

# Comparative Study of the Treatment Outcomes of Osteoporotic Compression Fractures without Neurologic Injury Using a Rigid Brace, a Soft Brace, and No Brace

## A Prospective Randomized Controlled Non-Inferiority Trial

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**Background:** The efficacy of brace application for the treatment of osteoporotic compression fractures remains unclear. The purpose of this study was to compare the treatment outcomes in patients with osteoporotic compression fractures with regard to whether the patients had no braces, rigid braces, or soft braces.

**Methods:** We randomly assigned sixty patients with acute one-level osteoporotic compression fractures within three days of injury to the no-brace, soft-brace, and rigid-brace groups through 1:1:1 allocation. The primary outcome was the baseline adjusted Oswestry Disability Index score at twelve weeks after compression fracture. The non-inferior margin of the Oswestry Disability Index was set at an average of 10 points.

**Results:** The baseline adjusted Oswestry Disability Index score at twelve weeks after compression fracture in the no-brace group was not inferior to that in the soft-brace or rigid-brace groups. The mean adjusted Oswestry Disability Index score was 35.95 points (95% confidence interval, 25.42 to 46.47 points) in the no-brace group and 37.83 points (95% confidence interval, 26.77 to 48.90 points) in the soft-brace group, with a difference of  $-1.88$  points (95% confidence interval,  $-7.02$  to  $9.38$  points) between the groups. Similarly, the mean adjusted Oswestry Disability Index score was 35.95 points (95% confidence interval, 25.42 to 46.47 points) in the no-brace group and 33.54 points (95% confidence interval, 23.79 to 43.29 points) in the rigid-brace group, with a difference of  $2.41$  points (95% confidence interval,  $-7.86$  to  $9.27$  points) between the groups. During the follow-up assessment period, there was no significant difference among the groups for the overall Oswestry Disability Index scores ( $p = 0.260$ ), visual analog scale for pain scores for back pain ( $p = 0.292$ ), and anterior body compression ratios ( $p = 0.237$ ). However, the Oswestry Disability Index scores and the visual analog scale scores for back pain significantly improved with time after the fractures ( $p < 0.001$ ), and the body compression ratios significantly decreased with time in all three groups ( $p < 0.001$ ).

**Conclusions:** The Oswestry Disability Index scores for the treatment of compression fractures without a brace were not inferior to those with soft or rigid braces. Moreover, the improvement in back pain and progression of anterior body compression were similar among the three groups.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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**B**enign osteoporotic compression fractures without neurologic deficits are inherently stable fractures, as they involve only the anterior column of the vertebral body<sup>1,2</sup>; these injuries result from axial compression load without shear, translational, or rotational force. Therefore, nonoperative treatment is considered as the initial treatment of choice<sup>3,4</sup>. Nonoperative treatment usually comprises short-term bed rest, analgesic therapy, and orthosis wearing<sup>5</sup>.

Theoretically, braces provide stability to the fracture site, reducing pain, maintaining alignment, facilitating early mobility, and preventing further kyphotic collapse of the fracture site<sup>6-8</sup>. However, braces do have some potential disadvantages, including muscular atrophy, deconditioning, skin irritation, additional costs, and delays in rehabilitation while waiting for brace application<sup>6</sup>; thus, the use of a rigid orthosis (for example, a thoracolumbosacral orthosis) is generally associated with low compliance rates in these patients because of impaired respiration and the cumbersome nature of the braces.

Nevertheless, bracing has been considered as a landmark step in the nonoperative management for osteoporotic compression fractures<sup>9-11</sup>. However, we are aware of no prospective, randomized, controlled clinical trial that has investigated the

efficacy of wearing rigid or soft braces for the management of osteoporotic compression fractures. We aimed to compare the improvements in disability and pain in patients with osteoporotic compression fractures who were treated with rigid, soft, or no braces. We hypothesized that the treatment outcomes in improvement of disability in patients without braces would not be inferior to the outcomes in patients using rigid or soft braces.

