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Original article

Vertebroplasty versus bracing in acute vertebral compression fractures: A prospective randomized trial

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ABSTRACT

Background: The treatment of stable vertebral compression fractures remains controversial.
Objective: To compare the efficacy of vertebroplasty and bracing for acute vertebral compression fractures.
Methods: We conducted a prospective, randomized, non-blinded, single-center study. Adult participants were randomized to undergo vertebroplasty or bracing. Both groups were stratified by age. The primary outcome was functional disability (Roland-Morris disability questionnaire [RMDQ]). Secondary outcomes were pain intensity (Visual Analogue Scale [VAS]), and change in vertebral body height and kyphosis angle. Outcomes were assessed on day 2, and 1, 3 and 6 months after treatment.
Results: Ninety-nine people were included, 51 in the vertebroplasty group and 48 in the brace group. Treatment was performed within 2 weeks of the trauma. On day 2 post-treatment, pain was lower in the vertebroplasty group (mean [SD] 2.3 [1.5] versus 3.4 [2.1], $p = 0.004$) but the difference was no longer significant at 6 months. Functional disability was significantly lower in the vertebroplasty than brace group at all time-points (RMDQ score 7.5 [5.7] vs 11.4 [5.3], $p<0.001$ at 1 month). At 6 months, the increase in kyphosis angle was smaller in the vertebroplasty than the brace group (+1.5°versus +4°, $p<0.001$).
Conclusion: In people with acute vertebral compression fractures, the immediate effect of vertebroplasty was greater than that of bracing on pain and function, and for restoring sagittal balance. At 6 months, the superiority of vertebroplasty decreased, except for the maintenance of sagittal balance.
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INTRODUCTION

Treatment for acute vertebral compression fractures with no neurological deficit or spinal instability is not consensual. Therapeutic options include passive observation, bracing, kyphoplasty or surgery [1–3]. Previous studies with small sample sizes failed to demonstrate whether surgery is superior to bracing and whether bracing is superior to passive observation [4–6]. Although a growing number of individuals are treated by kyphoplasty or vertebral expansion techniques, these techniques have never been assessed in randomized controlled trials [7–9]. Several non-randomized studies yielded promising results for vertebroplasty in acute compression fractures [10–12]. However, vertebroplasty has never been compared to bracing for this indication in randomized studies. The aim of our study was to compare the efficacy of vertebroplasty and conservative treatment by bracing for the treatment of acute compression fractures in adults.

METHODS

Trial design

VOLCANO was a prospective, randomized, non-blinded, single-center trial comparing conservative treatment (brace) and

Abbreviations: LKA, local kyphosis angle; MCS, mental component summary; PCS, physical component summary; RMDQ, Roland-Morris disability questionnaire; SF36, Medical Outcome Study Short Form-36; STIR, short-tau inversion recovery; TLSO, thoraco-lumbo-sacral orthoses; VAS, visual analog scale

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vertebroplasty for acute vertebral compression fracture type A according to the Magerl classification. The study was conducted between 2010 and 2013 at the University Hospital of Clermont-Ferrand. In case of failure of the assigned treatment, participants were offered the other treatment and were considered as crossovers. The study is reported according to the CONSORT guidelines for randomized trials of non-pharmacologic treatments [13].

Ethical considerations

VOLCANO (registration number 2010-A00332−37) received ethical approval from the Comité de Protection des Personnes Sud Est (Committee for the Protection of People South-East, ref 2010-17) as well as an authorization from the Agence Française de Sécurité Sanitaire du Médicament et des Produits de Santé (French Agency for the Safety of Health Products, ref UEC/LynAB/DA/2010 −152). All participants provided written informed consent for participation.

Participants

Participants were enrolled by 1 of 2 investigators, a neurosurgeon or a neuroradiologist. Inclusion criteria were aged ≥ 18 years, spinal trauma of <15 days, and type A Magerl traumatic vertebral compression fracture below T5. Trauma was defined as any damage caused by a sudden physical injury secondary to an impact or a fall from a height ≥ the individual's height. Before treatment, a CT-scan and an MRI with short-tau inversion recovery sequencing (STIR) were performed. Only vertebrae with STIR hyperintensity were considered for inclusion since acute vertebral compression fractures present an increased bone marrow edema resulting in intraosseous STIR hyperintensity [14].

The exclusion criteria were vertebral arch fracture, retropulsed bone fragments with vertebral canal narrowing >50% in the lumbar and >30% in the thoracic spine, neurological deficit, inability to provide informed consent, long-term analgesia, infection, malignancy, coagulation disorder, contraindication to general anesthesia, and pregnancy.

Interventions and procedures

Vertebroplasty

Procedures were performed by experienced interventional neuroradiologists under general anesthesia and prophylactic antibiotic treatment. All vertebroplasties were performed according to a standardized protocol. Participants were positioned prone on a fluoroscopy biplane examination table. Pillows were inserted under the chest and pelvis to increase the lordosis. A unilateral extrapedicular approach was performed after a 2% lidocaine injection. An 11 G trocar was pushed toward the ventral third of the vertebral body under biplane fluoroscopic guidance. Barium opacified polymethylmethacrylate cement (Osteopal®V, Hereus, Germany or OsteoFirm, William Cook Europe, Denmark) was injected using Duro-Ject® Vertebroplasty Injector Set (William Cook) under fluoroscopic guidance. The procedure was discontinued when the cement reached the dorsal quarter of the vertebral body or when epidural or venous extravasation was observed. In the case of recent multiple fractures, each vertebra with a STIR hypersignal was treated during a single anesthesiologic procedure. Outpatient physiotherapy (in a non-specialized clinic chosen by the participant) began on the tenth day postop and included massage, strengthening of the core muscles (abdominals and spinal muscles), pelvic tilting, stretching of the subpelvic muscles and general exercise. The intensity and duration of the rehabilitation was at the discretion of the physiotherapist.

