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ORIGINAL ARTICLE

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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Abstract
Background The three-point orthosis is the most commonly used brace in the conservative treatment of osteoporotic vertebral fractures. The Spinomed® dynamic orthosis represents an alternative.
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 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.
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 eight patients in the dynamic corset group ($p < 0.05$).
Discussion Biofeedback activation of back muscles is probably a key factor in improving functional outcome with dynamic orthosis.
Conclusions Compared to three-point orthosis, patients treated with dynamic orthosis had a greater reduction in pain and a greater improvement in quality of life and respiratory function, with equal effectiveness in stabilizing the fracture, and fewer complications.

Keywords Vertebral fracture · Osteoporosis · 3-Point corset · Dynamic corset · Quality of life

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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 fractures [2]. Moreover, osteoporotic compression fractures can result in progressive kyphosis, reduced pulmonary function, chronic pain, and limitation of patient's activity of daily living [3–6]. Traditional treatment for these patients includes 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 effective, although they can only prevent approximately 50 % of spinal fractures [8]. Improving back muscle strength is recommended to prevent bad outcomes because muscle atrophy parallels the decline of bone mineral density of the spine and contributes to kyphotic postural changes significantly [9].

Traditionally, spinal orthoses have been used in the management of thoracolumbar spine fractures. While the use of orthoses in the management of osteoporotic vertebral fractures (OVF) is not supported by evidence and no objective data are available on the effectiveness of orthoses in stabilizing OVF [10], a recent study has shown no difference between conservative treatment with or without bracing [11]. Nevertheless, 3-point orthoses (3PO) are the most 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 the 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 the dorsal-lumbar musculature, it responds to the biomechanical principle of the 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 OVF.

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 to G. 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 was 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 10 cigarettes a day.

The recruited patients were divided into two groups: patients in the 3PO group wore a standard 3-point corset, and patients in SDO group wore the Spinomed® corset. Each patient was assigned to either group according to his/her preference, after exhaustive description of the biomechanics, fitting, and cost of the two types of corset. All patients, in both groups, had the same corset 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 Pain 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. Union 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 preservation of vertebral height, sagittal alignment, spine stability, and union rate.

Results

One hundred and forty patients were eligible for the study. There were 40 males and 100 females, aging between 65 and 93 years (mean age 82.3 years) (Table 1). All had "wedge" fractures according to Genant's classification, with 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.

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 (29.2 %) 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 OLBPDQ 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 OLBPDQ score was 44.6 (range 34–70). On admission, mean VAS and OLBPDQ 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 28.9°, 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).

VAS, OLBPDQ, and FEV-1

At 1-month follow-up, average VAS was 7.6 (range 5–10) in 3PO group, and 7.3 (range 5–9) in SDO group, with no significant difference ($p > 0.05$). After 3 and 6 months, VAS was, respectively, 5.6 (range 4–8) and 5.6 (range 3–8) in 3PO group, and 4.3 (range 3–6) and 3.9 (range 1–4) in the SDO group with statistically significant difference ($p < 0.05$) (Fig. 2).

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,

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 (65–93)
Gender ratio (m:f)		0.41 (21:51)	0.39 (19:49)
Level of fracture *n* (%)	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 (6.95 %)	5 (7.35 %)
	L3	3 (4.16 %)	2 (2.94 %)
Patients on therapy for osteoporosis before trauma: *n* (%)		42 (58.33 %)	33 (48.53 %)
Patients on therapy for osteoporosis 6 months after trauma: *n* (%)		61 (84.72 %)	55 (80.88 %)

No statistically significant difference was found between groups for all data

Table 2 Summary of relevant morphological results

	3PO group ($n = 72$)	SDO group ($n = 68$)
	cm (range)	cm (range)
Height of patients before trauma (avg)	156.7 (145–190)	158.7 (150–193)
Height loss after trauma (avg)	5.8 (3.4–8.9)	6.2 (3.8–9.7)
Height loss after 6 months (avg)	6.2 (3.6–9.3)	6.3 (3.8–9.6)
	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 (14.3.3–23.4)
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 %)

$p > 0.05$ for all data

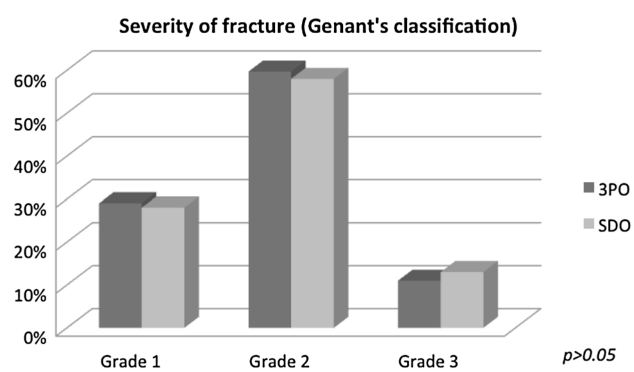

Fig. 1 Severity of fracture distribution according to Genant's classification, showing no statistically significant differences between groups

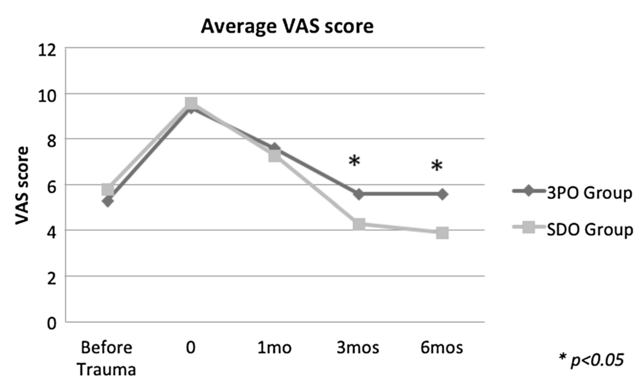

Fig. 2 VAS trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months

OLBPDQ was, respectively, 63.6 (range 56–84) and 43.6 (range 32–62) in 3PO group, and 57.3 (range 48–76) and 37.5 (range 28–54) 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).