## Materials and Methods

### Study Design and Participants

This study was approved by the hospital institutional review board, and all participants provided written informed consent before study entry. This was a prospective, randomized trial designed to determine the short-term efficacy of brace application for alleviating pain and improving disability in persons with acute osteoporotic thoracolumbar compression fractures who were assigned to three different treatment groups: no-brace, soft-brace, and rigid-brace application (Fig. 1). The inclusion criteria were patient age of fifty years or older and the presence of acute back pain caused by a single-level vertebral fracture within three days of minor trauma. The fracture was defined as an axial compression of only the anterior column of the vertebral body with intact posterior elements, confirmed on magnetic resonance imaging, and the patient was without neurologic deficit. Exclusion criteria included a history of more than two recent vertebral fractures, a malignant compression fracture, neurologic compromise, a state of not walking before the fracture, a history of

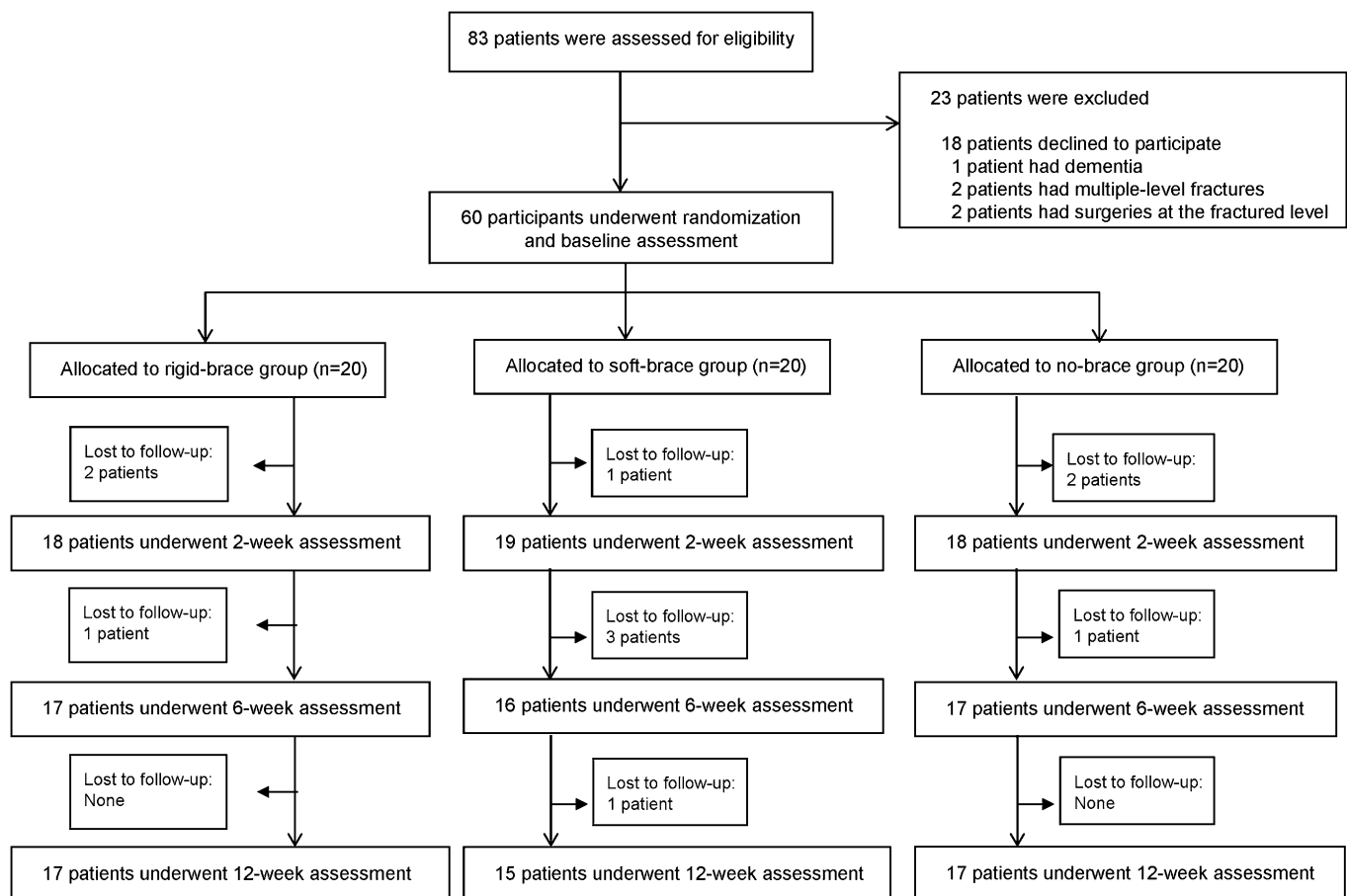


Fig. 1  
A CONSORT (Consolidated Standards of Reporting Trials) flow diagram showing the enrollment, randomization, assigned interventions, and follow-up of the study participants.