Bracing

Bracing consisted of tailor-made polypropylene rigid thoracolumbo-sacral orthoses (TLSO) with an anterior opening and velcro straps for fastening. The TLSO was modelled on a positive plaster mold of the participant. The participants were kept in strict supine lying while waiting to receive the brace. Once delivered, the brace was donned every morning with the participant in supine, before rising and was worn all day long for 3 months.

Toileting was performed in bed by a nurse. Outpatient physiotherapy (in a non-specialized clinic chosen by the participant) began immediately after reception of the brace and included isometric work of the extensor muscles of the spine for 3 months and dynamic work after brace removal. The intensity and duration of the rehabilitation was at the discretion of the physiotherapist.

Outcome assessment

The primary outcome was the between-group difference in back pain related functional disability at 1 month, measured using the modified Roland−Morris Disability Questionnaire (RMDQ) [15].

The RMDQ is a 21-item, self-report questionnaire about how low-back pain affects functional activities. Each question is worth 1 point and scores range from 0 (no disability) to 24 (severe disability). The original questionnaire and all translations are freely available. The minimal clinically important difference for this questionnaire is reported to be 3 to 5 points after 3 to 6 weeks of treatment [16,17].

Secondary outcomes included the assessment of the following criteria at day 2, and 1, 3 and 6 months after the procedure: pain using a visual analog scale of 0 to 10 (0 indicating no pain and 10 the maximum intensity of pain), functional outcome using the RMDQ scale, health-related quality of life using the Medical Outcome Study Short Form-36 (SF-36), including the mental and physical component summaries.

The SF-36 questionnaire rates health-related quality of life on 8 domains with scores ranging from 0 (poor quality of life) to 100 (satisfactory quality of life): physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. These domains can be regrouped into 2 distinct concepts: a physical dimension, represented by the Physical Component Summary (PCS), and a mental dimension, represented by the Mental Component Summary (MCS). All scales contribute to the scoring of both PCS and MCS measures in different proportions. The minimum clinically important difference for the SF-36 is 4.9 points [18].

Painkiller consumption and number of days off work were collected at each follow-up visit.

Morphological changes were assessed by comparing anterior and posterior vertebral body height and local kyphosis angle (LKA) to pretreatment measures. LKA was defined as the angle formed by the upper endplate of the vertebra overlying the fracture and the lower endplate of the vertebra underlying the fracture. In the case of multiple fractures adjacent to the fracture, the LKA was defined as the angle between the upper vertebral endplate of the most cranial non-fractured vertebra and the lower endplate of the most caudal non-fractured vertebra (Fig. 1). In the case of multiple non-adjacent fractures, the LKA was not calculated. Initial anatomical measurements were performed on the pre therapeutic CT-scan. Within 2 days of treatment, bracing was checked by X-Ray and vertebroplasty by CT scan. At 1 month a CT-scan was performed. At 3 and 6 months, a radiological assessment was performed using standing lateral spinal X-Ray. Measurements were made by 3 neuroradiologists (EC, EH and AK).

Sample size calculation

The study was initially powered to detect a 3-point difference between the groups with an assumed SD of 6 for a two-sided α=0.05 and a statistical power of 80% [19,20]. Considering possible

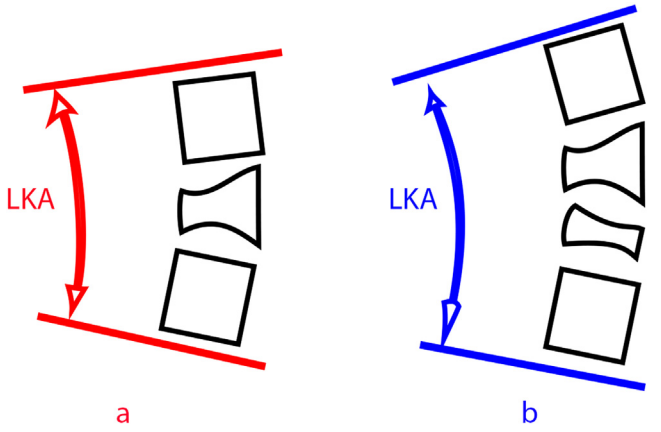

Fig. 1. Local kyphosis angle (LKA) calculation method in case of a single vertebral compression fracture (a) and in case of multiple vertebral compression fractures (b).

crossovers and losses to follow-up the sample size was fixed at 70 participants in each group. After the planned interim analysis, we reduced the target sample size to 100 participants after approval of the independent data and safety monitoring board. The decision to modify the target sample size was primarily driven by accrual rates and revised power calculations. The board used O'Brien–Fleming stopping rules of $p<0.015$ for prespecified interim analyses to evaluate the accumulating evidence of treatment efficacy. After 100 inclusions, the statistical significance of the between-group difference for the primary objective led us to stop the enrollment. One participant with incomplete data was removed from the study, therefore the overall sample consisted of 99 participants.

Randomization

Individuals with one or several acute compression fractures were randomly assigned to undergo vertebroplasty or bracing. Stratified randomization according to age was performed in both groups to achieve balanced groups. Randomization by random block sizes was performed using Stata software (StataCorp, Texas, USA).

