leading to low compliance [12]. The Spinomed[®] dynamic corset (SDO) (Medi GmbH & Co. KG, Bayreuth, Germany) has been used as an alternative since 1991. Based on the principle of biofeedback activation of dorsal–lumbar musculature, it responds to the biomechanical principle of three-point support while giving a lower degree of immobilization [12].

The aim of this prospective, comparative study was to determine the clinical, functional, and radiological results of these two corsets in the treatment of

Materials and methods

This was a prospective, nonrandomized study comparing the efficacy of two different braces in the treatment of vertebral compression fractures due to osteoporosis, having been referred to the University Hospital of Siena and Rummo Hospital of Benevento, between July 2011 and December 2014. The inclusion criteria were as follows: being 60 or older, with acute back pain caused by single-level osteoporotic vertebral fracture from T6 to L3, which due to minor trauma or strain, and was without neurological symptoms. The fracture was defined as an axial compression, involving only the anterior column of the vertebral body, with intact posterior elements. All patients underwent supine, full-spine X-rays and thoracic and lumbar spine spiral computed tomography (CT) to assess the vertebral fractures. Exclusion criteria were the following: multiple or previous vertebral fractures, disorders other than osteoporosis which affected bone metabolism, malignant compression fracture, neurologic impairment, an inability to walk, an inability to complete questionnaires, any severe lung diseases, and smokers smoking more than

regimen, wearing it for two and a half months when sitting or standing. Then they began weaning from corset, while beginning exercises to strengthen paravertebral, abdominal, and gluteal muscles. All patients were given medical treatment for osteoporosis with vitamin D and bisphosphonates.

On entry and at follow-up, patients were evaluated for pain, disability, and quality of life with Visual Analogue Scale (VAS) and Oswestry Low Back Disability Questionnaire (OLBPDQ). Patients were also asked to answer VAS and OLBPDQ regarding their status before trauma. The severity of fracture was defined according to Genant's classification [13]. Morphological evaluation included measurement of body height loss, Cobb's angle, vertebral body height of the fractured vertebra (i.e., the height measured at the middle of vertebral body in lateral film), regional kyphosis angle (RKA), and the Delmas Index (DI), in order to understand the range of deformity and instability of the fractured osteoporotic spine. Cobb's angle and RKA indicate the amount of kyphosis, which is a major factor of sagittal imbalance, significantly affecting functional outcome and quality of life, while DI indicates how dynamic the spine is, based on the amount of spinal curves [14, 15]. Seven days after trauma, forced expiratory volume in the first second (FEV1) was evaluated to test patient's respiratory muscle strength. Clinical and radiological follow-up with full-spine X-rays was completed at 1, 3, and 6 months after trauma. Urinary rate was also assessed with the method of vertebral dynamic mobility, by evaluating the difference of the vertebral height at the anterior and posterior borders of the fractured vertebral body, between the sitting lateral and the supine lateral radiography [16]. Miscellaneous complications during the 6 months of follow-up were also recorded. The data were imported in an electronic spreadsheet (Excel, Microsoft Office) for further processing and statistical analysis by T-Student test, with significance set at $p \leq 0.05$.

The primary endpoint of our study was functional recovery of the patients in terms of pain reduction, respiratory function, and quality of life 6 months after the injury. The secondary endpoint was the radiological outcome in terms of

40 (28.5 %) in grade 1 (mild deformity), 83 (59.3 %) in grade 2 (moderate deformity), and 17 (12.2 %) in grade 3 (severe deformity). Seventy-five patients were already undergoing therapy for osteoporosis, and after the 6-month follow-up, there were 116 patients on therapy.