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, and 4.9 cm in SDO group, with no significant difference ($p > 0.05$). After 6 months, average Cobb's angle was 27.1° in 3PO group and 27.3° in SDO group, while DI was 92.5 in 3PO group, and 93.6 in SDO

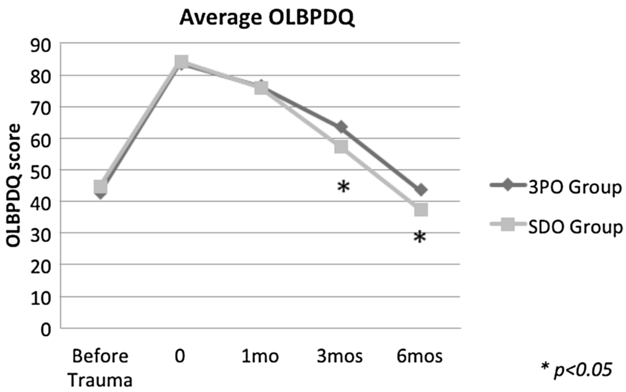

Fig. 3 OLBPDQ trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months

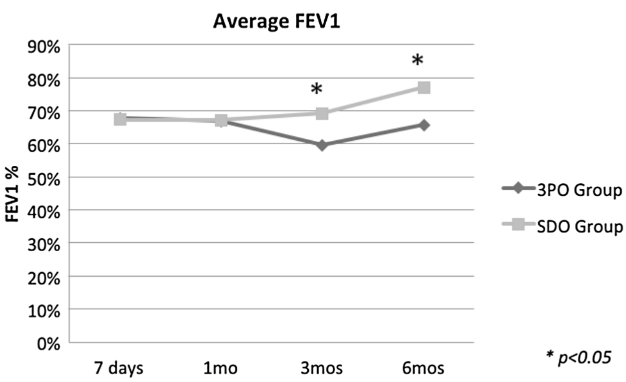

Fig. 4 FEV1 trend in 6 months of follow-up. There was a statistically significant difference in favor of SDO group after 3 and 6 months

group ($p > 0.05$). At 1-, 3-, and 6-month follow-up, there were with no significant differences between groups in mean RKA and vertebral body height. Union rate was 93 % in 3PO group, and 94 % in SDO group (Table 2).

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 diseases 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).

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

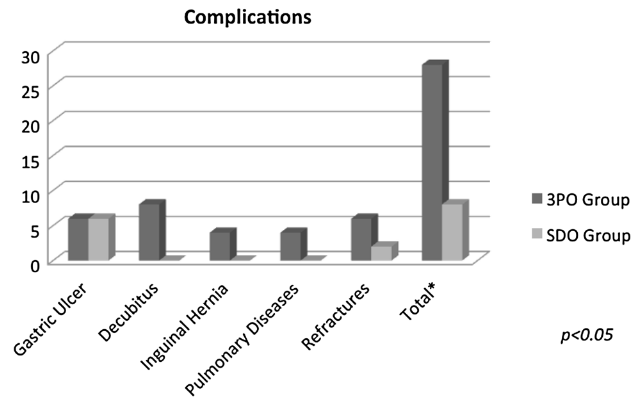

Fig. 5 Miscellaneous complications in 6 months after the trauma. Overall, there were significantly fewer complications in SDO group

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 used orthoses in the treatment of OVF in thoracic and lumbar spine, although their efficacy is rather certified by its widespread use than proven by evidence. However, rigid thoracolumbar braces have some drawbacks limiting their use, especially when osteoporosis is concerned [16]. In fact, muscle breakdown due to rigid immobilization may be deleterious for osteoporotic patients, because it can favor progression of kyphosis once the brace is removed. Pressure on support points can cause discomfort and even sores, especially in the hips. 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 similarly to a lumbar corset brace [18]. Increased abdominal pressure creates a semi-rigid 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.

Interestingly, the advantages of SDO came out after the treatment period, at 3- and 6-month follow-up, when the brace had been removed. This supports the concept that preservation of muscle strength is crucial in preventing progression of kyphosis. Pfeiffer et al. demonstrated a significant increase in trunk muscle strength, decrease in kyphosis, body sway, and pain in women with post-menopausal osteoporosis wearing SDO, compared to controls. These effects were likely related to an increased muscular activity while wearing the brace [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 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 e 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 deformation 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 OLBPDQ 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. After 6 months, this difference was maintained for OLBPDQ score and was even more marked for VAS score. Interestingly, VAS and OLBPDQ 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 recovery and global patient performance after immobilization.

Finally, we observed a significantly lower complication rate in the SDO group. Clinical experiences indicate that the pressure over bony prominences, and the abdominal compression forces especially are responsible for increased pain, muscle atrophy, reduced pulmonary function, and overall severe discomfort with rigid orthoses like 3PO.

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 corset in this study.

In our study on the conservative management of VOFs, patients treated with the 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 thoracolumbar OVF, with better functional outcome and less complications compared to standard 3-point orthosis.

Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Human and animal rights All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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

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