Statistical analysis

Univariate analyses were conducted. For the primary analyses, we used a modified intention-to-treat strategy with participants analyzed in their assigned group. A sensitivity analysis was also performed in the intention-to-treat population with an imputation data approach (Last Observation Carried Forward method). The per-protocol population was also analyzed, focusing only on participants with available data at all evaluation time-points. An unadjusted Student t-test was used for the primary outcome analysis. Secondly, the treatment effect was estimated using linear regression models with adjustment for baseline values of the outcome measure, stratification variables and clinically relevant parameters: sex, age, other lesions and number of spinal levels treated. Other continuous variables were compared using the unpaired Student t-test or the Mann–Whitney U test. The Shapiro-Wilk test was used to assess the normality of the distributions, and the Fisher-Snedecor test to assess homoscedasticity. Results are reported as effect-sizes and 95% confidence intervals. Unadjusted chi-square or Fisher exact tests were used for comparisons of categorical data. Random-effects models were performed to take into account within- and between-participant variability (as a random effect) to analyze longitudinal data with adjustment for the baseline values of the outcome measures. The following fixed effects were analyzed: randomization group, evaluation time-point, and their interaction. The normality of residuals from these models was checked as described above. Because fewer than 5% of data were missing or unavailable, procedures for handling of missing data were not applied. Analyses were performed using Stata version 13.0 (StataCorp LP, College Station, TX, USA). A two-sided p-value of less than 0.05 was considered to indicate statistical significance (except for the primary outcome analysis).

Results

Participants

Of the 260 potential participants admitted between September 2010 and September 2012, 99 met the inclusion criteria and were randomized: 51 to the vertebroplasty group and 48 to the brace group (Fig. 2). The study was initially designed to include 140 participants, but the statistically significant difference between groups for the primary outcome after the inclusion of 99 participants led us to stop the enrollment. Mean (SD) age of participants in the brace group was 45.3 (17.2) years and 44.5 (16.9) years in the vertebroplasty group. Age distribution according to group is shown in Figure A. In total, 60% of the fractures were A.1 type according to Magerl classification (Tables 1 and 2). One participant assigned to the brace group underwent a secondary vertebroplasty because of sustained pain at the 1-month assessment and was therefore considered as a crossover. No participants treated with vertebroplasty received braces. The baseline characteristics of the groups were similar (Table 1). At 1 month, 100% of the participants underwent a clinical and radiological assessment. At 6 months, complete data were available for 84 participants (88%) since 10 participants in the brace group and 4 in the vertebroplasty group were lost to follow-up.

Treatment

The time from trauma to treatment ranged from 1 to 12 days (mean, SD: 4, 2.4 days) with no difference between groups. In total, 13 participants (28%) in the brace and 14 (27%) in the vertebroplasty group received treatment for more than 1 spinal level. In the vertebroplasty group, participants received injections of a mean (SD) 6 (2) ml of cement (range 2.5 to 13 ml). Cement placement via a contralateral extrapedicular approach was never necessary.

Functional disability

The results are summarized in Table 3 and illustrated in Fig. 3. RMDQ score at 1 month was significantly lower in the vertebroplasty than the brace group: mean (SD) 7.5 (5.7) points vs 11.4 (5.3); $p<0.001$. These results were not influenced by the type of fracture. This superiority decreased gradually throughout the 6 months of follow up: 5 (5.2) vs 3.2 (4.6); $p = 0.06$. SF-36 scores improved throughout the follow-up, the physical component score of the vertebroplasty group tended to be higher than that of the brace group at 6 months: 68.5 (24.9) vs 58.3 (22.1); $p = 0.03$. RMDQ score at 3 months was significantly lower (ie, improved) than at 6 months for both groups. The results of the per-protocol analysis confirmed those of the intention-to-treat analysis.

RMDQ score at 1 month did not differ between age groups: 10.4 (5.6) (vertebroplasty group) vs 7.0 (5.9) (brace group) for participants ≥50 years old, and 12.5 (4.8) (vertebroplasty group) vs 8.1 (5.5) (brace group) for participants <50 years old ($p = 0.80$). The length of hospital stay did not differ between groups: 3.9 (1.6) days in the vertebroplasty group and 3.5 (1.3) days in the brace group ($p = 0.22$). Time to return to work tended to be longer in the brace group than in the vertebroplasty group, but the difference was not statistically significant (105 vs 90 days; $p = 0.19$).