Table 1

Details of patient population

		3PO group	SDO group
No. of patients		72	68
Average age years (range)		81.9 (65–90)	82.8 (73–93)
Gender ratio (m:f)		0.41 (21:51)	0.39 (19:49)
Level of fracture <i>n</i> (%)	T6	6 (8.33 %)	6 (8.82 %)
	T7	4 (5.56 %)	4 (5.88 %)
	T8	9 (12.5 %)	9 (13.23 %)
	T9	10 (13.89 %)	10 (14.71 %)
	T10	5 (6.94 %)	5 (7.35 %)
	T11	6 (8.33 %)	6 (8.82 %)
	T12	11 (15.28 %)	10 (14.71 %)
	L1	13 (18.06 %)	11 (16.19 %)
	L2	5	5

3PO group consisted of 72 patients, 21 males and 51 females, with a gender ratio (m/f) of 0.41, and a mean age of 81.9 years. Twenty-one patients (29.1 %) had grade 1, 43 (59.7 %) grade 2, and 8 (11.1 %) grade 3 fractures. Before trauma, average VAS score was 5.3 (range 4–8) and average OLPBDQ score was 42.6 (range 36–64). On admission, average VAS and OLPBDQ scores were 9.4 (range 9–10) and 83.7 (range 78–100), respectively. Patient's height before trauma was on average 156.7 cm, and average height loss at the time of fracture was of 5.8 cm. On admission to emergency, average Cobb's angle was 28.3°, average RKA was 12.3°, and average DI was 91.5.

SDO group consisted of 68 patients, 19 males and 49 females, with a gender ratio (m/f) of 0.39, and a mean age of 82.8 years. Nineteen patients (28.0 %) had grade 1, 40 (58.8 %) grade 2, and 9 (13.2 %) grade 3 fractures. Before trauma, average VAS score was 5.8 (range 4–8) and average OLPBDQ score was 44.6 (range 34–70). On admission, mean VAS and OLPBDQ scores were 9.6 (range 9–10) and 84.2 (range 78–100), respectively. Patient's height before trauma was on average 158.7 cm, and the average height loss at the time of fracture was on average 6.2 cm. On admission, average Cobb's angle was 28.3°, average RKA was 12.9°, and average DI was 91.8. Forty-two (58.33 %) patients in 3PO group and 33 (48.53 %) in SDO group were having medical therapy for osteoporosis before trauma; 6 months after trauma, 61 (84.72 %) patients in 3PO group, and 55 (80.88 %) in SDO group had been receiving this therapy. There were no statistically significant differences between 3PO and SDO groups concerning demographics, severity of fracture, VAS and OLPBDQ scores, height loss, DI, RKA, and therapy for osteoporosis before trauma and after 6 months (Tables 1, 2; Figs. 1, 2, 3).

Table 2

Summary of relevant morphological results

Height loss after 6 months (avg)	8.2 (5.6–10.9)	8.5 (5.6–11.3)
	DI (range)	DI (range)
Delmas Index on admission (avg)	91.5 (89.2–93.6)	91.8 (88.9–92.6)
Delmas Index after 6 months (avg)	92.5 (89.9–92.7)	93.6 (90.6–93.7)
	° (range)	° (range)
Cobb's angle on admission (avg)	28.3 (26.5–34.8)	28.9 (26.3–33.7)
Cobb's angle after 6 months (avg)	27.1 (25.3–33.2)	27.3 (24.9–32.9)
Regional kyphosis angle (avg)	RKA° (range)	RKA° (range)
On admission	12.3 (10.7–15.6)	12.9 (10.3–15.4)
After 1 month	11.5 (10.5–16.3)	11.7 (10.8–15.9)
After 3 months	10.1 (8.7–13.8)	10.4 (8.9–12.9)
After 6 months	9.8 (8.4–12.9)	9.8 (8.5–12.7)
Vertebral body height (avg)	mm (range)	mm (range)
On admission	18.3 (14.6–22.4)	18.5 (14.3–23.1)
After 1 month	16.5 (12.5–21.2)	16.9 (11.8–21.9)
After 3 months	15.7 (11.3–20.8)	16.4 (10.9–20.7)
After 6 months	15.5 (11.1–20.4)	16.1 (11.5–20.6)
Union rate	67/72 (93 %)	64/68 (94 %)
<i>p</i> > 0.05 for all data		