previous injury or surgery at the fractured level, and an inability to complete the questionnaires about pain and disability. The study was performed at the spinal center of a tertiary care teaching institution from December 2012 to October 2013. Patients were randomly assigned through a 1:1:1 allocation to the no-brace, soft-brace, or rigid-brace groups. This randomization was performed using a computer-generated randomization list, which was concealed from the first author (H.-J.K.) before the randomized allocation.

### Interventions

All participants were treated nonoperatively for osteoporotic compression fracture. Patients in the rigid-brace group were strictly maintained on bed rest until a thoracolumbar sacral orthosis (How Medicare, Seoul, Korea) was applied. Because the soft back braces (How Medicare) were ready-made, they could be worn immediately upon patient enrollment in the study. In both the rigid-brace and soft-brace groups, braces were to be worn at all times except when lying down. All patients were instructed to wear the rigid or soft brace for a total of eight weeks. The brace compliance was self-reported by the patients during the follow-up assessments. Patients in the no-brace group were allowed to walk without any brace as long as they were comfortable. All participants took pain medication as necessary and were counseled on restricting spine movement, heavy lifting, and carrying with no specific weight limit during the first eight weeks. After eight weeks, a two-week weaning period was initiated. The participants did not receive financial support for the treatments, including brace application and pain medication.

### Outcome Assessment

Baseline data, which were collected by a blinded clinical research assistant, included sex, birth date, height, weight, smoking status, and medication use. The primary outcome was the baseline adjusted Oswestry Disability Index (ODI) score at twelve weeks after the compression fracture. The ODI was based on a self-administered questionnaire measuring back-specific function<sup>12</sup>. The questionnaire comprised ten items, each with six levels of responses. Each item was scored from 0 to 5 points, and the total summation was converted to a 0-to-100-point scale<sup>12</sup>. Secondary outcome measures included ODI score, visual analog scale (VAS) score for back pain, general health status, progression of the body compression ratio over all follow-up assessments, and treatment satisfaction at twelve weeks after the compression fracture. The VAS for back pain comprised a 10-cm-long line with “none” on one end of the scale at 0 points and “disabling pain” on the other end of the scale at 10 points. Participants were asked to place a mark on the line, which represented their perceived level of back pain, and the measured distance from the mark to the zero point was considered as the VAS score. The ODI and VAS scores for back pain were assessed at two, six, and twelve weeks after the compression fracture. The general health status was assessed using the Short Form-36 (SF-36) at the initial enrollment and twelve weeks after the compression fracture<sup>13</sup>. The raw scores for the eight subscales and the two summaries of the SF-36 (Physical Function, Role Physical, Bodily Pain, General Health, Vitality, Social Function, Role Emotion, and Mental Health, as well as the Physical Component Summary [PCS] and the Mental Component Summary [MCS]) were transformed into norm-based scoring<sup>13</sup>. The anterior body compression ratio was assessed by calculating the ratio between the vertical height of the most compressed anterior section of the injured vertebral body and the posterior vertebral body height at that level<sup>14</sup>. This body compression ratio was measured at the initial enrollment and at two, six, and twelve weeks after the compression fracture, independently by one of the co-authors (J.M.Y.), who was unaware of the treatment method. Individual satisfaction of the treatment was assessed on a 5-point scale at twelve weeks after the compression fracture, with 5 points indicating complete satisfaction with the treatment.