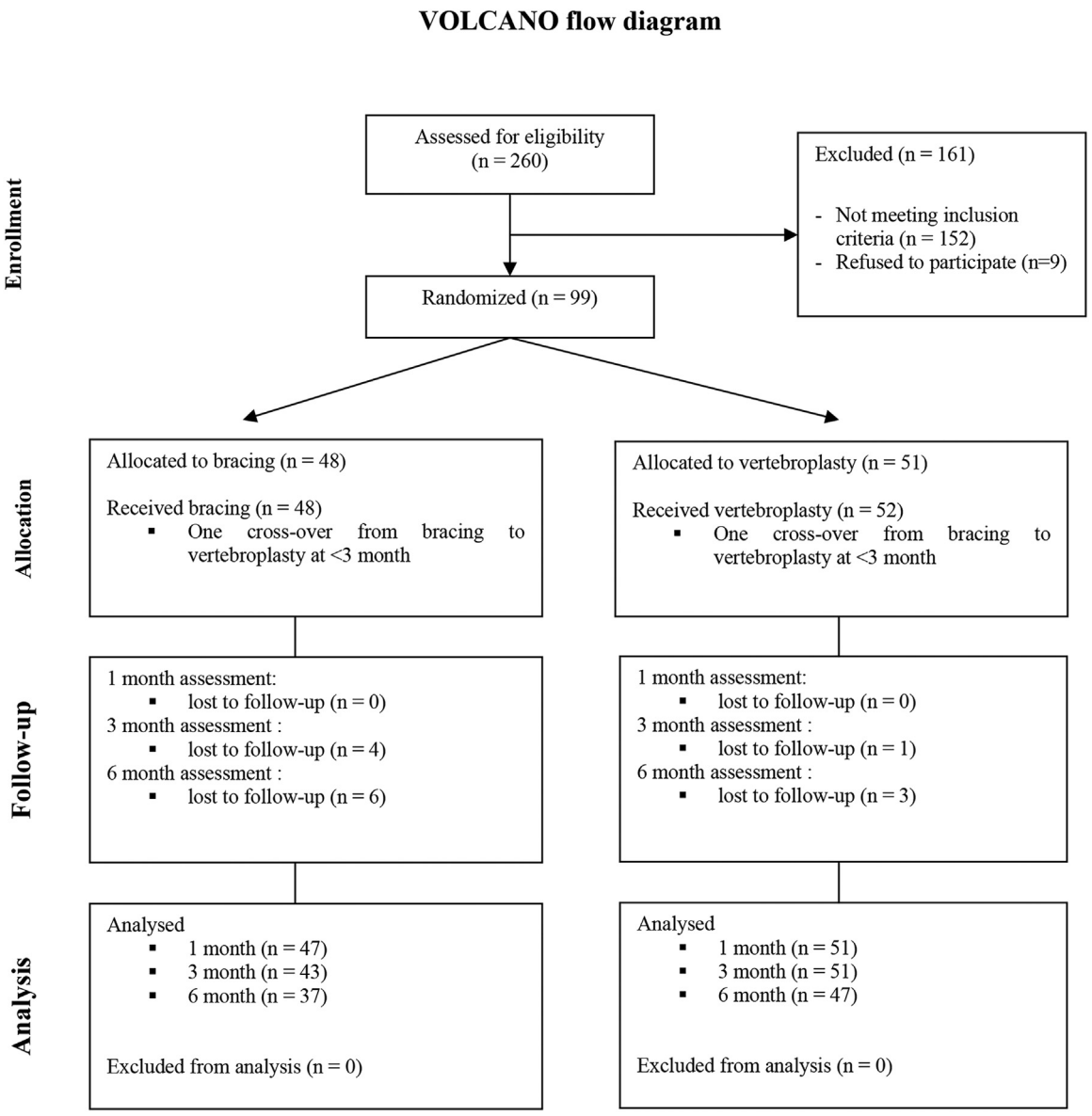

Fig. 2. VOLCANO flow diagram of participation.

Table 1
Baseline characteristics.

	Brace (n = 48)	Vertebroplasty (n = 51)
Age >55 years, no. (%)	21 (44)	21 (41)
Mean age (SD)	45.3 (17.2)	44.5 (16.9)
Male sex, no. (%)	35 (73)	30 (59)
Spinal levels treated >1, no. (%)	13 (28)	14 (27)
Fracture type (Magerl's), no. (%)		
A1.1, A1.2, A1.3	26 (54)	33 (65)
A2.1, A2.2, A2.3	6 (12)	6 (12)
A3.1, A3.2, A3.3	16 (33)	12 (23)
Other lesions*, no. (%)	7 (15)	12 (23)
RMDQ score, mean (SD)	23.8 (1)	23.7 (1.5)
Pain intensity, mean (SD)	6.7 (1.9)	6.7 (2.2)
SF36		
Mental Health, mean (SD)	73.1 (23.3)	72.8 (20.7)
Physical Health, mean (SD)	69.3 (27.3)	73.1 (25.6)
Time from trauma to treatment days, mean (SD)	4.0 (1.9)	3.9 (2.7)

RMDQ Roland-Morris disability questionnaire, SF36 Medical Outcome Study Short Form-36, *extra-spinal traumatic injuries.

Pain

There was no between group difference in pain at inclusion (Table A). At day 2, the VAS pain rating was 1.1 points lower in the vertebroplasty group than the brace group: 3.4 (2.1) vs 2.3 (1.5); p = 0.004. The results of the per-protocol analysis confirmed those of the intention-to-treat analysis. The results are summarized in Table 3 and illustrated in Fig. 3.

At day 2, VAS pain rating was > 3 points in 60% of participants in the brace group and 40% in the vertebroplasty group (p = 0.09). No between-group differences were found for VAS pain rating at 1, 3 and 6 months. However, the number of participants using opioid drugs at 3 months was significantly lower in the vertebroplasty group than the brace group (6% vs 23%; p = 0.02). Moreover, the VAS pain rating for the brace group decreased progressively and significatively from 1 month to 6 months. Opioid consumption was not conditioned by participant age.

Radiological assessment

Significant between-group differences were found in anatomical changes of the spine. At day 2, anterior vertebral body height was

Table 2
Number of participants with each fracture type (Magerl classification) and fracture location.