Fig. 1

Severity of fracture distribution according to Genant's classification, showing statistically significant differences between groups



Fig. 2

VAS trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months

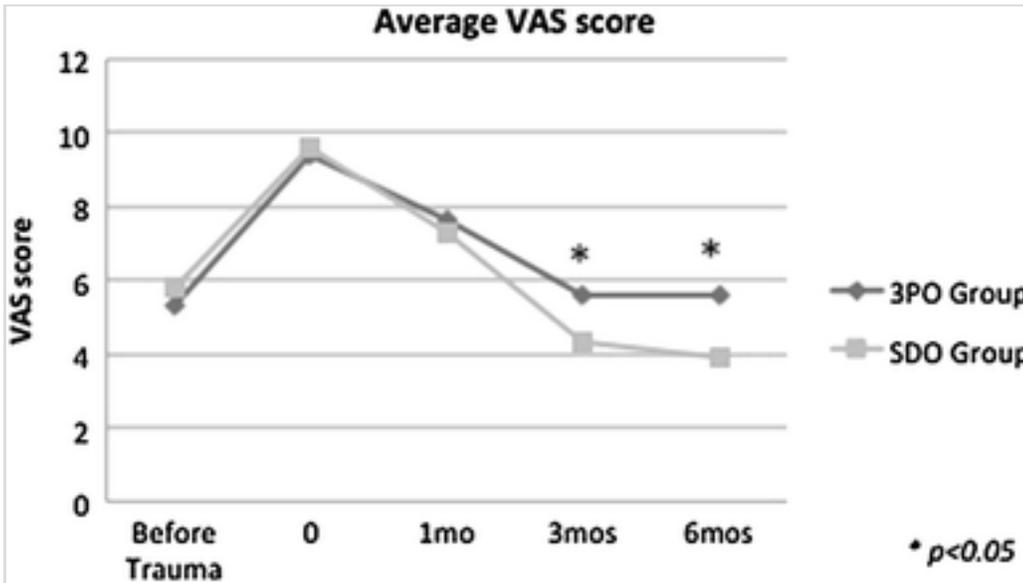
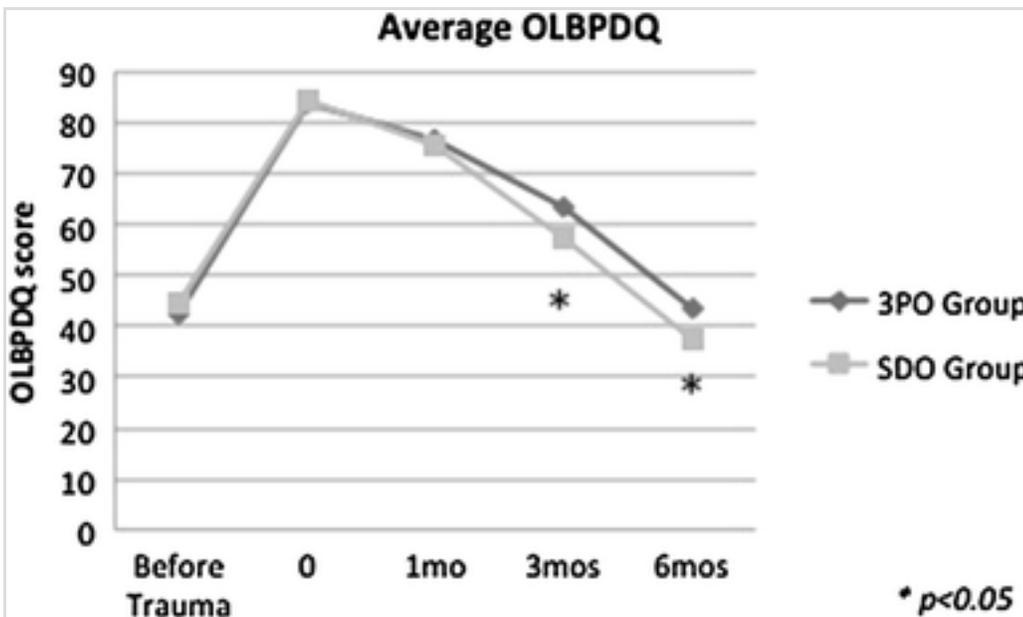