### Statistical Analysis

The outcome analysis was performed by comparisons between the no-brace and brace (rigid or soft) groups. The primary end point was the baseline adjusted ODI score at twelve weeks after the compression fracture. Using information from previous pilot studies on burst fractures<sup>15,16</sup>, we calculated that a minimum

sample of twenty participants per group would be required for the current study, with a non-inferior design, based on an alpha of 0.05, a beta of 0.10, a minimally important change of 10 points for the ODI score<sup>17</sup>, a difference in the mean ODI score of 3.5 points, a standard deviation of 6.5 points, and a follow-up loss rate of 20%. All data were evaluated with use of intention-to-treat analyses.

The baseline adjusted ODI scores at twelve weeks after the fracture were compared among the no-brace group and the brace (rigid or soft) groups with use of independent t tests and analysis of covariance. If the 95% confidence intervals (95% CIs) of the differences among the no-brace group and the brace groups were within the predetermined margin of non-inferiority (an ODI score of 10 points), the no-brace treatment was considered as non-inferior to the rigid or soft-brace treatments. Secondary outcome measures, including the overall ODI score, the VAS score for back pain, and the progression of the body compression ratio, were assessed for superiority among the three groups during all of the follow-up assessments, along with the 95% CIs. Analysis of variance for repeated measures was performed to examine the secondary outcome measures among the three groups over the follow-up assessment period as independent variables; in addition, the general health status and treatment satisfaction at twelve weeks after the fracture were examined with use of one-way analysis of variance. Furthermore, in each group, any changes in general health status, such as SF-36 PCS and MCS, from study enrollment to twelve weeks after the fracture, were compared with use of paired t tests. All statistical analyses were performed with use of the SPSS 20.0.0 statistics package (IBM, Armonk, New York), with significance set at  $p = 0.05$ . This study is registered at ClinicalTrials.gov, number NCT02049931.

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### Results

From December 2012 to October 2013, eighty-three patients were assessed for eligibility for the study. Sixty patients met the inclusion criteria and were randomly assigned to a study group (twenty patients each in the rigid-brace, soft-brace, and no-brace groups). Figure 1 shows the number of participants involved in the present trial, from the eligibility assessment through the twelve weeks of follow-up. One participant in the soft-brace group died during the follow-up period for reasons believed to be unrelated to the trial. At the twelve-week assessment, complete data were available for forty-nine (81.7%) of the sixty participants. The rates of missing data were similar among the groups at all follow-up assessments (Fig. 1), and there was no crossover among the groups at the twelve-week assessment.

The baseline characteristics of the participants were similar among the three groups (Table I). All participants had one vertebral fracture from T7 to L3 vertebrae. The mean age (and standard deviation) was  $72.25 \pm 10.40$  years for the no-brace group,  $66.75 \pm 11.00$  years for the soft-brace group, and  $71.75 \pm 7.96$  years for the rigid-brace group. The average body compression ratio (and the standard deviation) at the initial enrollment was  $0.69 \pm 0.11$  for the no-brace group,  $0.70 \pm 0.11$  for the soft-brace group, and  $0.71 \pm 0.09$  for the rigid-brace group. On the basis of self-reported compliance, one patient in the soft-brace group and one patient in the rigid-brace group admitted to not wearing the brace in the sitting position during the twelve-week follow-up period; however, these patients wore the rigid or soft brace in the standing or walking positions.