Magerl type	Fracture location													TOTAL
Magerl's type	**T5**	**T6**	**T7**	**T8**	**T9**	**T10**	**T11**	**T12**	**L1**	**L2**	**L3**	**L4**	**L5**	**TOTAL**
A1.1			1	2	1		4	6	5	5	2	1		27
A1.2		2	1	5	3	1	5	9	16	5	3	4	2	56
A1.3		1	1	1	1			4	6	1	2	1		18
A2.1								1		1				2
A2.2										1	1	1		3
A2.3								1	4		2			7
A3.1	1		1		2		1	8	10	3				26
A3.2				1				1	1					3
A3.3														0
TOTAL	1	3	4	9	7	1	10	30	42	16	10	7	2	142

slightly restored in the vertebroplasty group but not in the brace group: +1.2 (4.3) mm; $p \leq 0.001$, vs −0.5 (0.7) mm; $p = 0.003$. At 6 months, the decrease in anterior vertebral body height was significantly smaller in the vertebroplasty group than the bracing group: 0.1 (0.7) mm vs −2.5 (0.5) mm, $p \leq 0.001$; whereas the change in posterior vertebral body height was identical in both groups: −0.4 mm (1.5). At 2 days, the LKA slightly decreased after vertebroplasty but increased after bracing: −0.7° (0.3) vs +1° (0.1), $p = 0.005$. At 6 months, the increase in kyphosis angle (from pre-treatment values) was smaller in the vertebroplasty than the brace group: +1.5° (4.9); $p<0.001$ vs +4 °(12.9); $p<0.001$. The kyphosis angle increased and the anterior wall height decreased progressively at each follow-up (day 2, 1 month, 2 months and 3 months), ($p = 0.005$). The results of the per-protocol analysis confirmed those of the intention-to-treat analysis. The results are summarized in Table 3 and illustrated in Fig. 3.

Complications

No clinical complications were reported in either group. In the vertebroplasty group, cement leakage with no clinical consequences occurred in 30 cases (57%). No cement leakage occurred in the vertebral canal, the leakages occurred in the intervertebral disk (11/30), in the perivertebral veins (10/30) and in the perivertebral spaces (9/30). No additional compression fractures in adjacent vertebrae were reported over the 6-month follow-up period in either group.

Discussion

This study showed that functional outcome, measured by the RMDQ, was better after vertebroplasty than bracing in people with acute vertebral compression fractures. The RMDQ score was 3.8 (95% CI, −5.96 to −1.56) points lower (indicating better function) at 1 and 3 months in the vertebroplasty than the brace group.

The RMDQ scores of the brace group were 11.4, 7.6 and 5 at 1, 3 and 6 months respectively. The RMDQ scores of the vertebroplasty group, were 7.5, 3.8 and 3.2 at 1, 3 and 6 months respectively. A change between 3 and 5 points has been suggested as the smallest change after 3 to 6 weeks of treatment. We considered that the 3-point difference in RMDQ in sample size estimation (for a moderate effect-size of 0.5) guaranteed a minimal satisfactory sample size. Indeed, for a 3-point difference, 63 participants were needed per group whereas only 23 participants per group were necessary for a 5-point difference, with a two-sided type I error at 5% and 80% statistical power. The per-protocol analysis of the data confirmed this finding, and these values are consistent with the data from previous studies of bracing [2,6] and vertebroplasty [21,12].

Analgesia was adjusted on day 2 in both groups. However, the VAS score in the vertebroplasty group was more than 1 point lower than in the brace group (2.3 vs 3.4; $p = 0.004$). This difference is clinically relevant since the minimal clinically important difference for VAS pain ratings is 0.9 to 1.6 points [22,23]. However, the effect size was −0.59 (95% CI −0.18 to −0.99), which is considered moderate according to Cohen [24]. At months 1, 3 and 6, there was no difference between the groups despite the significant between-group difference in functional outcome. This apparent discrepancy between changes over time in RMDQ scores and pain ratings could be explained by the fact that the disability assessed by the RMDQ score is not only related to pain but also to overall mobility. The RMDQ score might also be a better global indicator of pain status than the VAS rating alone. Outcomes explored by the RMDQ score are multidimensional whereas pain intensity is only one component of this evaluation. In addition, pain is a multidimensional experience whereas the VAS is a one-dimensional instrument of assessment. The superiority of vertebroplasty over bracing was greater at the first assessment time-point (day 2) for both functional outcome and pain relief. Vertebroplasty is a minimally invasive technique that provides immediate stability and enables rapid mobilization of the individual. When professional and social activities are resumed, participants are not impeded in their movements, in contrast with bracing that limits movement amplitudes.

Although the study was randomized, participants could not be blinded to the treatment they received. Invasive procedures such as vertebroplasty may lead to higher expectations and may be associated with a greater placebo effect than bracing, which may have influenced the results [25]. However, the change in pain over time differed between the groups; it decreased progressively and significantly in the brace group but not in the vertebroplasty group. This is because of the greater immediate analgesic effect of vertebroplasty, which was also long-lasting. The improvement in function in the brace group was related to the decrease in pain. Indeed, the SF-36 mental health score did not increase significantly over time. This may be due to the physical limitations caused by the brace. One could therefore assume that the between-group differences in RMDQ score are the consequences of simply wearing a brace.

In the vertebroplasty group, anterior vertebral body height increased slightly just after the procedure was performed and remained stable over the 6-month follow-up. This kyphoplasty–like effect was intentionally obtained by placing cushions under the hips and upper thorax. Conversely, in the brace group, the vertebral body height decreased over time. This finding suggests that vertebroplasty could be more effective than bracing in preserving vertebral body height, even if vertebroplasty should not be expected to restore vertebral body height to the same extent as kyphoplasty [26–28]. A synergy between the hyperlordosis, resulting from the positioning, and the injection of cement which consolidates it, could explain this structural effect. LKA increased to a greater extent in the brace group

Table 3
Clinical and anatomical outcomes (univariate analyses).