Fig. 3

OLBPDQ trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months

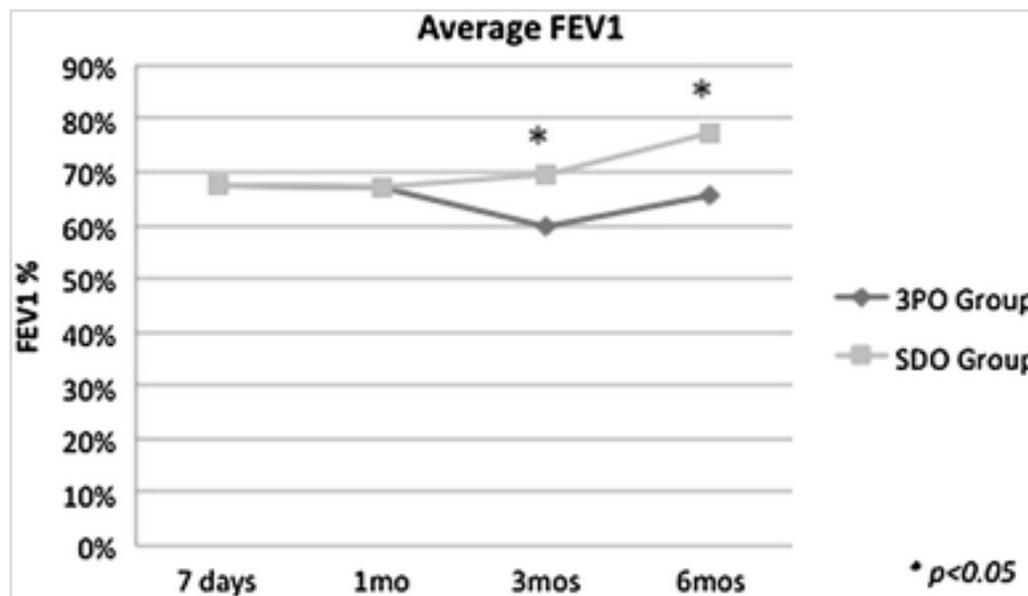


After 1 month, OLBPDQ score was 76.5 (range 68–100) in 3PO group, and 75.9 (range 68–100) in SDO group, with no significant difference ($p > 0.05$). After 3 and 6 months, OLBPDQ was, respectively, 63.6 (range 56–84) and 37.5 (range 32–62) in 3PO group, and 57.3 (range 48–76) and 37.5 (range 28–50) in SDO group, with statistically significant difference ($p < 0.05$) (Fig. 3).

After 7 days and 1 month of trauma, average FEV1 was, respectively, 67.8 % (range 54–88 %) and 66.9 % (range 52–88 %) in 3PO group, and 67.5 % (range 54–88 %) and 75.9 % (range 52–88 %) in SDO group, with no significant difference between the two groups ($p > 0.05$). After 3 and 6 months, FEV1 was, respectively, 59.6 % (range 42–74 %) and 65.8 % (range 54–84 %) in 3PO group, and 57.3 % (range 52–88 %) and 77.3 % (range 67–93 %) in SDO group, with statistically significant difference ($p < 0.05$) (Fig. 4).