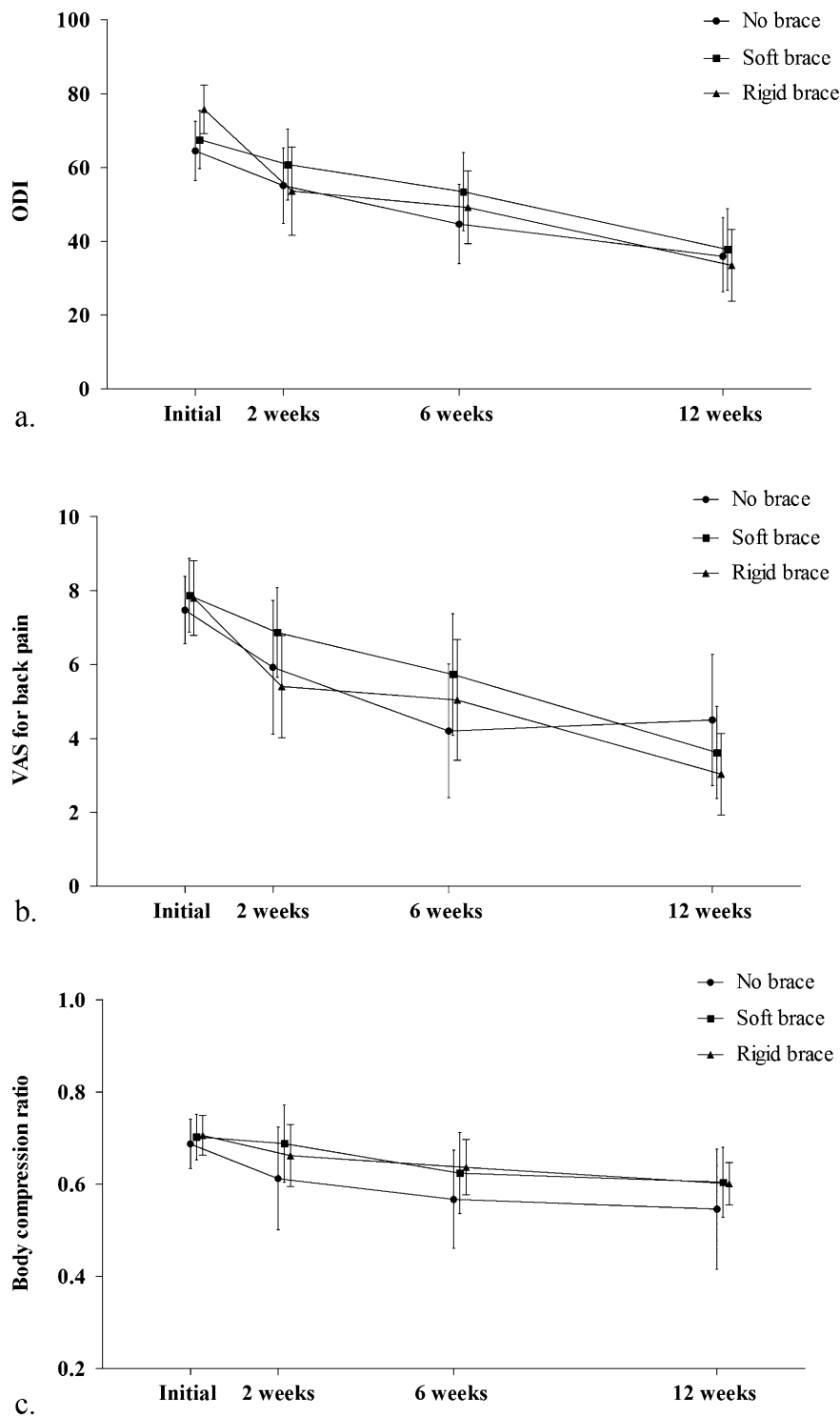


Fig. 2

Line graphs showing treatment outcomes at follow-up of two, six, and twelve weeks: ODI with non-inferior comparison at twelve weeks as the primary end point (**Fig. 2-A**), VAS for back pain (**Fig. 2-B**), and anterior body compression ratio at the fractured level (**Fig. 2-C**). Error bars indicate the 95% CIs.

The baseline adjusted ODI score (primary outcome) at twelve weeks after compression fracture in the no-brace group was not inferior compared with that in the soft-brace or rigid-brace groups (Fig. 2). At twelve weeks after the fracture, the

mean baseline adjusted ODI score was 35.95 points (95% CI, 25.42 to 46.47 points) in the no-brace group and 37.83 points (95% CI, 26.77 to 48.90 points) in the soft-brace group, and the mean difference of  $-1.88$  points (95% CI,  $-7.02$  to  $9.38$