	Brace	Vertebroplasty	ES (95%CI), p-value
Clinical outcomes			
RMDQ, mean (SD) - ITT with imputation data (LOCF)			
M1 (*n* = 48/51)	11.4 (5.3)	7.5 (5.7)	−0.70 (−1.11 to −0.30), *p*<0.001
M3 (*n* = 48/51)	7.6 (6.0) ***	3.8 (4.3) ***	−0.72 (−1.11 to −0.31), *p*<0.001
M6 (*n* = 48/51)	5.0 (5.2) ***	3.2 (4.6) ***	−0.37 (−0.77 to 0.02), *p* = 0.06
RMDQ, mean (SD) - per-protocol			
M1 (*n* = 37/47)	11.6 (4.9)	7.1 (5.3)	−0.86 (−1.31 to −0.42), *p*<0.001
M3 (*n* = 37/47)	7.6 (6.0)	3.6 (3.9)	−0.80 (−1.25 to −0.36), *p*<0.001
M6 (*n* = 37/47)	4.3 (4.6)	2.9 (4.2)	−0.33 (−0.76 to −0.10), *p* = 0.14
Pain intensity, mean (SD) - ITT with imputation data (LOCF)			
D2 (*n* = 46/51)	3.4 (2.1)	2.3 (1.5)	−0.59 (−0.18 to −0.99), *p* = 0.004
M1 (*n* = 48/51)	1.9 (2.1) ***	2.4 (1.9)	0.24 (−0.16 to 0.63), *p* = 0.24
M3 (*n* = 48/51)	1.6 (1.9) ***	1.6 (1.9) *	0.00 (−0.39 to 0.39), *p* = 0.99
M6 (*n* = 48/51)	1.8 (1.9) ***	1.4 (1.8) **	−0.21 (−0.60 to 0.18), *p* = 0.30
Pain intensity, mean (SD) - per-protocol			
D2 (*n* = 37/47)	3.4 (1.9)	2.2 (1.6)	−0.63 (−1.07 to −0.18), *p* = 0.006
M1 (*n* = 37/47)	1.5 (1.6)	2.3 (2.0)	0.43 (−0.01 to 0.87), *p* = 0.06
M3 (*n* = 37/47)	1.6 (1.9)	1.5 (1.8)	−0.05 (−0.48 to 0.38), *p* = 0.82
M6 (*n* = 37/47)	1.8 (2.0)	1.3 (1.6)	−0.28 (−0.71 to 0.16), *p* = 0.21
SF36 Mental Health, mean (SD) - ITT with imputation data (LOCF)			
M1 (*n* = 48/50)	50.2 (20.6)	52.5 (20.1)	0.11 (−0.28 to 0.50), *p* = 0.58
M3 (*n* = 48/51)	53.8 (19.9)	63.4 (21.3) ***	0.46 (0.07 to 0.86), *p* = 0.02
M6 (*n* = 48/51)	64.5 (21.9) ***	71.7 (23.1) ***	0.32 (−0.08 to 0.71), *p* = 0.12
SF36 Mental Health, mean (SD) - per-protocol			
M1 (*n* = 37/47)	49.0 (20.6)	54.4 (20.0)	0.26 (−0.17 to 0.69), *p* = 0.24
M3 (*n* = 37/47)	53.9 (19.2)	64.8 (20.6) ***	0.54 (0.10 to 0.98), *p* = 0.02
SF36 Physical Health, mean (SD) - ITT with imputation data (LOCF)			
M1 (*n* = 48/50)	38.5 (11.7)	44.8 (16.8)	0.43 (0.03 to 0.83), *p* = 0.03
M3 (*n* = 48/51)	49.3 (18.5) ***	29.4 (21.9) ***	0.49 (0.09 to 0.89), *p* = 0.02
M6 (*n* = 48/51)	58.3 (22.1) ***	68.5 (24.9) ***	0.43 (0.03 to 0.82), *p* = 0.03
SF36 Physical Health, mean (SD) - per-protocol			
M1 (*n* = 37/47)	38.3 (10.1)	46.2 (16.3)	0.56 (0.12 to 1.00), *p* = 0.01
M3 (*n* = 37/47)	50.6 (17.2) ***	61.1 (21.3) ***	0.53 (0.10 to 0.97), *p* = 0.02
M6 (*n* = 37/47)	62.2 (20.7) ***	72.3 (23.6) ***	0.45 (0.01 to 0.88), *p* = 0.04
Anatomical outcomes			
LOCAL KYPHOSIS ANGLE (°), mean (SD) - ITT with imputation data (LOCF)			