Fig. 4

FEV1 trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months



Height loss, Cobb's angle, RKA, DI, and union rate

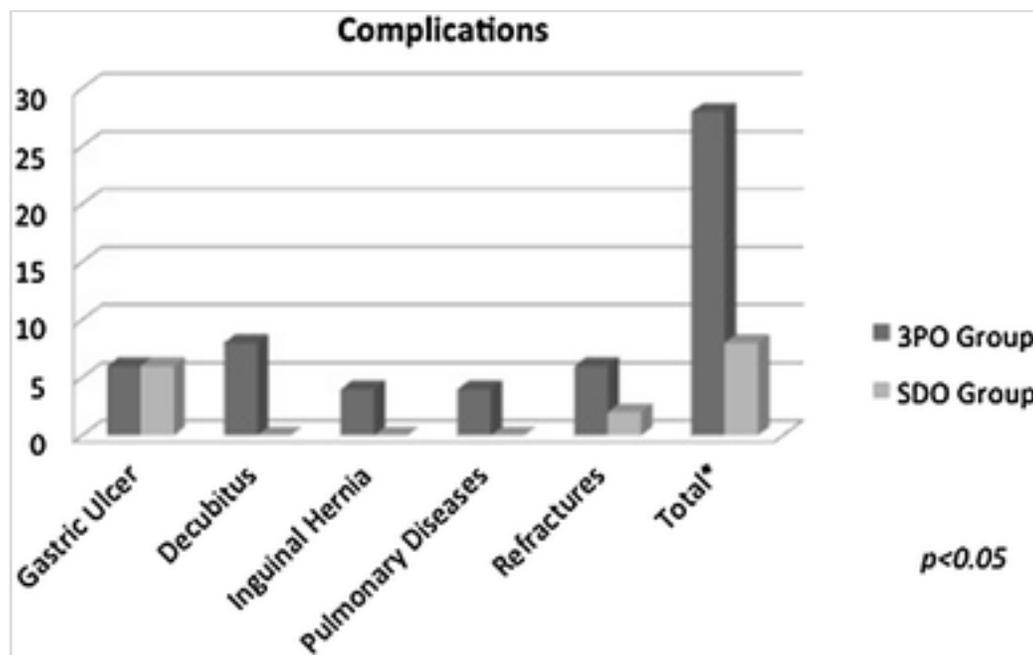
Six months after the trauma, average height loss was 5.3 cm in 3PO group,

Complications

Twenty-eight patients in 3PO group (38.8 %) and 8 in SDO group (11.7 %) suffered from miscellaneous complications; in 3PO group, gastric ulcer occurred in 6 patients, decubitus in 8, inguinal hernia in 4, pulmonary disease in 4, and refractures in 6, while in SDO group gastric ulcer occurred in 6 cases and refractures in 2, with a significant difference between the two groups in overall complication rate ($p < 0.05$) (Fig. 5).

Fig. 5

Miscellaneous complications in 6 months after the trauma. Overall, there were significantly fewer complications in SDO group



Discussion

Brace immobilization is a standard treatment of vertebral body fractures due to osteoporosis, when neural compression and major instability are excluded. The purpose of the static correction is preventing the increase in deformation, by supporting the vertebrae, and reducing pain. The effects on pain relief and posture correction are due to the reduction in thoracic kyphosis or to an increased lumbar lordosis. For decades, 3-point braces have been the most

Restricted respiration may worsen the reduced pulmonary function, which is often associated with spine and chest osteoporotic deformation [4].