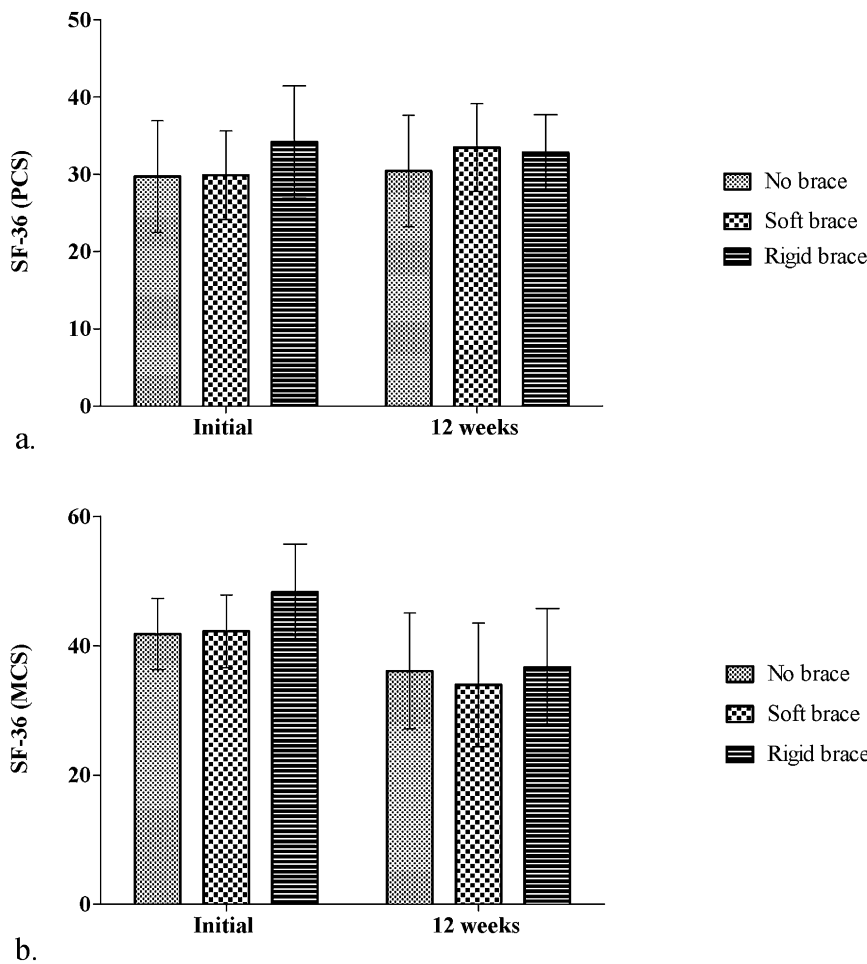


Fig. 3  
Bar graphs showing the quality of life represented by the SF-36 PCS (**Fig. 3-A**) and SF-36 MCS (**Fig. 3-B**) at initial enrollment and at twelve weeks after fracture. Error bars indicate the 95% CIs.

points) was within the predetermined margin of non-inferiority (an ODI score of 10 points). Similarly, the mean baseline adjusted ODI score was 35.95 points (95% CI, 25.42 to 46.47 points) in the no-brace group and 33.54 points (95% CI, 23.79 to 43.29 points) in the rigid-brace group, and the mean difference of 2.41 points (95% CI, -7.86 to 9.27 points) was also within the predetermined margin of non-inferiority (Fig. 2).

There were no significant differences ( $p > 0.05$ ) in any of the secondary end point variables, including the ODI scores, the VAS scores for back pain, and the body compression ratios across the follow-up assessments among the no-brace, soft-brace, and rigid-brace groups (Fig. 2). Over the follow-up assessment time (the interaction between the brace and the follow-up assessment time), there were no significant differences among the overall ODI scores ( $p = 0.260$ ), VAS scores for back pain ( $p = 0.292$ ), and body compression ratios ( $p = 0.237$ ). However, the ODI scores and VAS scores for back pain significantly improved ( $p < 0.001$  for both) with time after the fracture (the follow-up assessment time) in all three groups. The body compression ratios significantly decreased with time in all three groups ( $p < 0.001$ ). At twelve weeks, there was no significant difference among the three groups for general health status with regard to SF-36 PCS ( $p = 0.716$ ) and

SF-36 MCS ( $p = 0.889$ ) (Fig. 3), and similarly, the satisfaction rates during the follow-up assessments did not differ among the three groups ( $p = 0.421$ ) (Fig. 4). However, compared with