Inclusion (*N* = 37/39)	10.7 (7.0)	10.8 (6.2)	Baseline value
D2 (*N* = 40/39)	11.7 (7.1) *	10.1 (5.9)	−0.23 (−0.67 to 0.21), *p* = 0.30
M1 (*N* = 41/39)	13.5 (7.3) ***	11.5 (6.6)	−0.28 (−0.72 to 0.16), *p* = 0.21
M3 (*N* = 41/39)	14.7 (7.8) ***	11.9 (7.1) *	−0.36 (−0.80 to 0.08), *p* = 0.11
M6 (*N* = 41/39)	14.7 (8.3) ***	12.3 (7.3) ***	−0.30 (−0.74 to 0.14), *p* = 0.18
LOCAL KYPHOSIS ANGLE (°), mean (SD) - per-protocol			
Inclusion (*N* = 37/39)	10.7 (7.0)	10.8 (6.2)	Baseline value
D2 (*N* = 33/36)	12.3 (7.4) *	10.5 (5.8)	−0.26 (−0.72 to 0.21), *p* = 0.28
M1 (*N* = 39/37)	13.7 (7.4) ***	12.0 (6.4)	−0.24 (−0.69 to 0.21), *p* = 0.31
M3 (*N* = 32/38)	15.7 (8.1) ***	12.5 (7.0)	−0.44 (−0.91 to 0.03), *p* = 0.08
M6 (*N* = 28/35)	15.0 (8.5) ***	12.9 (7.4)	−0.31 (−0.80 to 0.18), *p* = 0.30
ANTERIOR HEIGHT (mm), mean (SD) - ITT with imputation data (LOCF)			
Inclusion (*N* = 44/51)	21.8 (3.9)	21.5 (4.1)	Baseline value
D2 (*N* = 47/51)	21.3 (4.6) **	22.7 (4.4) ***	0.30 (−0.10 to 0.69), *p* = 0.14
M1 (*N* = 48/51)	20.1 (4.6) ***	21.8 (4.6)	0.39 (0.00 to 0.79), *p* = 0.05
M3 (*N* = 48/51)	19.4 (4.6) ***	21.5 (4.6)	0.48 (0.08 to 0.88), *p* = 0.02
M6 (*N* = 48/51)	19.3 (4.4) ***	21.6 (4.8)	0.49 (0.09 to 0.88), *p* = 0.02
ANTERIOR HEIGHT (mm), mean (SD) - per-protocol			
Inclusion (*N* = 44/51)	21.8 (3.9)	21.5 (4.1)	Baseline value
D2 (*N* = 41/49)	21.2 (4.8) **	22.6 (4.4) **	0.30 (−0.11 to 0.71, *p* = 0.16
M1 (*N* = 45/51)	20.1 (4.7) ***	21.8 (4.6)	0.40 (−0.01 to 0.80), *p* = 0.06
M3 (*N* = 41/51)	19.3 (4.9) ***	21.5 (4.7)	0.50 (0.08 to 0.91), *p* = 0.03
M6 (*N* = 36/48)	19.4 (4.6) ***	21.3 (4.8)	0.45 (−0.02 to 0.88), *p* = 0.07
POSTERIOR HEIGHT (mm), mean (SD) - ITT with imputation data (LOCF)			
Inclusion (*N* = 44/51)	26.5 (3.2)	26.6 (3.6)	Baseline value
D2 (*N* = 47/51)	26.7 (3.8)	26.6 (3.6)	−0.03 (−0.43 to 0.36), *p* = 0.86
M1 (*N* = 48/51)	26.6 (3.9)	26.6 (3.5)	0.01 (−0.38 to 0.40), *p* = 0.95
M3 (*N* = 48/51)	26.6 (4.0)	26.5 (3.7)	−0.02 (−0.41 to 0.37), *p* = 0.91
M6 (*N* = 48/51)	26.3 (4.0)	26.3 (3.6)*	0.00 (−0.39 to 0.39), *p* = 0.99
POSTERIOR HEIGHT (mm), mean (SD) - per-protocol			
Inclusion (*N* = 44/51)	26.5 (3.2)	26.6 (3.6)	Baseline value
D2 (*N* = 41/49)	26.9 (3.9)	26.5 (3.6)	−0.09 (−0.50 to 0.32), *p* = 0.56
M1 (*N* = 45/51)	26.6 (4.0) *	26.6 (3.5)	0.02 (−0.37 to 0.42, *p* = 0.98
M3 (*N* = 41/51)	26.8 (4.3)	26.5 (3.7)	−0.04 (−0.45 to 0.36), *p* = 0.72
M6 (*N* = 36/48)	26.1 (3.4) **	26.2 (3.7)	0.07 (−0.36 to 0.50), *p* = 0.85