More recently, a dynamic corset, Spinomed[®], has been developed as an alternative to the standard 3-point brace, aiming to overcome the disadvantages of a rigid brace. It shares the biomechanical principle of the three-point support with a less rigid immobilization and a dynamic behavior allowing biofeedback activation of the dorsal-lumbar musculature. That is, when the patient tends to bend forward, the cushion-belt system exerts a gentle pressure causing the patient to extend their back by using dorsal muscles. The padded aluminum back support can be adjusted according to the shape of the vertebral column of individual patients, cushioning the thoracic and lumbar spine with main support at the thoracolumbar transition, and balancing pressure distribution from the sacrum to the top of the thoracic spine. In SDO, the sternal support is replaced by the shoulder belts, counteracting kyphotic posture, and the pubic support is replaced by abdominal pads and belts, supporting lumbar lordosis. Unlike the pubic symphysis support of the 3PO, lumbar support is guaranteed by the increase in abdominal pressure due to the ventral pad and belts, acting similar to a lumbar corset brace [18]. Increased abdominal pressure creates a semi-cylinder surrounding the spinal column and sharing the load and stress of the spine [19]. Moreover, a lumbar corset can decrease the intradiscal pressure by about 30 % [20]. In comparison with the usual 3-point brace, the belts also prevent slippage in both cranio-caudal and lateral directions.

The primary endpoints of this prospective study comparing the standard 3PO and the SDO in the treatment of OVF were the patients' functional recovery, measured by reduction of pain, and improvement of respiratory function and quality of life 6 months after the injury. In our study, SDO resulted in a greater reduction in pain and improvement of respiration and quality of life with fewer complications, compared to the 3PO, with equal effectiveness in stabilizing the fracture.

[17]. Based on the work of Lantz and Schultz describing an increased electrical activity of back muscles when wearing a lumbosacral orthosis [21], Pfeiffer et al. speculated that the so-called biofeedback may be an underlying principle of the efficacy of SDO. In their paper, they advocated stronger back muscles as a possible explanation of the decreased angle of kyphosis and the increased body height observed in their study, as well as a precondition for a better posture and a correction of the center of gravity, resulting in lesser body sway [17].

In our study, patients treated with SDO had a significantly better improvement of respiratory function, as compared to 3PO group, after 3 and 6 months. In this respect, Schlaich et al. [3] found a significant relationship between anterior vertebral deformation and reduction in pulmonary function in patients with OVF. Similarly, Leech et al. [22] found a correlation between worsening lung function and severity of spinal osteoporosis, with increasing spinal deformity and reducing body height. On the other hand, Pfeiffer et al. [17], in the above-quoted study, correlated better FEV1 and vital capacity to a decreased angle of kyphosis in patients treated with SDO. However, in our study, we could not find a correlation between improved FEV1 and reduced spinal deformity, since body height, DI, RKA, and Cobb's angle were similar, in both 3PO and SDO groups at all follow-up intervals. Notably, the difference in FEV1 was seen at 3- and 6-month follow-up, when orthoses had been dismissed. Therefore, improved respiratory function might also be explained by reduction in pain and better muscle strength preservation in SDO group.

VAS and OLBPQ scores were similar in both groups at 1 month, i.e., during treatment, while the pain after 3 months was significantly less, and quality of life was significantly better in the SDO group compared to the 3PO group. At 6 months, this difference was maintained for OLBPQ score and was even more marked for VAS score. Interestingly, VAS and OLBPQ scores at 6 months had improved, even compared to scores obtained before trauma. This, again, may be consistent with the preservation and strengthening of dorsal and abdominal muscles associated with the dynamic bracing, which could improve

In a recently published study, Kim et al. [11] have shown no difference in disability, pain, and vertebral body compression ratio comparing OVF treatment without bracing to either rigid or soft brace use. However, neither type of brace shares the principle of biofeedback activation, so further studies comparing dynamic orthoses to no-brace treatment would be necessary.

This is a nonrandomized study, which represents an important limitation. However, the two study groups showed no significant difference in demographics, and radiographic and clinical characteristics. Hence, we do not believe that patient's choice of brace influenced the results significantly. On admission, 75 patients were already undergoing therapy for osteoporosis, and all patients were treated upon entering the study, with 116 patients still having therapy at 6-month follow-up. However, there were no statistically significant differences regarding the use of anti-osteoporotic therapy between groups, before and after admission. Thus, anti-osteoporotic drug assumption does not seem to have any impact on the different results with the two types of braces in this study.