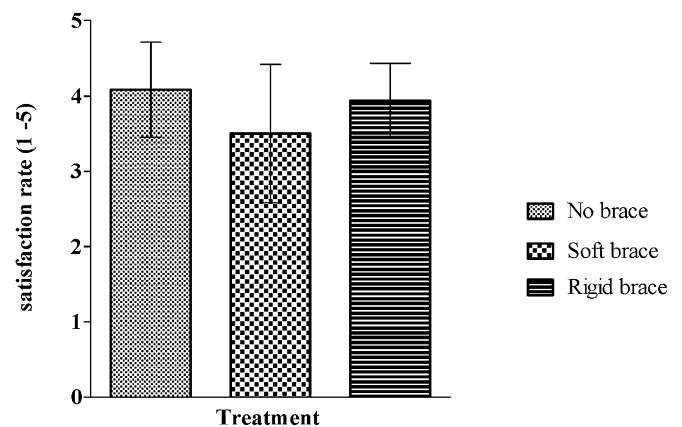


Fig. 4  
A bar graph showing treatment satisfaction among the three groups. Treatment satisfaction was scored from 1 to 5 points, with a higher score indicating higher satisfaction with the treatment. The error bars indicate the 95% CIs.

TABLE I Descriptive Statistics of the Subjects in the Study

	No-Brace Group (N = 20)	Soft-Brace Group (N = 20)	Rigid-Brace Group (N = 20)
Age* (yr)	72.25 ± 10.40	66.75 ± 11.00	71.75 ± 7.96
Female sex†	13 (65%)	14 (70%)	14 (70%)
Body mass index* (kg/m <sup>2</sup> )	24.37 ± 2.90	25.50 ± 3.20	24.89 ± 3.90
Bone mineral density* (g/cm <sup>2</sup> )			
Total lumbar spine	0.82 ± 0.17	0.93 ± 0.14	0.89 ± 0.14
Femoral neck	0.68 ± 0.13	0.74 ± 0.17	0.67 ± 0.11
Total hip	0.64 ± 0.27	0.80 ± 0.20	0.73 ± 0.11
VAS for back pain* (points)	7.47 ± 1.96	7.87 ± 2.07	7.80 ± 2.08
ODI* (points)	64.50 ± 17.06	67.58 ± 16.12	75.78 ± 13.56
Anterior body compression ratio* (kyphosis)	0.73 ± 0.05	0.73 ± 0.03	0.70 ± 0.03
Smoker†	10 (50%)	12 (60%)	10 (50%)
SF-36* (points)			
PCS	29.70 ± 13.55	29.87 ± 11.87	34.18 ± 14.58
MCS	41.79 ± 10.31	42.21 ± 11.75	48.29 ± 14.93
Level‡			
T7	1	0	0
T9	0	1	1
T10	0	0	0
T11	0	2	1
T12	5	3	5
L1	7	7	6
L2	3	0	4
L3	1	2	1
T scores for bone mineral density of <−2.5 g/cm <sup>2</sup> for lumbar spine or femur§	78.5%	69.2%	80.0%
Opioid use§			
No use	20.0%	15.0%	15.0%
Two weeks	88.9%	84.2%	83.3%
Six weeks	52.9%	50.0%	41.2%
Twelve weeks	17.6%	20.0%	23.5%

\*The values are given as the mean and the standard deviation. †The values are given as the number, with the percentage in parentheses. ‡The values are given as the number of patients. §The values are given as the percentage of patients based on the number of patients taking opioids per the number of actual follow-up patients.

the initial values, there were significant paradoxical decreases in the SF-36 MCS at twelve weeks for the rigid-brace group ( $p = 0.049$ ) and the soft-brace group ( $p = 0.014$ ), whereas the SF-36 PCS scores remained unchanged in all groups.

There was no significant difference ( $p = 0.912$ ) in opioid use among the three groups at twelve weeks. Of the patients who reported taking opioids after the fracture, at two weeks, 88.9% were in the no-brace group, 84.2% were in the soft-brace group, and 83.3% were in the rigid-brace group; at six weeks, 52.9% were in the no-brace group, 50.0% were in the soft-brace group, and 41.2% were in the rigid-brace group; and at twelve weeks, 17.6% were in the no-brace group, 20.0% were in the soft-brace group, and 23.5% were in the rigid-brace group (Table I).