ITT Intention-To-Treat, LOCF Last Observation Carried Forward method, RMDQ Roland Morris Disability Questionnaire.
*$p \leq 0.05$, **$p \leq 0.01$, ***$p \leq 0.001$: p-values for within-group comparisons.
ES (95%CI), p-value: effect-size, 95% confidence interval and p-value for between-group comparisons.

(+4 ° vs +1.5° at 6 months). The increase in LKA in both groups may be partially explained by a disk collapse that might have worsened the effect of anterior vertebral body compression. Indeed, in Magerl A fractures, damage to the vertebral endplate occurs in association with the disk damage. A collapsing disk can lead to an increase in LKA despite conservation of vertebral body height. This would explain the initial moderate worsening of the LKA for the vertebroplasty group, despite preserved vertebral height. Moreover, LKA and vertebral height remained stable over time in the vertebroplasty group. In contrast, LKA increased, and vertebral height decreased over time in the brace group. The latter results are in favor of the

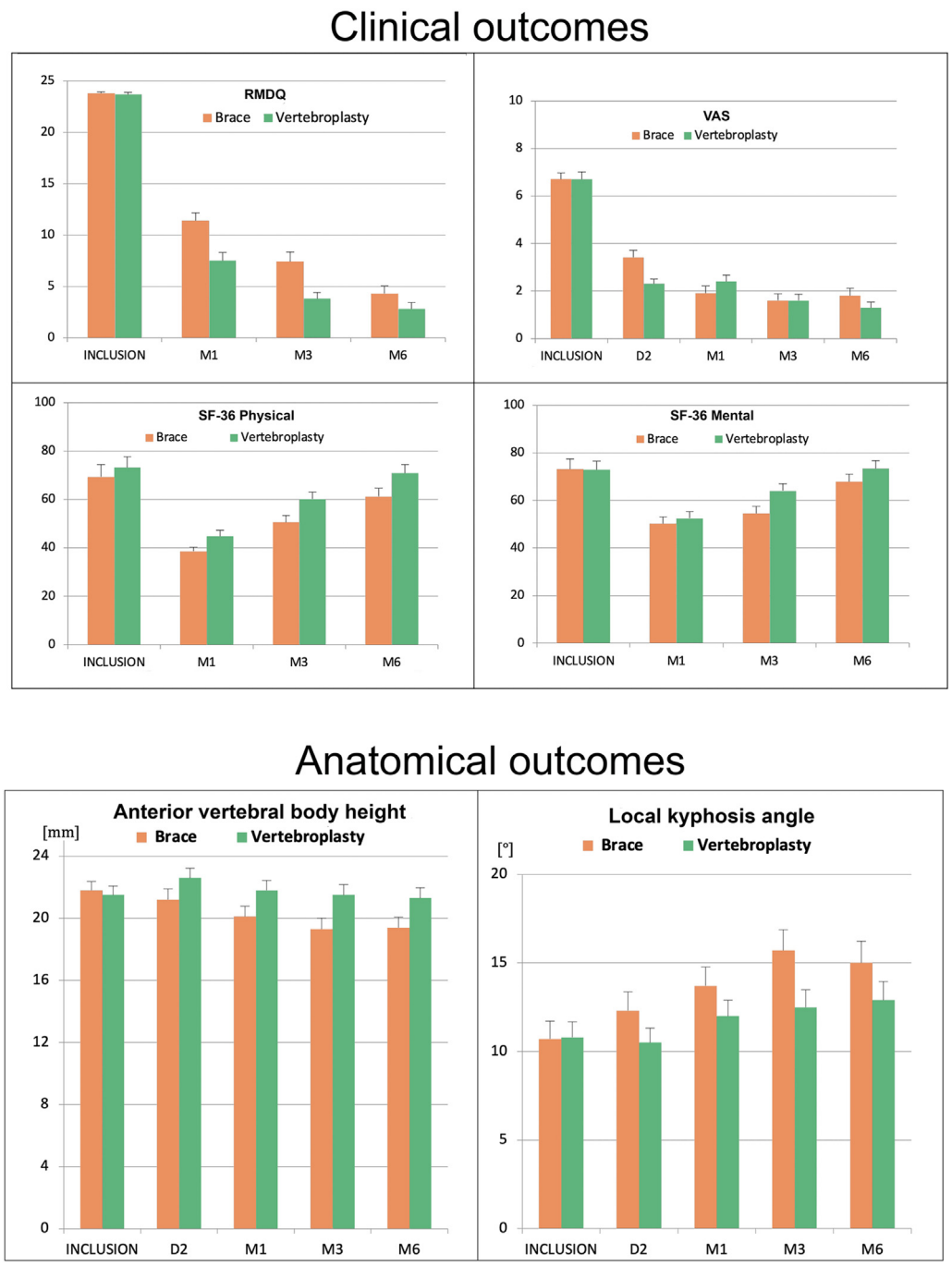

Fig. 3. Clinical and anatomical outcomes. Clinical outcomes included the score on the Roland–Morris Disability Questionnaire (RMDQ), the Visual Analog Scale (VAS), and the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) Physical Component Summary and Mental Component Summary. Anatomical outcomes included anterior vertebral body height and local kyphosis angle. D2 = 2nd day postop, M1 =1 month, M3 = 3 months and M6 = 6 months.

superiority of vertebroplasty. However, one limitation in the interpretation of these results is that the assessor could not be blinded to group allocation when performing the anatomical measurements because cement is radiopaque.

The percentage of cement leakage (57%) was similar to that reported by previous studies of vertebroplasty performed for the usual indications, osteoporotic compression fractures and malignant disease [29–31]. Like tumors, acute high energy traumatic fractures may lead to endplate damage, increasing the risk of leakage into the vertebral canal since the cement sinks into the interstices between bony fragments and exits the vertebra. In most cases, cement leakages have no clinical consequences [31,32]. We decided not to perform bone densitometry to avoid mobilizing the fracture or delaying the treatment. Some participants may therefore have had osteoporosis. However, the randomization should have ensured an even distribution of such participants in each arm. In addition, the age distribution was equivalent in each group. Therefore, there was no over-representation of older adults, who are more likely to have osteoporosis, in any group. Moreover, no additional compression fracture was observed in adjacent vertebrae after treatment (brace or

vertebroplasty), which may indicate a low proportion of osteoporosis in the sample.

Conclusion

Our study demonstrated a moderately greater efficacy of vertebroplasty over bracing in terms of functional outcome and pain after acute vertebral compression fractures. Moreover, the superiority of vertebroplasty over bracing was particularly evident early after the procedure, which may lead to an earlier resumption of professional activities. Vertebroplasty also provided greater prevention of ongoing vertebral collapse and kyphosis than bracing.

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Figure A: Age distribution according to vertebroplasty or brace group. The distribution by age group is comparable in the two groups. Mean age was 45.3 (SD 17.2) in the brace group and 44.5 (SD16.9) in the vertebroplasty group.

Declaration of Competing Interest

none

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.rehab.2023.101746.

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