In our study on the conservative management of VOFs, patients treated with dynamic orthosis had better pain control and breath function after 3 and 6 months, compared to patients treated with a 3-point orthosis. Their quality of life also showed greater improvement, even compared to pre-fracture status. As far as radiological results are concerned, the dynamic orthosis was at least as effective as conventional 3-point orthosis in stabilizing the fractured osteoporotic spine. In this study, the dynamic orthosis proved to be safe and effective in the treatment of thoraco-lumbar OVF, with better functional outcome and less complications compared to standard 3-point orthosis.

AQ6

Compliance with ethical standards

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. The European Prospective Osteoporosis Study Group (2002) Incidence of vertebral fracture in Europe: results from the European Prospective Osteoporosis Study (EPOS). *J Bone Miner Res* 17:716–724
2. Sinaki M (1998) Musculoskeletal challenges of osteoporosis. *Aging* 10:249–262
3. Schlaich C, Minne HW, Bruckner T et al (1998) Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int* 8:267
4. Begerow B, Pfeifer M, Pospeschill M et al (1999) Time since vertebral fracture: an important variable concerning quality of life in patients with postmenopausal osteoporosis. *Osteoporos Int* 10:26–33
5. Leidig-Bruckner G, Minne HW, Schlaich C et al (1997) Quality of life components and spinal deformity in women with chronic low back pain and women with vertebral osteoporosis. *J Bone Miner Res* 12:663–675
6. Lyles KW, Gold DT, Shipp KM et al (1993) Association of osteoporosis and vertebral compression fractures with impaired functional status. *Am J Med* 94:595–601
7. Klezl Z, Bhangoo N, Phillips J et al (2012) Social implications of balloon kyphoplasty: prospective study from a single UK centre. *Eur Spine J* 21:1880–1886

10. Deyo RA, Tsui-wu TJ (1987) Descriptive epidemiology of low-back pain and its related medical care in the United States. *Spine* 12:264–268

11. Kim HJ, Yi JM, Cho HG et al (2014) Comparative study of the treatment outcomes of osteoporotic compression fractures without neurologic injury using a rigid brace, a soft brace, and non brace. *J Bone Joint Surg Am* 96:1959–1966

12. Patwardhan AG, Li SP, Gavin T et al (1990) Orthotic stabilization of thoracolumbar injuries: a biomechanical analysis of the Jewett hyperextension orthosis. *Spine* 15:654–661

13. Genant HK, Wu CY, Van Kuijk C et al (1993) Vertebral fracture assessment using a semiquantitative technique. *J Bone Miner Res* 8:113–1148

14. Mrozkowiak M, Dobriański J (2013) Algorithm for physiological spine curvature within normative range. *J Health Sci* 3:102–134

15. Briggs AM, Wrigley TV, Tully EA et al (2007) Radiographic measurement of thoracic kyphosis in osteoporosis: Cobb and vertebral centroid angles. *Skelet Radiol* 36:761–767

16. Murata K, Watanabe G, Kawaguchi S et al (2012) Union rates and prognostic variables of osteoporotic vertebral fractures treated with a rigid external support. *J Neurosurg Spine* 17:469–475

17. Pfeifer M, Begerow B, Minne HW (2004) Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis. *Am J Phys Med Rehabil* 63:177–186

18. Brown T, Norton PL (1957) The immobilization efficiency of back

pressure discometry, a method for the determination of pressure in the lumbar discs. *J Bone Joint Surg Am* 46:1077–1092

21. Lantz SA, Schultz AB (1986) Lumbar spine orthoses wearing. Effect on trunk muscle myoelectric activity. *Spine* 11:838–842

22. Leech JA, Dulberg C, Kellie S et al (1990) Relationship of lung function to severity of osteoporosis in women. *Am Rev Respir Dis* 141:66–71