## Discussion

The present study demonstrated that treatment without a brace for benign osteoporotic compression fractures does not result in inferior outcomes in patient disability, as compared with rigid or soft-brace treatments. Furthermore, there were no differences in the improvement of back pain, radiographic anterior body compression ratio, general health status (SF-36 PCS and MCS), and patient satisfaction rates among the three treatment groups during the three-month follow-up assessments after the fractures. We had hypothesized that if the no-brace group showed non-inferior outcomes compared with the rigid and/or soft-brace groups, the no-brace treatment could be considered as a reasonable option for the treatment of osteoporotic compression fractures because of the



economic benefits and the reduction of brace-related complications such as muscle atrophy, deconditioning, skin irritation, and impaired respiration. Accordingly, a non-inferior trial design was chosen in this study.

Empirically, the treatment of acute compression fractures may consist of a short period of bed rest, followed by gradual mobilization<sup>6,18</sup>. External bracing with a spinal orthosis is believed to be beneficial for pain relief for up to the first six to eight weeks<sup>11</sup>. However, to our knowledge, their efficacy for relieving pain and preventing further anterior body compression has not yet been demonstrated. Many elderly patients tolerate braces poorly<sup>18</sup>, and given the additional costs and the cumbersome nature of braces, our findings suggest that the treatment of osteoporotic compression fractures using braces may not provide any additional benefits for the improvement of disability and relieving pain. In accordance with our results, recent studies have shown that the long-term results of treatments without braces with early mobilization for stable burst fractures are similar to the results associated with rigid-brace treatments<sup>15,19</sup>.

The current results do not deny the function of an external rigid brace in itself. Their effects on the stabilization of the vertebral body have been demonstrated by previous biomechanical studies<sup>6-8</sup>, and they provide not only pain control, but also sagittal plane hyperextension and reduction of gross spinal motion or segmental motion at the injured segment<sup>9,10</sup>. However, in osteoporotic compression fractures, which are inherently stable fractures, only the anterior column is injured, and the middle and posterior columns remain intact<sup>1,2</sup>. Thus, in the present study, treatment without a brace did not result in inferior outcomes in disability and resulted in similar outcomes for pain and progression of body compression, compared with treatment with rigid or soft braces.

Our results showed that the progression of the anterior compression ratio did not differ among the no-brace, soft-brace, and rigid-brace groups. Although several studies have demonstrated that spinal orthoses can allow restriction of segmental and overall motion of the trunk<sup>7,8,10</sup>, the restriction of overall or segmental motion did not result in the prevention of segmental kyphosis. Even though the spinal motion is restricted with a brace in a patient with osteoporotic compression fracture, this does not guarantee the prevention of segmental kyphosis. Previous studies have also shown results consistent with this finding<sup>15,19</sup>.

The SF-36 MCS scores were decreased at twelve weeks after compression fractures, compared with the initial values in the present study. Previous studies have shown that compression fractures in osteoporotic elderly patients substantially influence their quality of life, both physically and mentally<sup>20-23</sup>. Similarly, our findings clearly corroborate that the mental aspect of quality of life deteriorates after a fracture, although pain and disability improve as the fracture heals. We noted that although back pain decreased after bone union, the mental aspect of quality of life could not be restored, but worsened over time, thus emphasizing the clinical

importance of prevention of osteoporotic vertebral compression fractures.

This study had several important limitations. First, we only investigated the short-term outcomes (twelve weeks) for compression fractures, and evaluation of the long-term outcomes may provide more comprehensive data about brace treatment for osteoporotic compression fractures. However, the acute pain arising from a new vertebral fracture usually resolves over a period of six to twelve weeks<sup>9-11</sup>, and therefore, we considered that a follow-up period of twelve weeks after the fracture would be sufficient to compare the efficacy of brace treatments. Second, the brace compliance was a critical concern in the present study, which may have influenced the results. However, we do not believe that the present compliance influenced the results significantly as only two patients in each group did not wear braces in the sitting position. Third, relatively small numbers of patients were included in each group.

In conclusion, we demonstrated that the disability outcomes of treatment without a brace for osteoporotic compression fractures were not inferior compared with those associated with treatment with soft or rigid braces. Furthermore, the progression of the anterior body compression ratio at the fractured vertebral body was not different with orthosis use compared with treatment without braces. ■

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